Submissions analysis

PHARMAC and hospital medical devices – Obtaining clinical input

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PHARMAC
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CONTENTS

SUMMARY OF THE REPORT

1. This report summarises the 81 submissions made in response to PHARMAC's consultation document on obtaining clinical input into PHARMAC's management of medical devices. Fifty-seven per cent of submissions were from clinicians (individuals and groups) and allied health practitioners, and 22% from industry companies or associations. The submissions received from various groups did not present conflicting opinions.

2. In the analysis and reporting of this summary, emphasis has been placed on the range of views presented, rather than on the numbers of submitters expressing a particular view.

Key themes from the submissions

Sources of evidence (page 6)

3. There are numerous sources of evidence available, but standards of evidence for devices may not be as robust as those for pharmaceutical products; and it is not always possible to independently assess the value of a device prior to its use.

4. The information required to inform a medical device management system will vary according to the device, but consistency is essential in evaluation processes for clinical and related products.

5. Any assessment framework needs to include international and local evidence, input from affected stakeholders (including clinicians and other health professionals, and the medical devices industry) and lessons learned from the development of the pharmaceuticals management system in New Zealand and overseas.

Clinical perspectives on what is essential in a medical device management system (page 8)

6. Among the many factors to consider in developing a medical device management system the overarching considerations are:
   - a focus on patient safety and the delivery of high quality healthcare services, and
   - a genuinely multidisciplinary approach that includes clinicians, allied health professionals, and the medical device industry.

7. The device purchasing process must allow clinical choice, with the flexibility to change product according to patient needs.

8. Any process should support multiple suppliers, take account of supplier quality (as well as device quality), the product support available and supply issues.

9. The process should also take a long term view, considering the total care pathway and the total cost of products. In addition the process should ensure that, in the long term, New Zealand remains an attractive place to practise medicine.

10. Submitters proposed a number of general principles to be applied to a medical device management system process, including factors such as stakeholders having agreed expectations and objectives, transparency, clarity, and monitoring and evaluation of the process.

Clinical aspects of the systems in place for assessing and procuring medical devices (page 21)

11. Processes and clinical autonomy vary throughout District Health Boards (DHBs) but most submitters described systems involving clinical review by senior clinicians and then

assessment through product evaluation committees. These committees involve clinical and non-clinical representatives, as well as managerial and financial representatives.

12. Overall, product evaluation committees with a multidisciplinary approach were considered to work well (if slowly) with a generally satisfactory level of clinical input.

13. Key issues with the current system related to the length of time the process took, inefficient replacement of existing devices with newer versions and poor communication with stakeholders.

14. Suggestions for improvement (from both clinicians and industry submitters) included: having more comprehensive input into the process, better communication with stakeholders throughout the process and more flexibility with being able to keep up to date with devices.

15. Industry submitters further suggested improvements to device trials and a more integrated approach to assessing and procuring devices.

Ways for PHARMAC to obtain input (page 31)

16. Submitters put forward a number of principles to guide communication from PHARMAC on the devices project. Having a dedicated project website was also recommended.

17. Clinical colleges and other clinical networks are able to provide expert input to the project. Engagement through DHB clinical leaders was considered a critical aspect of this as they have operational and clinical accountability for implementation. Any assessment of equipment will involve a substantial amount of work and PHARMAC must recognise the timeframes and costs associated with this. The complexity of managing relationships with multiple clinical groups in different locations was noted.

18. Opportunities for PHARMAC to attend meetings and conferences are listed in an appendix to this report. Relevant publications are also appended.

INTRODUCTION

Background

1. In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices. In August 2012, Cabinet approved the plan for transitioning this work to PHARMAC. This decision is intended to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into health.

2. PHARMAC consider that to be successful in this role, it is critical to include clinicians and other District Health Board (DHB) staff in the decision-making process. To help achieve this, PHARMAC, as part of their formal consultation on this work, issued a document, *PHARMAC and hospital medical devices: Obtaining clinical input*. This document sought feedback on how PHARMAC could best work with users of medical devices in the clinical setting (clinicians and non-clinicians) and other stakeholders, and what sorts of information PHARMAC needs to consider to ensure sensible funding decisions for medical devices (including consumables).

Method

3. During the submission response period from 27 November 2012 to 28 March 2013, 81 submissions were received. Submissions were entered into a database, using a coding framework developed from the questions in the submission document.

4. In the analysis and reporting, emphasis has been placed on the range of views presented, rather than on the numbers of submitters expressing a particular view. This analysis provides a summary of these views, outlining themes raised, rather than recounting and responding to each individual submission. Counting was made difficult because some of the submissions 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 (using terms such as 'a few', and 'many') to show how widely held particular views were.

5. Quotes have been used to give a sense of the submitter's voice. Comments outlined in this summary have not been attributed to particular individuals.

Overview of submissions

6. Submissions were received from industry groups, clinicians and allied health practitioners, medical union groups and others, as shown in the table below. The submissions received from these groups did not, on the whole, present conflicting opinions. Rather they were focused more or less narrowly, or were extensive or brief on particular points.

Description of submitters

7. The majority of the 81 submissions received were from clinicians (either groups or individuals). Approximately a fifth of the submissions were from medical devices companies or industry associations. Twenty-seven medical specialities or areas were represented by submitters with anaesthesia and cardiology being the most strongly represented (see the table in Appendix 1). Twelve DHBs were represented in the submissions.

SUMMARY OF SUBMISSIONS

8. The summary of submissions begins with some general comments made by submitters. It then presents submitters' responses to the questions asked in the consultation document.

Submitters' general comments on the project

9. The submission document did not specifically ask whether respondents agreed with PHARMAC's involvement in managing the purchase of medical devices. However, almost all submitters implicitly accepted the principles behind the project and some welcomed it – with caution ('properly managed this has the potential to benefit the whole health sector - badly managed and it will cause huge damage'). Two clinical respondents expressed doubt about the project largely because they did not consider it feasible 'to expect PHARMAC to make insightful decisions on the indications for, use of, regional peculiarities of, servicing and maintenance implications etc. of all medical devices across all the different specialties.'

10. Several submitters commented on the definition of a device remaining unclear, thus leaving the scope of PHARMAC's responsibility unknown. An industry submitter considered it was essential that PHARMAC 'define and publish a clear roadmap outlining the scope of medical devices that PHARMAC will manage in due course.'

11. A small number of clinical and industry submitters questioned what role other agencies such as Health Benefits Limited, healthAlliance and the National Health Committee have currently and would have when PHARMAC began managing medical device procurement. Other questions submitters posed about the process are listed on page 21.

SOURCES & TYPES OF CLINICAL INFORMATION PHARMAC SHOULD CONSIDER

12. The following section of the report summarises submissions made in response to Question 1 in the consultation document response template:

    - **What sources and types of clinical information should PHARMAC consider when making medical devices funding decisions? How will PHARMAC best be able to obtain this information for the group of devices of particular relevance to you?**

Main themes from submissions

13. Overall, submitters (industry representatives, clinicians and allied health practitioners) considered that:

    - there are numerous sources of evidence available, but standards of evidence for devices are not always as robust as those for pharmaceutical products and it is not always possible to independently assess the value of a device prior to its use
    - the information required will vary according to the device but consistency is essential in evaluation processes for clinical and related products
    - any assessment framework needs to include:
        - international and local evidence as well as input from affected stakeholders (including clinicians and other health professionals, and the medical devices industry) for the New Zealand perspective
        - lessons learned from the development of the pharmaceuticals management system in New Zealand and overseas.

Sources of evidence

14. Almost all submitters proposed sources of published and other evidence that could be drawn upon to inform assessments about new devices. These sources are listed in Appendix 2. In making these suggestions, many submitters pointed out that the evidence supporting use of devices was either less available or less robust than the evidence relating to pharmaceuticals. In addition, reliable cross comparisons of products are hard to find.

Factors to consider when assessing information

15. It was noted by submitters that the required information would vary according to the device in question: high volume and low cost devices will, generally, require less information to support their implementation. However, with high cost and low volume items, such as imaging devices, it would be desirable (although not always feasible) to have Health Technology Assessment data available or clinical information supported by evidence including trials. The submitters considered that the highest standard of rigour should be applied, that information used must be current and where there are uncertainties or conflicting evidence, these issues would need to be addressed.

16. Submitters also noted that in an assessment framework, various sources of evidence would have different weightings. In addition, consistency is essential in evaluation processes for clinical and related products. A clinical submitter suggested the Scottish Intercollegiate Guidelines Network (SIGN) as an example of an evidence-based framework for the assessment of medical devices (including proposals to stop funding certain devices). Several submitters stated that health technology assessment activities must be undertaken independently of funding decisions.

17. Some industry submitters, commenting on trans-Tasman regulatory reforms and the Australian Therapeutic Goods Agency model, suggested a flexible approach to health technology assessment using a range of tools appropriate to the type of assessment being conducted. For example, a different methodology would be used when assessing new and complex technology compared to assessment of a product where expanded clinical-use indications are being requested. Subsequent to regulatory reform, these submitters anticipated that the majority of products demonstrating substantial equivalence to products already on the market would not require a Health Technology Assessment review. These industry submitters also proposed greater harmonisation of Health Technology Assessment processes for new medical technologies across compatible countries with similar clinical practice (particularly European countries) to avoid duplication of effort by manufacturers and regulatory agencies.

18. Several (industry and clinical) submitters stated that data to validate health improvements are generally collected over time alongside the use of a device. It is therefore not always possible to independently assess the value of a device prior to its use. The use of many medical devices involves an interaction between the device, a clinical procedure, and the clinician (or operator), where important improvement in technical performance of a new technique may occur over time – a 'learning curve' effect. These submitters noted that evidence shows the performance of users of devices improves over time, so it is important to assess the value of a device after an average performance level has been achieved.

Establishing a database

19. Several submitters referred to PHARMAC establishing a registry or database to compile relevant data on devices, stating that it should be reviewed regularly, and must record

more than price (for example, it should state whether a device had Therapeutic Goods Administration, US Food & Drug Administration or European approval certificates).

20. One clinical submitter strongly recommended that PHARMAC engage with the Australasian Foundation for Plastic Surgery 'who have been on a steep learning curve in terms of setting up a database that is thorough yet useable, manages to traverse a number of commercially sensitive product lines and also that is achieved by, and for, multiple specialty groups.'

CLINICAL PERSPECTIVES ON WHAT IS ESSENTIAL WHEN DEVELOPING A NATIONAL MEDICAL DEVICES MANAGEMENT SYSTEM

21. The following section of the report summarises submissions made in response to Questions 2 and 3 in the consultation document response template:

- **From a clinical perspective, what is essential when developing a national medical devices management system?**
- **What other comments do you wish to make regarding clinical input into medical devices decision making?**

Main themes of submissions

- There are numerous factors to consider, however, the overarching considerations are:
  - a focus on patient safety and the delivery of high quality healthcare services, and
  - a multidisciplinary approach that includes clinicians, allied health professionals, and the medical device industry.
- The device purchasing process must allow clinical choice, with the flexibility to change product according to patient needs.
- Any process should support multiple suppliers, take account of supplier quality (as well as device quality), the product support available, and supply issues.
- The process should also take a long term view, considering the total care pathway and the total cost of products. In addition the process should ensure that New Zealand remains an attractive place to practice medicine in the long term.
- Other considerations included having national consistency and equity of access, and taking account of the implications for DHBs.
- Submitters proposed a number of general principles to be applied to a medical device management system process, including factors such as stakeholders having agreed expectations and objectives, transparency, clarity, and monitoring and evaluation of the process.

Who has input

22. The strongest theme to emerge from submissions on this topic was the importance of having input into PHARMAC's medical device management system from clinicians, allied health professionals, and industry, with almost all submitters emphasising the importance of clinical input into decision making. Several submitters (consumer groups and stomal therapists) also referred to patients having input.

Involving all health professionals concerned

23. Submitters emphasised the importance of involving all health professionals concerned with any particular device. While it was noted by one submitter that clinical input is required mostly within procurement, it was also considered by this submitter that a solid understanding of clinical issues is required for effective health technology assessment reviews to take place. Thus, depending on the device in question, it was thought it might be necessary to have a range of health professionals (such as infection control or other specialties) involved in all aspects of the device management process. It was noted that major capital purchases often involved compromise and 'without clinical involvement the benefits and risks of key decisions cannot be adequately assessed.' In addition, materials management and procurement team staff (with their knowledge of suppliers, equipment and consumables), IT staff or clinical engineers, may need to be involved from the inception of a process as applicable.

> *Nursing and medical input is a must, we will be the ones operating the devices, troubleshooting the devices, fitting devices to a patient, determining efficacy of devices and reading or deciphering information from devices. We have a vested interest in our client base, we are constantly striving for optimum outcomes and best practice, we have years of experience and at present we determine all our equipment needs based on these principles. In order to maintain quality and safety standards our expertise and knowledge is paramount in the decision making process for medical devices.*

24. Additionally on this topic, submitters noted that input to the process could not be allowed to be dominated by larger specialties or larger hospitals but must involve all those with an interest in the use of the device and a variety of healthcare provider facilities.

25. It was emphasised by submitters that stakeholders involved in consultation over a particular device should play a pivotal role in the whole process. This means full engagement and communication with relevant stakeholder groups, including, one submitter noted, sharing knowledge about financial constraints, and, if appropriate, meeting with potential providers. Submitters considered it critical that all relevant stakeholders feel included in any and all decision-making processes, have confidence that their group is being represented, and believe that their requirements of the medical devices are fully understood.

26. Further, when options are being analysed and decisions being made, input must be gathered by 'carefully identifying the people who need to be consulted in a proactive way.' For example, in radiology, consumables (such as needles and vascular catheters) mostly need input from the radiologists and nurses, 'who are the ones who actually use these.'

27. It was noted by several submitters that obtaining this input could take some time; however, the breadth and depth of input would be related to the specificity or generality of a device. For example, in ophthalmology, 'consultation with regard to intraocular implants will of necessity be more rigorous than consultations with regard to types of eye-pads.'

The process of gaining clinical input

28. Submitters made a number of comments related generally to the process of obtaining clinical and other input. Key considerations were that consultation be genuine, occur at an early stage and use a transparent decision making process. It was also seen as important that clinical staff perceive some benefit for their patients from this process and not just a cost saving exercise. In addition, the process must recognise the difficulties of gaining clinical input from many sources in relation to the timeframes and costs of clinical input.

Finding a mechanism to communicate and engage with medical staff in product management or review processes, was described by one submitter as 'one of the foremost and concerning issues Clinical Product Co-ordinators are required to deal with.'

29. A DHB manager submitted on the necessity of 'enfranchising clinicians in supply reform.'

> *It's not a matter of getting buy-in from the procurement managers, it's more on the lines of getting buy-in from the DHBs, especially the physicians/clinicians. They are the stakeholders that we need to garner clinician support and manage utilisation to drive cost down. … We should not underestimate the power of bringing clinicians to the negotiating table when negotiating with suppliers. We need to recruit clinicians to help with negotiations and demonstrate the dramatic impact they can make during vendor contract negotiations (rather than alienating doctors and nursing staff and losing significant revenue when standardising to a few brands or products).*

Clinical groups

30. Several submitters addressed the topic of clinical reference or expert advisory groups specifically. These submitters considered that such groups should be sought from across the country to avoid 'a consistent bias' in decisions, and also to ensure that the correct participants are in a project group for these decision processes.

31. Submitters considered the composition of such groups needs to include well respected users from around the country in different sized centres, because of the differing needs of different sized centres. They contended that these groups should consist of people with regular 'coal face exposure' rather than being only 'high level users.'

32. It was suggested by two clinical submitters that clinical advisory groups (or expert advisory panels) be created comprising practising clinicians and allied health members who have been selected by one of more of their peers, colleges or associations. These submitters considered that establishing an expert advisory panel is the most effective process to gain comprehensive advice on medical devices. One of these submitters noted that highly specialised knowledge is required when purchasing medical devices and a generalist would not have the in-depth and ongoing experience using particular medical devices to provide the level of detailed analysis required to assess these devices. It was also suggested that multiple speciality groups could work together to collaboratively review devices when the devices are used by different specialities. Related speciality groups could provide independent review of decisions.

33. Reference groups should also be inclusive. For example, the establishment of an Ostomy specific Clinical Group, would be inclusive of Stomal Therapy Nurses, Stoma Nurse Specialists, Colorectal Nurse Specialists, Clinical Product Co-ordinators, Infection Control Nurse Nurses and Clinical Educators. The committees need to be big enough to allow for varieties of input and experience, but small enough to be workable. 'They cannot include everyone who may wish to be involved.'

34. It was acknowledged by submitters that implementing a national device management system will require significant clinical input from clinical colleges. As such, sector engagement will need to be managed in planned stages so that the key clinicians are able to provide input and 'avoid information overload.' The demand on the members of clinical colleges was referred to in several submissions, with implications for the timeframes of the device management process and other costs.

> *Current demands on our members are such, both clinically and as part of the clinical leadership process, that their time is very circumscribed. Longer time frames are needed*

> *for our members to give considered input than is customary for many managers. A one or two week turnaround, for instance, for a busy clinician is not a reasonable time frame. Consultation with clinicians is in itself a cost and cannot be simply added onto already onerous workloads. Part of the cost of making the right decisions may be backfilling the clinical workload of key clinicians involved for a time in an intense decision making process.*

35. One submitter stated that clinical specialist groups must share information and be comfortable with a peer(s) making decisions on their behalf. This was considered to be a process improvement that should be commenced 'sooner rather than later' as it is time consuming to acquire that trust. Because collaboration is essential in this process, a procurement specialist suggested that the clinical advisor role could be tendered (through a Request for Proposals), which was more transparent than only receiving nominations from a clinical college.

36. For expensive and complex categories (for example, cardiac surgery), a submitter suggested using an international reference group. 'Such a group could help to set criteria weightings and participate in the evaluation. This reduces the risks of conflict of interest - an issue in New Zealand, because the country is so small.'

37. One submitter suggested targeting specific groups of devices in a structured way with predetermined time frames and liaison with link personnel within each speciality to formulate the required working party. It was noted by a clinical college that, given the diversity of medical devices, it may not be possible to bundle devices together when seeking expert medical opinion.

Input from industry groups

38. Many submitters (clinicians and industry representatives) stressed the importance of medical device companies as a source of information and other support. With reference to orthopaedic medical devices, a clinical society submitted:

> *Here you have a symbiotic model where the service/implant requirements are often 50:50. By this we mean that service from medical technology companies accompanies the delivery of the prosthesis and the technician often assists with the implantation. If implant company support was not readily available DHBs would have to make significant changes to ensure DHB nursing staff had the specific technological knowledge required. … Where the hospital is smaller and the surgeon does not often undertake a particular procedure then it is often the medical technology company staff who accompanies the equipment who provides the assistance. PHARMAC will need to consider how to factor this concept into their purchasing model to ensure supply and support is most effectively maintained.*

39. One industry submitter considered that industry expert advisory committees, related to surgical and medical specialties, would be necessary in the medical device management system for specialised information regarding products, services available, and essential support required. Industry companies submitting were prepared to provide relevant information to PHARMAC from a number of evidential sources.

Other essential factors to consider

Flexibility

40. Flexibility was another major theme of the submissions. All submitters were in favour of the device purchasing process allowing clinical choice. Being able to provide high quality healthcare was the primary reason for the demand for flexibility; submitters were also

concerned about continuing innovation, and clinical satisfaction with working in New Zealand.

High quality healthcare

41. Many submitters expressed concerns regarding a lack of competition and choice that a medical device management process may incur. A 'one size fits all' approach could result in poorer health outcomes, and re-admissions ultimately increasing the total cost of an episode of care. Most submitters explicitly stated that a focus on patient safety and the delivery of high quality healthcare services is critical, and should be 'first and foremost' in any process of national medical device management.

> *The fundamental objective of a national medical devices management system must be to facilitate the right investment decisions to ensure capacity to deliver the right care in the right place at the right time. Assessment and procurement methodologies are tools to assist with delivering the best health system and patient outcomes and must support sound clinical practice.*

42. Several submitters emphasised that equipment was very specific to particular specialities. For example:

> *Neonatal intensive care equipment is neonatal specific; it cannot translate to paediatrics in most cases and is very different to adults. This is a quality and safety issue. Neonatal Intensive care is not only very different to paediatrics and adult departments, each Neonatal intensive care Unit (NICU) differs from each other in many respects. The type of treatment strategies varies from NICU to NICU. Every NICU [surgeon or neonatologist] has different treatment strategies for the same disease and will therefore require a different approach and equipment. Furthermore some NICU's perform procedures that others do not for various reasons such as expertise, staffing, equipment, cost etc. … Maintaining consistency with equipment has advantages with training, education and support.*

43. Submitters considered that any device management process should provide the flexibility to change product according to patient needs, or as products are modified or technology changes. It was considered essential that cost containment was not valued more highly than access to and choice of treatment.

44. Several submissions made by ostomy clinicians, suppliers and consumers addressed the need for patient choice with ostomy products. 'Any loss of access to reliable, secure, quality ostomy products will detrimentally impact on patient's quality of life and ability to fully participate in a normal lifestyle. All ostomates are not the same and have differing requirements with respect to types of devices and adhesives.'

Clinical autonomy in support of optimum patient outcomes

45. Many submitters (clinical and industry) stated that the actual decision making must be in clinicians' hands, particularly in relation to individual patients. Noting that there will always be situations that do not fit the prescribed model, these submitters considered that a clinician's choice of the most appropriate device for particular patients was integral to the clinician's ability to provide the best care for that patient. Submitters noted that having this choice related not only to the performance of the device with particular types of patient, but also to the experience and expertise that a clinician has with the use of the device.

> *It will be important to match the clinical requirements with the system and so details of those clinical requirements must be obtained. Clinical usability and work throughput is very important to consider. Two systems may be comparable technically and price wise, but if one is easier and faster to use, it has a clear advantage in productivity.*

46. An industry company stressed the importance of clinicians having this choice, because any national medical devices management system should maintain high levels of clinical responsibility and accountability.

47. Related to the topic of clinical autonomy, one of these submitters added that clinicians need the ability to keep utilising the latest technology, not least because later models often address problems that have been limitations or areas of concern in earlier models.

Having choice built into the process

48. Some submitters addressed ways of having choice in a medical device management system. Several clinical submitters suggested that clinicians must have the freedom to trial devices that were new to the market before procurement decisions are made.

49. One clinical submitter noted that there is currently 'a lot of purchasing of non-catalogue devices even by clinicians who purchase with their personal credit card without approval, then expect reimbursement.' These purchases are barely visible within the DHB and it can take a lot of time for the item being used in practice to be more widely known about. This submitter suggested there needs to be a clear and simple process for seeking to purchase outside the system when there is a specific clinical need. 'This could be an agreed local or regional process put in place to be used when required.'

50. Two other submitters also suggested that a clear set of criteria was required for assessing extraordinary cases, 'for example time-dependent decisions where non-funded devices are indicated.' Because there would always be exceptional cases, another clinical submitter suggested that any tender decision should allow for 'roughly 10% of overall product use' outside the tender.

Grandparenting currently used devices

51. Related to retaining flexibility, several submissions (clinical and industry) referred to any medical device management system making provision for grandparenting existing devices and managing the 'technology tail.' For example, 'some cardiac devices are not easy to extract. … Current devices must continue to be supported and any procurement decision must not jeopardise that.' In addition, 'the hip and knee implant device tail of over 180,000 New Zealand patients must continue to be managed in future and this requires the ongoing viability of suppliers to service these existing devices.'

52. These submitters considered that existing patients should not be required to stop using a product that they are currently using for the purpose of any new contractual arrangements (only if a clinical issue for an individual arises). One of these submitters noted that there are cases where people have been using their current devices for a long time 'and they identify with these, there may be clinical harm in changing them to a new product now.'

Supplier related concerns

Not having a sole supplier

53. Most submitters emphasised that a national medical device management system should support multiple suppliers. Submitters considered that having comparators was essential in allowing clinicians to trial products, and in supporting innovation. Therefore any tender decisions should not allow a single company to dominate to the extent that other companies lost interest in the New Zealand market. While many of these submitters acknowledged that rationalisation and standardisation were key considerations, any system

required a balanced approach to ensure innovation and market competition was not removed. Some submitters noted that 'sole source' supply arrangements were not appropriate for high-end medical devices in particular. It was also noted that, in the long term, a sole supplier model would drive up costs.

Supplier quality control

54. Several submitters referred to the need for clinicians to have confidence in the company supplying the device. Submitters considered the medical device management system would need to include a process for assessing suppliers as well as the device in question. Suppliers need to be assessed in the areas of quality control (for example, an independently audited quality management system), research and development investment, reputation and financial soundness, and responsiveness to product related issues such as back orders, recalls and product failures. A further consideration was the risk of a supplier exiting when a product 'might stay in situ for years.'

55. One submitter suggested there be clear guidelines and expectations for the behaviour of suppliers' representatives in the performance of their business in DHBs. These expectations should be expressed in a Code of Ethics for medical companies and their representatives, and compliance with the industry Code of Conduct in the performance of their work.

Product support

56. In relation to supplier quality, many submitters stressed the importance of any medical device management system factoring in the level of service that can or should be provided with a product. This service may include training and technical support to users, and after sales service during the product life cycle. Thus the potential cost of maintenance of medical devices and the amount of skill and in-servicing required and by whom should be part of device management decision making.

57. Submitters emphasised that a medical device management system must ensure that device providers retain sufficient incentives to provide the ongoing support and training that is frequently required for many products to be used effectively. This training is essential in the utility of the devices, particularly the high risk surgical devices and must be taken into consideration. In addition, on-site support may be provided by the company where the device is complex, rarely used and subject to frequent change. One clinical submitter noted that 'for commonly used devices such as pacemakers the DHB may be able to give that support. It would not usually be the funder that provides the on-site support and it is hard to see how this would be feasible.'

58. Another clinical submitter commented on the current reduction in staff training on new devices.

> *Previously, product reps had a significant role to play in staff training. This is now limited and results in less training options. In order to control product purchase, product reps are seeing staff individually rather than in the multi-disciplinary teams, this has the effect of losing shared feedback, discussion, viewpoints and learning about new products.*

59. A further clinical submitter pointed out that the cost of implants includes the service of representation in the operating room and this needs to be acknowledged if standardisation of devices and contracts for pricing are undertaken.

> *We often encounter ourselves in complex situations where we are unclear which implant is appropriate for the surgical situation. There have been times when I have ordered different implants from different companies to be available and have only been able to*

> *assess the suitability of each implant once the problem that I am dealing with has been fully dissected out and displayed. To this end, it is not uncommon for representatives to fully prepare all of their implants and have them available in the operating room only to have me to select a different implant. Obviously, this occurs at considerable cost to the implant providers and this is currently included in the costing. Failure to recognise this and limitation of this aspect of the service would again be deleterious to patient care and at times be a risk to quality outcomes.*

The partnership between clinicians, DHBs and the suppliers of medical technology

60. Several clinical and industry submitters commented on the innovations that had emerged from the partnership between clinicians, DHBs and the suppliers of medical technology. It was noted that changes to technology are usually incremental and that clinicians are instrumental in working with device providers on continued improvements to both the devices themselves and the procedures they were used in. These submitters noted that in managing the medical technology budget, PHARMAC should not lose sight of the benefit to New Zealand that will come from strengthening partnerships between clinicians, administrators and suppliers.

61. It was also suggested by one clinical submitter that the process of selection for any medical product may affect the attendance of medical device companies at medical or health conferences, if incentives for attendance were removed. Lack of attendance would increase costs in the health sector and 'directly impact ongoing professional education across all sectors.'

Supply issues

62. Related to supplier quality, seven submitters stated that PHARMAC needed a deep understanding of the supply chain model in New Zealand. Submitters considered that supplying companies must have a New Zealand presence, with devices available for use at short notice and in case of pandemic or other adverse event.

63. In addition, any medical device management system must take into account effects that could result from a product recall. One submitter gave the example of the Ondansetron glass ampoule change, which required the additional cost of filter needles to be used with all drawing up of medication. Therefore the capability of the supplier to move efficiently to a reliable national supply situation must be considered, as suppliers must have real capacity in the event of an issue, 'either force de majeure or recall related.' There was particular concern that with a sole supply model, providers could be left with no supply – 'especially if there is an epidemic and every country is trying to stockpile.'

Taking a long term view

64. Several points were made by submitters relating to the need for PHARMAC to take a long term view in the development of a national medical device management system.

Ensuring New Zealand remains an attractive place to practice

65. Several clinical submitters pointed out that medical device companies are businesses. Profitability is essential for these companies to remain in the market, continue to invest in research and development, and for healthcare to continue to evolve. Pricing must take this into account. One clinical submitter stated that New Zealand must remain internationally competitive if it is to continue to attract clinical practitioners 'of the calibre expected by New Zealanders.' A narrow range of products 'will not ensure New Zealand remains an

attractive place to practice and a consequence may inadvertently mean our highly trained, highly skilled young surgeons decide not to remain in New Zealand.' Succession planning should consequently be a strong factor in medical device choice and range.

The total cost of products

66. Many submitters asked that the overall health economics be considered when costing products. Cost assessment should thus include not only the capital cost of the device, but the ongoing costs during the life of the device. These costs include:

- administration
- consumables - the assessment should also include whether there are more cost effective options for the necessary consumables (for example, whether the consumables are used for other devices)
- service costs
- training
- the compatibility of the device in question within the clinical environment
- the expected life of the product (how soon will it be obsolescent)
- whether devices (including software) can be upgraded easily, and the degree of flexibility they allow in accessing technology advances.

The care pathway

67. Another strong theme expressed by submitters was that a medical device must be viewed in the context of a continuum of care for patients, that is, as part of a complete treatment or procedure. This meant, for example, taking into account other investigations, monitoring, and therapies that would be necessary as a result of funding a particular device compared with another. For example:

> *Closed infusion systems and open infusion systems serve in principle the same purpose. However, closed infusion systems remain sealed and do not require external venting to enable fluid displacement; hence the risk of bacterial contamination is significantly reduced. This leads to fewer blood stream infections for patients, a lower mortality rate and lower costs for hospitals and payers.*

68. An industry submitter suggested that it would be better to measure the health-impact of a medical technology used as a part of the sum of treatment rather than a unit-price in isolation. Several submitters noted that the most costly part of the healthcare system is the length of stay in any tertiary centre, so devices that reduce the length of stay and place people back into the work force must be taken into consideration.

69. In addition the effects over a patient's lifetime must be considered. Two submitters gave the example of bariatric surgery and its effect on comorbidities.

70. One submitter further noted that the value of long term medical devices such as orthopaedic implants has to be considered in a longer timeframe than other devices. With such devices, value calculations have to include considerations of survivorship, cost of complications and revision, long term availability of componentry, as well as support, service and education. 'What may appear to be a cost saving at the time of procurement may turn out to cost more over the life of the patient.'

National consistency & equity of access

71. Several submitters welcomed the prospect of a national medical device management system in the hope it would bring national consistency and equity of access to medical devices. These submitters expected a national device management system to purchase and place high cost devices within the most appropriate centres (related to clinical expertise, track-record and population). It was considered vital that equity of access to 'limited centre devices' would allow all New Zealanders to benefit and not just those within a particular DHB.

72. Related to this topic, training in the use of particular devices would have to be ongoing and supplied by the same people throughout the country to ensure the device is used to the same standards everywhere.

Implications for DHBs

73. One submitter stated that the capacity of health providers to purchase, rent, maintain, and train staff would also have to be factored into decision making.

74. In addition two submitters noted that 'ripple effects' on other services must be considered; particularly any impact on fragile services. Decisions on devices should not drive decisions on what services are offered.

75. Another submitter questioned whether a national decision would mean that all users of non-contract equipment would be required to change within a certain period of time, which may be inconsistent with the projected life of the equipment already in use. Additionally, would there be any penalties associated with not doing so? This submitter stated that PHARMAC needed to understand the clinical environment and consider costs to DHBs – and to the (natural) environment long term.

Environmental considerations

76. Further to this last point, an industry submitter noted that comparisons between 'reusable or disposable items were rarely properly researched or costed. While disposables were cheaper, 'only lip service is paid to cost of disposal and/or effect on landfill.'

The private sector

77. One clinical submitter suggested that PHARMAC also needed to be mindful of the fact that over time the private sector has followed the public sector in device purchases; 'although often at a slower rate.' Thus there may be a patient safety factor in purchasing the 'upgraded version' of an old machine rather than the new machine from a different company. This had the advantage of providing consistency across sectors and familiarity.

Equipment replacement policies

78. One submitter noted that the development of an equipment replacement policy is critical for the range of medical devices. This including proposed refreshes, upgrades and potential asset life cycle optimisation to alternative sites.

General principles to be applied in the medical device management process

79. Many submitters suggested that the process for PHARMAC procurement of devices should have particular attributes.

Transparency

80. Many submitters commented on the importance of transparency in the process. In particular, the tendering system should use a fair and open product evaluation process. This included the clinical and commercial evaluation forms used for feedback from users, and the accountability and responsibility for procurement decisions. In addition, the criteria for decision making should be publicly available.

81. It was suggested that a medical device management system should contain a trial process for devices in several different types of healthcare settings. Prior to any final funding decision leading to national implementation, there should be feedback to evaluate the effectiveness of products in terms of meeting the clinical needs of the patient and the healthcare facilities. This feedback should include a cost analysis of the consumables and any additional equipment required.

Clarity

82. Many submitters also stressed the importance of clarity in the scoping of projects, evaluation and tendering processes, and the roles and responsibilities of all agencies involved.

Concise timeframes

83. Both industry and clinical submitters stated that timeframes need to be clearly set and concise, with reviews and assessment completed within a reasonable period of time, and updates communicated to clinicians or other expected users throughout the process. Submitters considered it essential that any process could adapt quickly to keep up to date in a rapidly moving market, so that patients had timely access to innovative technology solutions. One submitter noted that the timeframes for assessment of devices must take into account any impact on the continuation of supply.

Agreed expectations & objectives

84. Two submitters noted that PHARMAC and clinicians needed to have the same expectations about the system and how it will operate. The project would also require a set of guiding principles and governance structures that indicated how clinical input would be incorporated into the development, implementation and day-to-day operation of the system.

85. One of these submitters noted that the medical devices management establishment project needed agreed objectives, including but not limited to the following:

- optimising patient outcomes
- clinical engagement
- the importance of clinical trials and innovation in different fields
- visible cost benefits retaining the ability for companies to provide a service while maintaining a competitive edge.

Managing conflicts of interest

86. Several submitters considered that any process needed strong governance procedures for identifying and managing any actual or perceived conflicts of interest. These need to appropriately balance the need for independent, unbiased advice and decision making with the reality that in a country as small as New Zealand there may be a limited number of

experts to draw upon. One submitter from a health consumer group stated that clinical input into medical devices decision-making must be independent of the medical devices industry. 'Clinicians with vested interests or financial ties to the manufacturers of medical devices should be required to declare these details.' A clinical submitter acknowledged that:

> *Conflicts of interests abound but the issues are no different to pharmaceuticals with the exception that in New Zealand there are many first in man studies and clinicians have a vested interest in products that they have helped design and trial. Whilst there may be a conflict of interest it may also mean that there is already local experience and a faster implementation of a product into the clinical market.*

Evaluation and monitoring

87. Several submitters stated that the development and implementation of the medical device management system must be monitored and evaluated. Evaluation should assess the impact of the system on clinical practice and expenditure on devices. This was considered essential in terms of identifying and correcting any problems during development and implementation, and tracking the impact of the new system. Additionally, there must be processes for affected stakeholders to give timely feedback regarding access to devices, including a publicly accessible process for reporting problems with devices.

88. The system should also have a transparent and reproducible cost/utility/effectiveness model for assessment of devices, a clear risk/benefit approach to standardisation and to decisions about funding (or not funding) specific devices, and the use of an agreed accounting standard.

Procedural fairness

89. The system should be procedurally fair (for example, manufacturers or providers must be given the opportunity to rebut any claims made by other parties regarding their products). It should also have an appeals process that operated efficiently.

Contracting considerations

90. Several submitters made suggestions about the actual contracting process:

Including new product technologies in existing contractual arrangements

91. They contended that there should be a robust national process for the assessment and inclusion of new product technologies in existing contractual arrangements.

Purchasing major items

92. A clinical submitter noted that major capital expenditure items (costing millions of dollars) are not required every year but sometimes there may be a number at the same time and any funding model by PHARMAC with the DHBs will have to be flexible enough to accommodate the large fluctuations from year to year necessary to keep departments such as Radiation Oncology functioning.

93. In relation to major capital purchases, one industry submitter suggested that a system where PHARMAC pre-approves vendors may be better than PHARMAC recommending specific devices.

Exit strategies

94. Two submitters commented on the necessity for exit strategies in supply contracts. These submitters stated that in the past decisions made by DHB managers have resulted in items that were not fit for purpose but with contracts that allowed no way out. Exit strategies need to be put in place to deal with these situations, and these strategies will need to include back up suppliers.

Involvement of other agencies

95. An industry company supported the involvement of the National Quality & Safety Commission in medical device decision making.

96. One clinical submitter suggested that PHARMAC, Health Benefits Limited and all DHBs adopt Product Evaluation Health NZ (PEHNZ) new product introduction and evaluation process. Similarly an industry submitter suggested a PEHNZ office be located within PHARMAC: 'industry can then approach PHARMAC with new technology/alternative products for tender and PHARMAC PEHNZ would nominate the reference hospital.'

Procurement models

97. One industry submitter suggested that PHARMAC review procurement models involving partnering with private sector providers such as a Technology Partnership or Managed Equipment Service. Such models may include the acquisition, planning, installation, training, maintenance, asset management and possibly funding of medical technology products.

98. Two (non-industry) submitters suggested that a price banding system could achieve cost containment outcomes while allowing clinical freedom. A pricing and technology banding strategy could allow DHBs to select appropriate medical device models and applications suitable for their clinical needs.

99. Another submitter suggested panel contracting agreements so that clinicians have some flexibility and if necessary, a choice. Panel agreements also provide ability to seek substitute product from an alternative supplier if there is a backorder or recall situation.

100. One DHB manager considered that there was a significant opportunity to reduce price without incurring the risks of product standardisation risks through standardising in price instead of product.

> *The key goals include winning surgeon support for hospital initiatives and leveraging relationships to share physician performance data which encourages physicians to challenge each other's practices and eliminate unused or routinely wasted items. We should be looking at contract negotiations, rather than standardising products, by investing in quality price benchmarking information. The materials management team can devote their resources to identifying accurate price data, which can be leveraged in negotiations with vendors. Comparative pricing data improves a hospital's position during contract negotiations, demanding a known lower price proving a much more palatable option than committing to shift preference item volume. Understanding the drivers of hospital behaviour is critical.*

101. One submitter suggested that in the case of commonly used equipment where there is considerable local experience, decisions could be made at DHB or individual hospital level without having to obtain national approval. 'Such an example might be endoscopic technology, where there is already competition to keep prices down and drive innovation.'

102. An industry submitter recommend expanding PHARMAC's role to encompass shared accountability for the growth of the NZ medical technology-manufacturing sector.

> *This would empower PHARMAC to make more balanced procurement decisions. With responsibility for procurement and assessment alone, PHARMAC's decision making has the ability to negatively impact upon the success of New Zealand's medical technology exporters.*

Questions about the medical device management system process

103. The questions submitters posed to PHARMAC were:

- What is the scope of devices purchasing, for example:
  - what are the definitions of a device
  - what are the targets (in terms of device numbers or cost savings), and
  - what are the priorities (low volume/ high cost items or high volume/low cost items)?
- What are the decision making criteria (plus corresponding weightings and thresholds)?
- Who will evaluate the effectiveness of products?
- What is the envisaged methodology for cost-effectiveness assessments?
- Will there be a legislative obligation for PHARMAC to stay within budget (as is the case with pharmaceuticals)?
- How will requests by clinicians or services within a DHB be processed, noting that clinicians frequently want to introduce devices they have used overseas?
- What are the processes (if any) for exceptions?
- How will innovation be managed?
- How will the system work with existing structures (for example the National Health Committee, Health Benefits Limited) and avoid duplication?
- How will the process work with low volume devices?
- Given that there are likely to be a number of changes to clinical practice as a result of this process, what support will clinical staff receive in the roll out of these changes?
- What measures are being proposed to ensure the transparency of processes and decisions relating to the management of hospital medical devices?

CLINICAL ASPECTS OF THE SYSTEMS IN PLACE FOR ASSESSING AND PROCURING MEDICAL DEVICES

104. This section summarises submitters' descriptions of the clinical aspects of the systems in their organisations for assessing and procuring medical devices, and how well these systems work. (Questions 4, 5 & 6 in the submission document response template.)

Main themes

- Processes and clinical autonomy vary throughout DHBs but most submitters described systems involving clinical review by senior clinicians and then assessment through product evaluation committees that involved clinical and non-clinical representatives, as well as managerial and financial representatives.

- Generally, product evaluation committees with a multidisciplinary approach were considered to work well with a satisfactory level of clinical input.
- Key issues with the current system related to the length of time the process took, inefficient replacement of existing devices with newer versions, and poor communication with stakeholders.
- Suggestions for improvement (from both clinicians and industry submitters) included: having more comprehensive input into the process, better communication with stakeholders throughout the process, and more flexibility with being able to keep up to date with devices.
- Industry submitters further suggested improvements to device trials, and a more integrated approach to assessing and procuring devices.

The processes used

Overview

105. There was some variation in submitters' descriptions of DHB processes for assessing and procuring medical devices. Descriptions included no discernible formal system, decisions made by committees with no relevant clinical input.

106. Processes also differed depending on whether the item was major or minor. With consumable products, clinical submitters described a range of processes. In one case, 'we take what we are given by materials management;' in another case, DHB-wide smaller consumables go through the product evaluation team, while others that affect only one department are simply bought. One submitter noted that with more specific items such as biopsy needles there was more freedom to purchase what is clinically appropriate.

107. However, most commonly (and in relation to most of the DHBs represented), submitters described process involved clinical review committees and product evaluation committees

Clinical review committees

108. A small number of submitters commented on departmental clinical review committees. One submission described the establishment of a departmental centre for outcomes research and evaluation to help in the review of existing evidence through systematic reviews and meta-analyses, as well as the formal evaluation of medical devices through bench and clinical research.

Product evaluation committees

109. Commonly (noting the DHBs that submitters were associated with listed in Appendix 1) submitters stated that current systems for assessing and procuring medical devices involved clinical review by senior clinicians and then assessment through product evaluation committees that involved clinical and non-clinical representatives, as well as managerial and financial representatives. These submitters described how a new product may be introduced through various means. For example due to a new clinical requirement, a review of an existing contract, a request from a clinician, or a request from a company representative.

110. The product evaluation committee would then review current products or processes, trial the proposed new product(s) and undertake an evaluation of all aspects of its use and costs, including the availability of training. In the case of new contracts various manufacturers' products are reviewed simultaneously. Once the documentation and

pricing has been approved a clinical evaluation period occurs with the product or company representative demonstrating and answering questions over a certain period.

111. In general, submitters' descriptions of their product evaluation committees' role matched that of the list provided by one submitter:

- ensuring that safe, effective and appropriate products and equipment are consistently available for clinical use
- providing a forum for discussion of product and equipment performance and usage
- communication between Materials Management and representatives of clinical end users (for example, in the case of product supply difficulties, practice changes affecting product purchase and purchase decisions and/or recommend changes)
- approval of equipment/supplies specifications
- approval of items for Materials Management purchase tenders
- identification of products and equipment which are consistently used throughout a DHB and advice on suitability for bulk purchase
- identification of items where several brands are being used for the same product or equipment line and advise on appropriateness for standardisation
- evaluation of products and equipment with appropriate end user input prior to recommendation for purchasing
- providing a full cost/clinical benefit analysis to support recommendations
- communication of up-to-date information from scientific research/published articles etc. which have relevance to clinical practice, product and equipment choice and future practices
- making decisions about product and equipment use and evaluation practices when problems are identified
- serving as a focal point for product and equipment evaluation and as a clinical and Materials Management (and pharmaceutical services) resource.

Product trials

112. Submitters described how the product evaluation committee trials items considering factors including any price advantage, improved technology, and sufficient samples to carry out a realistic trial. A manager is appointed to administer the trial and evaluation forms are completed by all staff using the product or equipment over the trial period. The manager presents a full report including cost analysis to the product evaluation committee for approval as appropriate. The product evaluation committee provides a single point of contact to introduce and trial products.

113. Involvement in a trial has implications for the procurement of medical devices, as one submitter described:

> *We currently carry out phase 1 trials. … Companies see an advantage in getting their devices into our hands for a trial. … We are the biggest site carrying out trials in this area in the world. Because of this we are getting reduced prices from the manufacturers. Sixty to seventy per cent of our devices are high volume single use that could be just farmed out but the other 30-40% need to be managed carefully. We need to remain in that trial market and due to this we can't use an evidence based approach which is used in selection of drugs.*

Procurement

114. Subsequent to satisfactorily trialling a product, procurement of medical technology was through an individual DHB procurement office, regional buying, or centrally led (by Health Benefits Limited). Irrespective of whether there was a regional or central process in the organisation where they worked, a few submitters stated that departments within DHBs had independently run some independent competitive tender processes. One submitter described using a rotation of procurement between three companies. 'This creates competition in the market and provides good training opportunities for registrars.'

Stock management

115. Two submitters noted that, where applicable, old items are used before new products were available. Managing existing stock and new medical device stock management may be done by the product evaluator or the procurement officer.

Industry perspectives

116. Industry submitters' also described these DHB processes. These submitters considered different DHB processes they were involved with to be broadly similar; although the processes were 'applied more efficiently within some DHBs.'

117. Some industry submitters also described how new medical devices and technologies were introduced into New Zealand through medical device supply companies.

> *Suppliers attend international meetings and trade exhibitions. We search the internet and have partnerships with overseas manufacturers. Local clinicians who have also attended overseas meetings will sometimes request that we source product for them. Medical device companies decide to invest and import products based on some or all of the following criteria: clinical need, new cost saving technology, regulatory status. New products are then introduced to the health system through PEHNZ system or clinicians in private practice. They then must be notified to Medsafe for the WAND database. When the product meets these criteria, clinicians are trained and the product trialed, and if successful, added to inventory.*

118. It was noted that new product evaluation committees are pivotal in this process ('and most DHBs have them'). These committees are the entry point for new technology.

Clinical staff involvement

119. Both industry and clinical submitters stated that relevant clinical staff and experts, for example, infection prevention and control specialists are involved in the evaluation and review of products. The extent of this role varied according to the type of equipment being purchased. Clinical input was elicited through:

- registry information review
- regular clinical audits
- journal clubs and CME literature meetings with local DHB clinical product coordinator staff
- international meetings and shared networks
- medical technology clinical trials and research work
- post-marketing clinical-studies, and
- relationships with industry (local and international).

120. One submitter described the process when clinical staff want to initiate buying a product.

> *They speak to their colleagues, then their immediate manager who will then discuss this further with other staff to gauge interest. Consultation is needed at this stage between all end users, particularly the consultants to ensure the majority are prepared to consider a change. The manager may contact the company rep and approach purchasing to determine if it is able to trial. Purchasing Department do the rest then notify the clinical manager when documentation and pricing have been completed. Clinical staff are involved in the evaluation phase of the trial and should be asked to complete and evaluation form and given plenty of opportunity to discuss the product with the company rep.*

121. Several submitters described the wide clinical input to a product evaluation committee. Additionally, product evaluation committees could co-opt other members as and when required.

> *The committee consists of representatives from Director of Patient Safety and Clinical Effectiveness, Materials Management and Pharmaceutical Services, Purchasing, Tissue Viability Service, Infection Prevention and Control, Intravenous Therapy CNS, Operating Theatre, Occupational Health, Emergency Department, Medical, Surgical, ICU Wards, and Anaesthetics.*

122. In particular, clinicians were described as having the major role in identifying the need for any new equipment and participating in trials and evaluation. For example, with radiology equipment:

> *A tender template is sent to manufacturers and the completed information reviewed by a team of radiologists, MRTs, medical physicists, IT and procurement staff. The equipment is scored on many criteria such as technical specifications, service costs and ability to keep the equipment going well, PACS and treatment planning system connectivity, usability and workflow, cost, etc. The overall rating then guides the selection of the equipment. Site visits and evaluations are often arranged to properly assess equipment and give local staff hands-on experience before purchasing. They have an essential role in assessing the tender documents and that seems to work well.*

123. Several clinical submitters provided detailed descriptions of this involvement. For example, in a neonatal intensive care unit:

> *We have a dedicated nurse/technician who is an expert on the NICU population and equipment/devices/consumables. He has the support of all NICU staff and an educator of technology and equipment who works alongside him. … All equipment purchases are made following discussions and consultation with NICU management team. … Input from clinicians (doctors and nurses) is paramount in any decision to acquire equipment or consumables. Clinicians regularly rotate through NICU from other centres and have valuable experience and information on products that they may have used (positive and negative). Clinical staff partake in trials and evaluation processes.*

What works well with current processes

124. In general, submitters considered that product evaluation committees worked well. Having a product evaluation committee with a wide representation meant that the utility of the product (or otherwise) could be recognised for more than one area of practice, resulting in a more robust trial. Submitters commented that a collaborative and multidisciplinary approach ensured all aspects of the new product could be discussed; this ensured a consultative approach prior to implementing new products.

125. In addition, two submitters noted that their product evaluation committee had a good process of trial before use, with an evaluation process that was objective with clear criteria making it possible to compare and score items, and resulting in 'better compliance than when a device is introduced without a trial period.'

126. Other factors submitters pointed to in the good performance of their product evaluation committee were:

- there is always management involvement and also someone skilled in contractual issues, which is very important
- all major decisions need Board approval, and the documentation needs to be comprehensive
- it is transparent and makes it difficult for there to be undue influence from suppliers
- having a selection panel involved with any major purchases means it is much harder for one person to dominate (as was the case in the past).

127. Further, one submitter noted that in the current process, the users of the equipment know the local needs and are experts in their field. 'If they get it wrong they have to suffer using inadequate or unsuitable equipment for a number of years! The other side of this situation is that the responsibility is on the involved clinicians to get it right, and to spend public money wisely.'

128. Several submitters from the Auckland region noted that procurement through healthAlliance was effective, with systems for ensuring quality, safety and competitive pricing and promoting the standardisation of equipment. One submitter noted that while there may be some duplication of effort across DHBs purchasing similar equipment, high cost items are often purchased as part of a cluster of DHBs to reduce cost and effort.

129. One submitter commented specifically on the satisfactory level of clinical autonomy currently available.

> *Currently clinical staff make the choices of what we implant and the spread and percentage across the companies. We are aware of prices, and this is a factor in our decisions, but the choice is always what will be the best fit for the patient and their indication. … We have the freedom of choice to use new devices as soon as they become available. I like having the freedom to offer the patient the very best fit for their condition. I like not being tied into percentages promised to companies. It enables us to be free to choose with the important items influencing us: that is, best fit for the patient, spreading the risk across companies, and considering price (which includes longevity).*

130. Referring to their own departmental process with the system, another submitted noted that having a dedicated nurse/technician who is an expert with the particular population and equipment in one DHB unit had enabled the unit to save money, streamline equipment needs and maintain quality and safety for clients.

> *This system works very well and enables us to make calculated and evidence based decisions. Trial processes are well supported by this role and new devices are also well supported when introduced. I don't think this could be improved as the nurse/technician does extensive homework into costing and all other details, the decisions made are calculated and supported in detail*

131. Overall, industry submitters also considered the current system has served New Zealand well.

> *A competitive supplier environment and well-trained clinicians have created a market that has relatively easy access pathways for new medical technology. It should be noted that this environment has NOT caused clinicians to act irresponsibly or to spend excessively. New Zealand medical technology pricing has been favourably benchmarked against similar sized markets.*

132. A medical union noted that internal DHB processes do allow for innovation to occur in clinical teams when the DHB and the clinicians in the service consider that the change will

lead to better patient care and that it is affordable. However, mechanisms are needed 'to ensure that funding is in place for medical devices to support such innovation and improvement.'

What doesn't work so well

133. Outside of particular DHBs, there were submitters (representing cross-DHB groups and clinical societies) who considered that there were currently poor, expensive services at DHB level. Dissatisfaction centred on inefficient replacement of existing devices with newer versions. 'New versions of existing devices are being produced very regularly and systems are often not reactive enough to take advantage of these innovations and possible cost savings.'

134. Another submitter, referring to the situation generally, commented that the variation of views between clinicians on equipment and devices meant some DHBs may carry a larger than necessary stock. However, another submitter noted that use of inventory could at times be difficult to predict 'and, as we are sole stockists of a number of items (in New Zealand), we need to hold sufficient inventory for safety while wishing to minimise the risk of purchased stock reaching "use by" date prior to utilisation.'

Time consuming

135. The strongest theme from submitters within DHBs was that the product evaluation committee process is time consuming. Submitters referred to the length of time and paperwork required to get permission to purchase as onerous. One submitter considered that the capex system had a useful filtering function: 'capex (capital expenditure) does weed out some of the 'wants' within the system because staff can't be bothered going through the process.'

136. The Chair of one DHB's product evaluation committee noted that the capital expendituresystem 'involves a bunfight over which most appropriate or required device takes precedence over another department's.' And, further, that the tender process was not always cost effective.

137. After a decision had been made, the timeframe to acquire the equipment was also considered unreasonably long by several industry submitters:

> *Currently, a tender process and securing a contract can take up to two years. This timeframe is unacceptable for placing a device on the market. Once a clinical decision has been made the process for funding and procurement needs to be undertaken in a timely manner.*

138. The length of time the process took also related to obtaining agreement between participants. One submitter noted that sometimes it was not possible to get agreement ('different case mix, different clinical environment, different clinical training and preference, different ideas about need'), and attempts to get consensus make the process slow: 'there is lobbying and strident opposition to decisions.' The process was not immune from, 'personality based gridlock.'

> *The reasons for opposition to a decision are usually cogent and have merit. Unfortunately the blind adherence to 'standardisation' is an impediment to good clinical practice, relationships and, in the end, savings. While standardisation is an important goal, it should not be an endpoint in its own right.'*

139. Procurement of items was also thought to take too long, and there was some criticism of the format by which healthAlliance requested information: the IMF document 'has the potential to create confusion which results in increased time.'

140. Communication was another issue. Several submitters stated that little feedback was provided to the initiating clinician as to progress - even when requested. 'Communication could be more timely and transparent.' (Another submitter commented that their DHB was currently enhancing the web-capability of their third party procurers, so assessors (clinical staff) can access catalogues on-line, and can track deliveries online.)

141. In one smaller DHB, which previously had a product evaluation committee ('which was beneficial to some degree'), a submitter considered there was now no workable system.

> *If a clinician wants a product they need to source the information; cost and best practice evidence and work with their manager to set up a group which looks at the product to decide if it should be introduced. This does not allow for devices which are suitable to be used in other areas moving across departments, and no one person has an overall idea of what is being used. Reps also have no port of call and in desperation are known to have approached clinical staff at inappropriate times. We also have no evaluation of the introduced product once it has been implemented. There is tension between cost and clinical benefits with at times the financial implications driving the decisions and the final decision being made by those without strong clinical understanding of the need.*

142. Similarly, another submitter, from a DHB operating a product evaluation committee but where individual departments could also 'just buy things', consumable items were purchased that could be useful to others 'but no one knows about them, meaning duplication of some consumables.'

143. A clinician not directly involved in ordering or using devices, commented that when new batteries are needed (for devices installed in patients elsewhere) 'we need to apply for funding each time, which is a chore.'

Clinical input

144. One submitter considered that where there was one point of contact for products to be introduced and trialled, it was more difficult for clinicians to initiate a product trial. Further, in this type of system there was not enough consultation with end users.

145. Related to this, one submitter considered that although nurses have the major responsibility for managing and using medical devices, nursing input was currently marginalised in the process (due to 'traditional structures of power and authority') - 'thus the well-documented potential of the profession to maximise efficiency and improve health outcomes is not realised.'

146. Another submitter noted that when all those that will be using the product are not involved bad decisions are made. For example, when staff were not involved with a decision on beds, the new model was not able to fit room doors.

147. With reference to a particular speciality, ostomy medical devices, one clinical submitter considered assessment and procurement systems appear to be inconsistent across DHBs. Additionally, in some areas it appeared that non-clinician staff may make these decisions with no clinical basis for decision making

> *[The] generally held view is that clinicians have been marginalised from the decision making process with regard to ostomy medical devices. This marginalisation has led to conflict and in some instances a deteriorating relationship with procurement staff.*

148. This submitter also noted that changes to existing product ranges should be regarded as upgrades and should not be viewed as new products, as this is costly and time consuming. This view was supported by an industry submitter

> *All national HBL/PHARMAC contracts need to ensure a robust mechanism and transparent process is in place to allow current contracted suppliers to add new product innovations/technologies to these contracts in recognition of ostomists within the community whom wish to upgrade to new technologies.*

Suggested improvements

149. Both clinical and industry submitters suggested there should be more comprehensive input into the assessment and procurement process:

- End users should be part of any evaluation processes in a specific high use area, so that regular or frequent use of the product elicits a well-rounded view.
- There should be strong nursing participation and representation in all management and decision-making structures.
- Use of cross functional assessment panels that include representation from relevant clinical and other functions (biomedical, procurement, manager) rather than individuals, would avoid bias, assure a broader level of clinical awareness, and a greater understanding of the total cost/benefit of ownership.

150. One submitter noted that while clinical input was critical, it should be appropriately sized to maximise efficiency.

151. In addition, clinical submitters suggested having:

- A right of reply to any decision, with a more open-approach to sharing information with suppliers, including why decisions are made and constructive feedback.
- A mechanism to prevent side stepping agreed organisational processes:

  Although a National Contract exists, it exists in name only. Too many non-contract items make their way into hospitals by informal means, often undercutting items that have previously been awarded at fixed agreed prices. This places the original awardees in a challenging position as their business immediately becomes at risk. If there is a need to re-evaluate pricing it should be done at fixed intervals or the tender periods should be shortened. As a suggestion a maximum of a fixed three year contract. There could be a formal process mid-way through the contract to either escalate or de-escalate prices on application following a formalised set of guidelines. The current process also devolves too much power to the DHBs to independently negotiate prices outside of the National Contract.
- An open submission system with a pre-ordained time line for reviews and a six-monthly report and review of the 'approved' list.
- A greater quality focus on clinical effectiveness to ensure public resources are used most efficiently - further embedding the principles of clinical governance and quality into service delivery will enhance this.
- An automatic replacement process instead of capital expenditure.
- More flexibility with being able to keep up to date with devices – 'currently the device's life expectancy is reached before it can be replaced with a more suitable/updated device.'

Industry perspectives

152. Industry submitters also suggested the following improvements:

Better communication

- Greater clarity of what the sector requires from a product or vendor.
- Increased opportunity for vendors to offer additional evidence-based features and benefits that the sector may not be aware of.

A more integrated approach

- Centralised clinical guidance should be disseminated to manage occasional 'outlier' usage of medical technology that is deemed unnecessary, too expensive or ineffective. Monitoring outliers will allow those responsible for managing public funds to be assured that effective spending has occured.
- A more integrated approach to the assessment and prioritisation of medical devices for procurement. Working with suppliers would help all those involved in the procurement process to understand the intricacies of the supply chain and where costs can be eliminated.
- Where a decision making process has been thorough, the tender could be used elsewhere providing it is current (duplication of tenders can be an unnecessary cost for all parties).
- Completing one product evaluation with the results shared across all other DHBs, HBL and PHARMAC for inclusion on existing national contracts ('as opposed to the current system of individual evaluations twenty times separately for every DHB').

Improvements to the trial process

- If a product meets specification and warrants further scrutiny under trial conditions:
  - trials should be time-bound (for a maximum of three weeks)
  - the importance of trials and the responsibilities of staff involved in them (such as remaining impartial) should be reinforced through staff communication immediately before or upon trial commencement
  - only two to three competing products should proceed to trial to avoid staff 'trial fatigue'
  - impartially developed feedback forms should be unbiased and the same for all trialing parties
  - feedback forms should collect both useful data and opinion for evaluation, including the ability for open feedback
  - vendors should be given the opportunity to receive and rebut feedback they believe may be based on erroneous assumption or user knowledge gaps
  - terms should be agreed nationally regarding pricing of trial items as some small companies cannot afford to provide free trial items, creating an unfair advantage and trials should not be used as a cost avoidance opportunity for DHBs.

Other improvements

- More focus on patient flow and the cost to the whole hospital, not just individual departments (as opposed to 'the silo mentality' from individual departments that will sometimes not invest in equipment that will stop escalation or transfer to other more costly departments).
- Panel contracts allow fairer market competition and some contracts provide suppliers with the ability to introduce new technology at predetermined intervals, which

ensures the provision of state of the art solutions, in particular, when contract terms are three years or longer.

WAYS FOR PHARMAC TO OBTAIN INPUT

153. The submission document asked respondents to consider which key clinical groups, meetings or publications PHARMAC should consider becoming involved in to help develop the national management of medical devices (Questions 7 and 8 in the response template.) This section of the report presents the general comments made about obtaining input. Submitters' specific suggestions relating to clinical networks, DHBs, publications, meetings and conferences are listed in Appendices 3, 4, 5 & 6.

Main themes

- Submitters put forward a number of principles to guide communication from PHARMAC on the devices project. Having a dedicated project website was also recommended.
- Clinical colleges and other clinical networks are able to provide expert input to the project. Engagement through DHB clinical leaders was considered a critical aspect of this as they have operational and clinical accountability for implementation. Any assessment of equipment will involve a substantial amount of work and PHARMAC must recognise the timeframes and costs associated with this. The complexity of managing relationships with multiple clinical groups in different locations was noted.
- Opportunities for PHARMAC to attend meetings and conferences are listed in an appendix to this report. Relevant publications are also appended.

General comments

154. Commenting generally on the process of obtaining input, one submitter noted it was very complex to manage relationships with multiple clinical groups in different locations.

155. Further to this, several submitters noted that any assessment of equipment involved a substantial amount of work (potentially hundreds of hours) and should therefore have some employment contract associated with it.

> *The issue of who pays is important. Does PHARMAC pay these specialists directly, noting that [they] are rather expensive!? Or are they seconded from their DHBs? How often do the committees meet and how often do they assess a category of equipment? With rapidly changing technologies is yearly often enough to assess which is the most appropriate ultrasound machine? Who pays for site visits? Or does PHARMAC pay? Will [specialists] be prepared to fly economy on the cheapest carrier half way around the world to spend a day assessing equipment, stay in the cheapest hotel, eat a Maccas at their own expense, then fly straight back again!? Do companies pay, thus saving lots of money for PHARMAC, but allowing for the chance of undue influence?*

156. Submitters put forward a number of principles for a communications plan covering different phases of any process:

- consultation must be widely distributed to the actual user - users should have the most input into making the decisions
- ongoing communication should be accessible through the use of all forms of media such as, teleconferencing and skyping so those in remote areas have input
- communication must:

- allow sufficient time for the process so that stakeholders have the opportunity for informed input.
- have clear visible pathways of implementation so everyone understands the scope, purpose and implications on them and their practice.

157. Industry submitters reiterated previously discussed points about the need for PHARMAC to engage with industry as changes are undertaken and implemented.

Ways of communicating

Website

158. Several submitters suggested that a website would be useful or even crucial to the successful progression of this project.

> *The existing PHARMAC site is perceived as being a useful vehicle for the provision of information relating to pharmaceuticals. It is felt that a similar website for medical devices would be of considerable benefit. Allowing clinicians to engage on this initiative by disseminating timely and relevant information via an easy-to-use website is likely to be a key enabler of clinical input.*

159. A procurement specialist suggested using Notice of Intents on the Government Electronic Tendering Service ('they advise the sector quickly about a piece of work'). Although most clinicians don't access GETS, the notification can be emailed to clinical colleges and societies to be sent to their members.

Email

160. Many submitters stated that they were most easily contacted by email. A procurement specialist also noted that regular communication with the health sector required email addresses.

Face to face/via teleconference

161. Submitters also wanted face to face meetings or teleconferences with PHARMAC where appropriate. For example, clinical colleges' committees meet face-to-face or via teleconference during the year and would appreciate a representative from PHARMAC attending one of these meetings to discuss any matters arising as the system is developed and implemented. Submitters from some clinical groups wanted face to face meetings to outline requirements of their particular patient group. Similarly several manufacturers stated they would welcome a visit from PHARMAC to their manufacturing facility so they could gain an understanding of the manufacturer's role in the medical device supply chain.

Organisations & people

162. Several submitters made general comments on the topic of people and organisations PHARMAC should be working with in the medical device management system process. One submitter requested clarity about the role of the National Health Committee in the process, and further stated that there was considerable confusion regarding the roles of HBL, PHARMAC and NHC with respect to PHARMAC's medical device management system proposal.

163. One submitter considered that, in the first instance, there should be comprehensive sector engagement including clinicians at the higher strategic level, 'as it is these higher level decisions that set the health sector context underpinning the entire initiative.'

Clinical networks

164. A medical union submitted that meaningful engagement with all the relevant nationally representative speciality groups was critical to ensuring successful clinical input. In addition, it was submitted that PHARMAC also needs to determine who represents each core area of interest (for example, orthopaedics, vascular surgery, interventional radiology, cardiology, etc.) and then confirm that this group is suitably qualified to provide input on behalf of the entire speciality or sub-specialty. The submitter considered it essential for clinical advisory groups to encompass both public and private representation, and for clinical input to come from doctors that are truly representative of their peer group 'and definitely not from individuals that are shoulder tapped.'

> *Furthermore, individuals that are chosen as part of any clinical advisory body must be from the appropriate national body rather than from a more general entity. In addition it will be important to ensure these advisory groups/committees are, and retain, their independence throughout the entire process.*

165. Another submitter pointed out that clinical colleges and other clinical networks will provide expert opinion but are not accountable for the delivery of services and the implementation of new processes. PHARMAC should not neglect the provider clinical leadership capacity.

166. Clinical networks suggested by submitters are listed in Appendix 3.

DHBs

167. Several submitters commented on PHARMAC engaging with DHBs. Engagement through DHB clinical leaders was considered critical, 'more so than with external professional groups that do not have operational and clinical accountability for implementation.' However, while it was important to seek relevant clinical leadership it was also important to acknowledge that this must be provided with the approval of the employing organisations: 'It is not appropriate to appoint clinical advisors without the mandate of the primary employer, particularly when an appointee's substantive role is potentially compromised.'

168. It was also suggested by one submitter that PHARMAC have dedicated account managers for DHBs that sit alongside procurement teams; and category managers for the key areas of NICU, ICU and Cardiac Surgery. It was also suggested that DHBs could be grouped in terms of size with representatives from each grouping as key contacts. It was noted that given the regional work underway between DHBs, these regional groups could be approached to provide information, input and individual representatives. Submitters' suggestions of people (roles) to consult in DHBs is given in Appendix 4, and relevant publications are listed in Appendix 5

OTHER COMMENTS

169. Several submitters made comments outside of the questions posed in the consultation document. These comments related to:

- tracking medical devices used in the community. ('It is very difficult to contact families requesting the return of expensive equipment following a death.')
- Trans Pacific Partnership Agreement regulatory reforms:
  - concern that PHARMAC's role will be 'gutted by the provisions for patent term extension, data protection and patent linkage which will significantly deter generic drug development and supply,' and
  - the effect of investor state dispute mechanisms (which enable private investors to sue governments) on the ability of governments to legislate for public health good.
  - assessing the potential for introducing part-charge-payments for government-funded medical technology.

APPENDIX 1 AREAS OF PRACTICE & DHBS REPRESENTED

Areas of practice represented by submitters

	No. of submissions
Anaesthesia	5
Cardiology	3
Clinical engineering	2
Intravenous and Related Therapies	2
Radiology	2
Breast surgery	1
Ostomy & Stomal therapy	2
Colorectal	1
Diabetes & endocrinology service	1
Emergency nursing	1
Gastroenterology	1
Infection prevention & control	1
Intensive care	2
Medical Physics and Bioengineering	1
Neurology	1
Obstetrics & gynaecology	1
Oncology	1
Opthalmology	1
Neonatal Services	2
Paediatric and Congenital Cardiac Service	1
Paediatrics	1
Physicians	1
Plastic surgery	1
Radiation oncology	1
General surgery	1
Tissue viability	1
Urology	1
Total	**39**

DHBs represented by submitters

	No. of submissions
Auckland	8
MidCentral	4
Canterbury	3
West Coast	3
Capital & Coast	2
Bay of Plenty	1
Counties Manukau	1
Hawke's Bay	1
Lakes	1
Southern	1
Waikato	1
Wairarapa	1
Total	**27**

APPENDIX 2 SOURCES OF EVIDENCE

In response to Question 1 of the consultation document, submitters suggested the following sources of evidence.

a) International peer reviewed literature
b) Data on clinicians' requirement for service linked to the specific technology from industry and clinical users
c) Clinical papers and conference presentations
d) Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S)
e) Health Technology Assessments[1]
f) Testimonials from end users
g) Cochrane reviews and the Balliol Collaboration (scholarly appraisal of device assessment)
h) Information from specialist training bodies, particularly to ascertain if the medical technology usage contributes to training and research within the applicable clinical-specialty
i) Evaluations from National Institute for Health and Care Excellence (NICE UK) and similar bodies in the UK, Europe, the US, Australia and Canada
j) World Health Organisation' guidelines (minimum product requirements), and recognised international standards such as those of the US Food & Drug Administration, Therapeutic Goods Administration (MedSafe) certification, CE certification, ISO accreditation for manufacturing and quality, Centres for Disease Control guidelines
k) Medical information websites, for example, the Institute for Health Care Improvement, NHS Centre for Evidence-based Purchasing, ECRI Institute[2]
l) Suppliers' or sponsors' clinical trial data or validation evidence that may be available
m) Health economics reports, including analysis on the total cost impact to the health sector such as potential de-investment of other medical equipment or procedures in the current clinical pathway
n) Recall history from global regulatory agencies
o) Reviews of programmes used in other countries - one submitter noted that the WHO has worked with a number of countries to develop their own Essential Health Technology Package
p) DHB records (eg, global/regional centres of excellence)
q) International comparator pricing from markets of similar size and disease-state profile
r) Manufacturers' data sheets
s) Local usage and utility data (registries and clinicians records)

[1] It was noted by an industry submitter that challenges for Health Technology Assessments include the lack of a skilled assessment workforce, the timeliness of assessment reviews and difficulties in mounting robust medical technology studies (compared to pharmaceuticals.

[2] One industry submitter recommended that PHARMAC engage the ECRI Institute. '[This] is a nonprofit organization, dedicated to bringing the discipline of applied scientific research to provide advice on best practice medical procedures, devices, drugs, and processes to enable improvements in patient care. ECRI are designated an Evidence-Based Practice Center by the US Agency for Healthcare Research and Quality and listed as a federal Patient Safety Organization by the US Department of Health and Human Services. ECRI have a global member and client list of more than 5,000 hospitals, health systems, public and private payers, US federal and state government agencies, ministries of health, associations, and accrediting agencies worldwide.'

t) Close consultation and site visits with relevant manufacturers of particular device groups to understand their respective research and development pipeline and emerging technology programmes
u) Data on patient demand-matched recommendations for medical technology use from clinical associations, societies, colleges, leading experts and industry
v) Live demonstrations
w) Current clinical product committee work (already happening within and between DHBs)

APPENDIX 3 CLINICAL NETWORKS

In response to Question 8 of the consultation document, submitters suggested the following clinical networks.

Australian Safety and Efficacy Register of New Interventional Procedures
Australasian College of Emergency Medicine
Australasian College of Physical Scientists and Engineers in Medicine - NZ Branch
Australia & New Zealand Association of Stomal Therapy Nurses
Australia and New Zealand College of Anaesthetists
Australia and New Zealand College of Anaesthetists
Australian & NZ Society of Nephrology
Australian & NZ Society of Nephrology
Australian Council of Stoma Associations
Biomedical engineering
Burns Association
Cancer Society
Cardiac Society of Australia and New Zealand
College of Emergency Nurses NZ
College of Primary Health Care Nurses
Colorectal Surgical Society of Australia & New Zealand
Continence society
Department of Surgery, University of Auckland
Gastroenterology Society of New Zealand
Heart Rhythm Society NZ
Infection Prevention & Control Nurses College, NZNO.
Infection Prevention and Control Society
Intensive Care Society
Intravenous Nursing New Zealand Incorporated Society
National Blood and Transfusion Service
National cardiology network,
National Clinical Engineering Advisory Group
National Clinical Engineering Managers Forum
National Health IT Board
National Neonatal Network
National Quality & Safety Commission
Neonatal Nurses College of Aotearoa NZNO
Neonatal Society
New Zealand College of Public Health Medicine
New Zealand Medical Association
New Zealand Ostomy Association
New Zealand Rheumatology Association
New Zealand Society for Oncology
New Zealand Urology Nurses Association
NZ Association General Surgeons
NZ Association of Plastic Surgeons
NZ College of Nursing
NZ College of Urgent Care Physicians
NZ Nurses Organisation
NZ Orthopaedic Association Council of Medical Colleges
NZ Podiatry Board
NZ Royal College of Surgeons
NZ Wound Care Society Society
Paediatric Society
Prostate society
Radiation Oncology Work Group (an advisory group to the Ministry of Health)
Radiation Therapy Advisory Panel
Royal Australasian College of Intensive Care Medicine
Royal Australasian College of Physicians
Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Royal Australian and New Zealand College of Ophthalmologists
Royal Australian and New Zealand College of Radiologists
Royal NZ College of General Practitioners
Vascular Society of New Zealand

Consumer groups

- Auckland Women's Health Council
- Federation of New Zealand Ostomy Societies

Industry groups

- Medical Technology Association of New Zealand
- Independent Medical Distributors
- Individual medical technology supply companies

Individual clinical areas

Cardiology

- Regional cardiac networks should have representative on the clinical advisory board in the three key areas of medical devices: cardiac intervention - stents and balloons; cardian rhythm management - pacemakers and ICDs; cardiac surgery - valves
- Implanting centres in NZ

Medical flight teams

- The flight teams using the devices (through those in hospitals who co-ordinate or manage Flight & Retrieval teams).

Neonatal Intensive care

- Neonatal Nurses and doctors can provide specifications needed for neonates with input from other disciplines. Clinical Specifications will be based on evidence for best practice and health outcomes for neonates, which are quite different to adults. Medical device information can be obtained from procurement team including DHB clinical product co-ordinator after clinical input communicated to procurement.

Stoma therapy

- Stomal therapists - Stoma therapy was considered by clinical, industry and consumer submitters on the subject to be an area of particular significance for nursing input
- The National Stomal Therapy Nursing Section of NZNO
- UK & Australian authorities
- Ostomy supply companies - to determine developments and improvements being introduced
- Clinician and consumer testimony, including any institutional recommendations based on their experience with ostomy products.
- The National Federation of Ostomy Societies

Wound care

- Wound Care and Tissue Viability Specialists from a variety of DHBs and practice settings (ACC Providers, Residential Care, Primary and Secondary Health Care Services).
- New Zealand Wound Care Society members (via the President), Nurses at the 'coal face', Clinical Quality and Service Improvement Department, Surgeons, Occupational Therapists, ACC providers.

APPENDIX 4 PEOPLE (ROLES) TO CONSULT IN DHBS

In response to Question 8 of the consultation document, submitters suggested the following people (roles) be consulted in DHBs.

Allied Health Directors
Anaesthetic technicians
Asset and Capital Committee
Biomedical technicians
Capital planning committees
Chief Financial Officers Forum
Chief Medical Officer
Chief Operating Officers
Clinical Educators
Clinical Leaders & Heads of Department
Clinical Product Co-ordinators
DHB budget holders
Directors of Nursing
Neonatal Intensive Care Units and Special Care Baby Units
Procurement teams
Product and Infrastructure Safety Group
Theatre managers

APPENDIX 5 PUBLICATIONS

In response to Question 8 of the consultation document, submitters suggested that PHARMAC use the following publications and websites.

General

- Performance reports, Uptodate.com, Pubmed, *New England Journal of Medicine*, The Auckland Women's Health Collective monthly newsletter, all national health professional publications
- A simple infection prevention pathway/flowchart that is followed for each device to ensure patient safety in the particular domain is considered
- *Dissector* plus doctors' journals

Anaesthesia

- Regular newsletters and publications from ANZCA and the NZSA.

Implantable cardiac devices

- Product performance reports from companies that provide New Zealand with implantable cardiac defibrillators, pacemakers, implantable loop recorders, remote monitors and accessories for these.

Gastroenterology

- Gastrointestinal publications dealing with technological advances:
- GI Endoscopy
- Endoscopy

Nursing

- NZ Nursing Review
- NZNO nurses magazine *Kai Tiaki*
- NZNO Section magazines or newsletters
- Emergency Nursing - College of Emergency Nursing NZ Journal
- Intravenous Nursing - Individual websites include:
- www.ivnnz.co.nz Intravenous Nursing New Zealand Incorporated Society
- www.ins1.org Infusion Nurses Society (USA)
- www.ivteam.com Web-based resource (UK)
- www.ihi.org Institute for Healthcare Improvement (USA)
- www.avainfo.org Association for Vascular Access
- http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html Centers for Disease Control and Prevention
- http://www.wocova.com/ World Congress on Vascular Access
- http://www.iv-therapy.net IV Therapy Web resource

Orthopaedics

- NZOA clinical guideline publications
- NZOA website

Stomal therapy

- NZNOSTS publication *The Outlet*
- AASTN Journal, Ostomy Australia Journal
- NZNO Stomal Therapy Section Journal
- NZNOSTS webpage
- Ostomy Federation quarterly publication

Radiology

Tender documents are the usual way that manufacturers supply detailed specifications for the equipment they provide. A template should be given to the manufacturers to ensure they all provide the relevant information in a similar format to make comparisons more easily. The template should include:

- technical performance parameters, for example, kVp range, spatial resolution, speed of imaging, dose to the patient, image quality metrics
- treatment modality support (IMRT, VMAT, gating, electrons, etc.), DICOM and PACS connectivity details, and anti-virus provision
- connectivity to the treatment planning and patient management systems.
- service contract details
- power supply requirements
- room shielding requirements
- cost.

Wound and Skin Management and Pressure Injury Prevention and Care

Published clinical trials and evaluation studies

NHS, NICE, AWMA, NPUAP websites for Clinical Practice Guidelines for Pressure Injury Prevention and Management

Best Practice Guidelines, Consensus and Position Statements from EWMA, WUWHS, Wounds UK

APPENDIX 6 CONFERENCES, MEETINGS & MAJOR PRODUCT EVENTS

Submitters suggested PHARMAC could gain input into the process through attendance at the following events:

General

- NZ Healthcare Congress 25th & 26th June 2013, Auckland
- DHB clinical meetings
- Meetings with clinical advisory groups
- National scientific meetings, which are well attended by a wide cross section of clinicians - discussion around device options and procurement could become an integral part of these meetings
- Relevant international medical device conferences (such as the Radiological Society of North America, European Congress of Radiology, International Society for Magnetic Resonance in Medicine,) to further engage with manufactures and innovators and gain timely insight in emerging technology trends

Individual clinical areas

Anaesthesia

- Annual NZ Anaesthesia Scientific Meetings

Gastroenterology

- Gastroenterology Societies meetings
- NZ Society of Gastroenterology
- Attend meetings where devices are 'exposed' to clinicians; for example, the AGM of the NZ Society of Gastroenterology, Digestive Disease Week of the Gastroenterology Society of Australia, Digestive Disease Week in the USA

Emergency Nursing

- College of Emergency Nurses NZ Annual conference (Oct 2013)
- College of Emergency Nurses NZ committee meetings

Orthopaedics

- Meeting with NZOA representatives on a regular basis
- NZOA Annual Scientific meetings
- Continuing Orthopaedic Education meetings

Ostomy

- NZNOST National Conference (2014)
- AGM of Federation of NZ Ostomy Societies

Radiology

- Major equipment events around the world, for example, the Radiological Society of North America annual conference
- Site visits when a specific piece of equipment is being considered
- Annual meeting of diagnostic and therapy medical physicists in NZ
- ACPSEM NZ branch annual conference

APPENDIX 7 FACTORS TO CONSIDER WITH READY TO USE INJECTIONS

The detailed information provided by an industry submitter on factors to consider when procuring ready to use injections that have been filled into a medical device is presented below.

i. Electronic Infusion pumps

Electronic Infusion pumps are required to fill a variety of roles, both within the hospital and for patients at home (who remain under the care of hospital based clinicians). Key considerations for electronic pumps used in the hospital include:

- must be capable of use in wide range of roles including constant infusions, infusions of variable flow rates, and for infusions including bolus dosing (for example patient controlled analgesia)
- accommodate a range of methods of medication administration including intravenous, epidural, and subcutaneous
- pumps must be compatible to infuse solutions from infusion bags and/ or pre-filled syringes
- when used for administration of Controlled Drugs the pump requires facilities for securely locking/ storing the Controlled Drugs reservoir (for example a locked box facility to hold the infusion bag or pre-filled syringe)
- "Smart pump" technology to ensure safe infusion of medications.

Key considerations for electronic pumps used in the home (particularly when used for administration of parenteral nutrition, pain management, and antibiotics) include:

- Ease of use with pumps being easy to be programmed and when required reprogrammed, which may need to be undertaken by patients or their care givers, with no calculation of flow rates, ramp up/ down etc. When entering data enter Total Volume, Total Hours, Ramp Up and/ or Ramp Down hours for infusion, and pump to calculate the required flow rate(s)
- Pump capable of infusions flowing at constant rate, or multiple infusion rates, and options for bolus dosing
- Pumps must be robust and reliable (we have experienced patients who have dropped pumps from a moving car, and into a bath)
- Pumps should have both electric and rechargeable or disposable batteries as the power source
- For ambulatory patients pumps should be small and light weight and capable of fitting into a back pack.

ii. Disposable Infusion Devices

Disposable infusion devices can be used for a variety of classes of medications including antibiotics, analgesics, and cytotoxic chemotherapy allowing patients to be discharged earlier from hospital while still allowing medications to be administered intravenously. Features of these products include:

- Simple to use, while still allowing medications to be infused at a constant infusion rate over pre-determined infusion periods, with options for bolus dosing
- Devices must be robust, reliable, and of a physical size to allow patients to be fully ambulatory

- The choice of the internal lining of the central bladder/ reservoir is very important as this can effect drug stability, especially as infusions may run over extended periods of greater than 24 hours, and needs to be compatible with a wide variety of medications
- Easy to fill by hand - many brands have high resistance bladders that are very hard to fill by hand and may cause Repetitive Strain Injuries in staff filling these devices (pharmacy, nursing, or contract manufacturers)

iii. Syringes

When selecting syringes:

- Available in a wide range of sizes (1 ml to 100 ml)
- Available in both luer slip (for ease of use, especially for administration in complex situations such as administration of intrathecal medications) and luer locking systems (to ensure syringe is not detached from catheters when medications are administered particularly for cytotoxic chemotherapy)
- Biomed use syringes for packaging of medicines, and for each brand of syringes must undertake stability trials which are expensive and time consuming to undertake. Biomed suggests third party manufacturers may need to be exempted from using Pharmac listed brands until stability studies on new brands can be completed
- Biomed has identified unwanted peaks in HPLC analysis of solutions when undertaking product assays due to changes to the components of the syringe, which we were not notified of by the syringe manufacturer. On discussions with the syringe manufacturers we were advised the peaks were due components that are not harmful to patients, although these substances may interact with medications in the syringe
- The shape and dimensions are important for ease of use and especially if medications are to be administered via a syringe driver (most syringe drivers will only use accept specific brands, although they may be used with alternative brands if reconfigured by DHB biomedical departments, for example BD and Monoject can be used interchangeably as their shape and size are very similar, while Terumo brand is very different shape and dimensions and would require pumps to be recalibrated by hospital Biotech Engineers or the pump supplier
- Materials used in construction of syringes, and whether any materials can be leached that may be harmful to patients and/ or interact with drugs when syringes are used to administer medications, with the syringe manufacturer placing specifications for the syringes in a public domain
- Manufacturer to have an alert system to advise when changes are made in the materials used in the components of the syringes, with system to allow 6 months notice of changes, and supply samples of the changed devices.

iv. Giving Sets

- Giving sets need to be suitable for administration with medications and other products from a variety of containers including rigid containers such as glass bottles and infusion bags (requirement for vented sets), infusion bags (requirements for spike compatible with infusion bags) which may or may not need to be vented (vented lines can prevent pump alarms)
- Choice of construction materials (eg will plasticizers or other materials be leached from the giving sets)
- Low sorption sets are required for number of medications and blood products
- Light protective (for administration light sensitive drugs such as dacarbazine)

- Length of lines may be important, particularly for ambulatory patients

v. In-line Filters

Many medications and other products require filtration immediately before the products are administered, with a range of filter sizes (eg 0.22 micron, 0.45 micron, 1.2 micron, and 5 micron). Some hospitals require depyrogenating 0.2 micron filters if they have validated extended hang times for infusions of parenteral nutrition and analgesia

vi. Infusion Bags

Infusion bags are used for administration of medications, and especially parenteral nutrition where considerations include:

- Capacity of the infusion bags, will need a range to cover infusions of 50 ml through to 3,000 ml
- Number of chambers is important, particularly for administration of parenteral nutrition solutions, and would require single, double, and triple chamber bags
- construction materials, preferably low absorption materials such as EVA (ethyl vinyl acetate).

APPENDIX 8 LIST OF SUBMITTERS

Jason Clare, Cubro
Jennifer Dawson, personal
John Mottershead, Consultant Neurologist MSTAC; PTAC subcommittee member Southern DHB
Rachel Stedman, personal
Barbara Weckler, Physician, Grey Base Hospital
Mary Meendering, MidCentral Health
Doug Birnie, Howard Wright Ltd
Kieran Davis, Auckland DHB
Jacqui McKanny, Business manager, Fisher & Paykel Healthcare Limited
Jeremy Cooper, Senior Cardiac Anaesthetic Specialist, Auckland DHB
Glyn Thomas, personal
Ross Wilson, paediatrician, Capital & Coast DHB
Andrew Holden, Associate Professor of Radiology Auckland University & Director of Interventional Radiology, Auckland Hospital
College of Emergency Nurses, NZ
Karl Moen, Federation of New Zealand Ostomy Societies
Dr Peter Ruygrok & Helen McKenzie, Northern Region Clinical Cardiac Network
Desley Johnson and Karen Huxtable, Tissue Viability Service, Midcentral Health
Marilyn Head, Policy Analyst, NZ Nurses Organisation
Australia & NZ College of Anaesthetists and NZ Society of Anaesthetists
Deidre Maxwell, Northern Regional Oncology Operations Group
Chris McKenna, Director of Nursing, Hawke's Bay DHB
Jenny Gower, Neonatal Intensive Care Unit, Capital & Coast DHB
David Knight, ANZ Intensive Care Society
Surgical Heads of Departments, Auckland DHB
West Coast DHB
Iain Ward - Clinical Director Radiation Oncology; Rob Hallinan, Clinical Manager Radiation Therapy; Andy Cousins, Principal Physicist, Department of Radiation Oncology, Canterbury Regional Cancer and Blood Services
Colorectal Surgical Society of Australia & NZ
Peter Robertson, personal
Chris Black, West Coast DHB
Pieter Wijnhoud, Obex Medical Ltd
Pene Meiklejohn, New Zealand Urology Nurses Society
Ruth Barratt, Infection Prevention & Control Nurses College, NZ Nurses Organisation
Kate Garland, Radiation Oncology Working Group
Maree O'Connor, NZNO Stomal Therapy Committee
Sharron Matthewson, Charge Cardiac Physiologist, Christchurch Hospital
Hamish Allison, Jackson Allison Medical & Surgical Ltd
NZ Cardiac Network
Lynda Williams, Auckland Women's Health Council
Department of Anaesthesia, Auckland District Health Board
Henny Nicholls, Flight Nurses Section, NZ Nurses Organisation
Clare O'Donnell, Paediatric and Congenital Cardiac Service Interventional group, Starship/Auckland Hospitals
Steven Muir, NZ Branch of Australasian College of Physical Scientists and Engineers in Medicine
Bruce Hastie, Biomed Ltd
Ken Rackham, Independent Medical Distributors NZ
Martin Thomas, Chief Medical Advisor, Lakes DHB
Annie Marshall, Neonatal Nurses College of Aotearoa, NZ Nurses Organisation
Michael Rogers, Omnigon
Nicola Austin, Chair, Newborn Clinical Network Committee, The Paediatric Society of NZ
Neil Aburn, Chair, RANZCO Therapeutics Committee
Karen Longdill, USL Medical
Steve Hamilton, Vento Consulting
Angela Belich, Assistant Executive Director, Association of Salaried Medical Specialists
Helen Pocknall Chair, 20 District Health Boards Lead Directors of Nursing
Andrew Hickey, CEO, InterMed Medical Ltd
Faye Sumner, CEO, Medical Technology Association of New Zealand
Lucy McLaren, Nurse Educators, Wairarapa DHB
Wendy Guthrie, Operating Room Managers, Auckland DHB
Jane Cumming, Executive Officer, NZ Office, NZ Committee of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Rosemary Matthews, Senior Executive Officer, Royal Australasian College of Physicians
Chris Mundell, Country Manager, Smith & Nephew
Paul Ockelford, Chair, New Zealand Medical Association
Margaret Wilsher, Chief Medical Officer, Auckland DHB
Lara Wilson, Ainscorp Pty Ltd

Dr Geoff Long, Chair New Zealand National Committee, Australian & New Zealand College of Anaesthetists
David Waddell, General Manager - New Zealand, Baxter Healthcare Limited
David Meates, Chief Executive, Canterbury DHB
Dr Tony Williams, NZ Chair, College of Intensive Care Medicine; Dr David Knight, NZ Chair, Australia & New Zealand Intensive Care Society; Jeanette Bell, Chair, Critical Care Nurses Section of NZ Nurses Organisation
Grant Alecock, National Sales and Marketing Manager, Dansac
Anna Shaw, Business Development Manager NZ, GE Healthcare
Catharine O'Hara, Clinical Nurse Specialist in IV and Related Therapy, MidCentral DHB
Catharine O'Hara, President/Editor, Intravenous Nursing New Zealand
Angus Brown, NZ National Account Manager, Johnson & Johnson
Louis Havinga, Clinical Engineering Manger, Counties Manukau DHB
Tony Blackler, Chairperson, National Clinical Engineering Advisory Group & Manager, Clinical Technologies
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Flora Gilkison, Chief Executive, New Zealand Orthopaedic Association
Helen Cameron, President, Product Evaluation Health New Zealand
Royal Australasian College of Surgeons
Russell Walmsley, Secretary, New Zealand Society of Gastroenterology
Johnny Louie, Portfolio Manager - Child & Youth, Oral Health and Pharmacy, Bay of Plenty DHB
Rob Carpenter, President, NZ Society of Anaesthetists
John de Waal, NZ Association of Plastic Surgeons

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