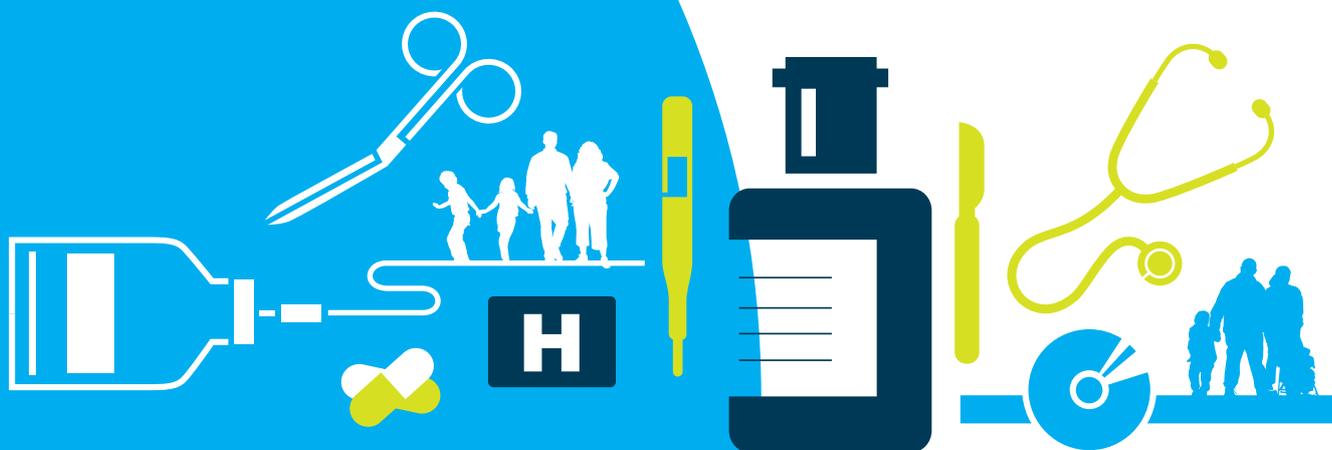


Summary of consultation feedback

PHARMAC's initial medical device activity

July 2013



INTRODUCTION

1. This report presents a summary of the feedback received by PHARMAC on their proposed initial medical device activity. Consultation documents were sent to medical device suppliers and district health boards (DHBs) and other health providers.

BACKGROUND

2. 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.
3. As part of this work, PHARMAC intends to embark on some specific procurement activities to help develop its systems and generate benefits for DHBs over the next 12-18 months.
4. PHARMAC's preliminary work, including that with Health Benefits Limited and the National Health Committee, has identified the following categories of devices as possible projects for PHARMAC to begin with:
 - a. Anti-embolism stockings
 - b. Disposable sterile instruments
 - c. Hand hygiene
 - d. Interventional cardiology
 - e. Mechanical compression devices and consumables
 - f. Orthopaedic implants – maximisation of suite of contracts
 - g. Sterile surgical gloves
 - h. Sterilisation wrap, tray liners and associated consumables
 - i. Sutures
 - j. Thermometers
 - k. Wound care.

PREPARATION OF THIS SUMMARY

5. PHARMAC requested feedback on its initial medical device activity from suppliers of medical devices, DHBs and associated groups during May and June 2013. Suppliers and DHBs were asked slightly different questions using two separate consultation documents.
6. During the response period from 14 May to 13 June 2013, feedback was received from 46 organisations and people. These responses were entered into a database, using a coding framework developed from the questions in the two consultation documents.
7. Although DHBs and suppliers were asked some different questions in the consultation documents, responses from both groups have generally been presented together.
8. In the analysis and summary, emphasis has been placed on the range of views presented, rather than on the numbers of respondents expressing a particular view. Counting was

made difficult because some of the responses represented a single voice, while others represented several or many people. An indication of the level of support for various positions has been given in places (using terms such as 'a few', and 'most') to show how widely held particular views were.

9. Quotes have been used to give a sense of the respondents' views. In the interests of privacy, individuals' names have not been supplied.

KEY THEMES FROM SUBMISSIONS

The proposed medical device categories

10. In general, the categories suggested by PHARMAC for initial medical device activity were supported by most health providers responding, including DHBs, clinical colleges, suppliers and professional organisations. There were more mixed views on the value of inclusion of anti-embolism stockings, hand hygiene products, sterile surgical gloves and sterilisation wrap, tray liners and associated consumables than the higher cost areas.
11. Few DHBs specifically addressed questions of the relative importance of the device categories proposed, however DHBs had various views on the best initial activity. It was variously suggested that PHARMAC look first at capital equipment, higher spend areas, areas with high variability in practice, areas where there is clinical acceptance of rationalising the use of products, and categories without an undue amount of complexity.
12. Other issues mentioned by DHBs reflect those submitted to PHARMAC during their March 2013 consultation (PHARMAC and hospital medical devices – obtaining clinical input). Important considerations were:
 - a. The need for consultation.
 - b. Including a wide range of products within device categories to support choice.
 - c. Maintaining flexibility to accommodate advances in devices and technology.
 - d. Taking into account the complexity of devices, and the amount of skill, training, in-servicing and rep support required in some categories.
 - e. Analysing the total health economics of a device.
 - f. Keeping more than one provider in the market.
 - g. Assessing the strength of evidence supporting any devices selected for use.
 - h. Considering the feasibility of achieving standardisation in practice
 - i. Wider market effects of decisions made and how they could affect the primary care industry.
 - j. Special consideration be given to standards products meet, especially in the areas of infection control, electrical safety, and processing requirements.
 - k. Supplier service history and supply chain implications.
13. DHBs suggested numerous additional areas for PHARMAC to focus on but did not necessarily consider these areas as higher priority than those categories proposed. It was suggested that PHARMAC remain open to undertaking new categories of work or reprioritising categories if conditions change. Some of these included various areas of capital equipment, anaesthesia related devices, respiratory equipment and laparoscopic consumables.

14. Most Clinician respondents were unaware of, or unfamiliar with, the national terms and conditions templates provided by the National Procurement Taskforce in 2010, although several DHB Procurement professionals considered they were still appropriate.

Opportunities for suppliers

15. In general suppliers saw opportunities across the device categories listed, largely due to their own company attributes such as vertical integration or the support they could provide to clinicians.
16. Suppliers considered PHARMAC should take the following into account when conducting a commercial process:
- Developments in the medical device area can occur very quickly – Technology changes are rapid.
 - Procurement based on a lowest price model does not address the sourcing of the most cost effective healthcare and finding value for money.
 - Companies promote New Zealand physicians and patients as a lead market – consideration must be given to how to continue to foster that environment.
 - The process must take account of the value provided by medical device companies to healthcare professionals in professional education and training.
 - Whose role will it be to investigate new technology and evaluating the effectiveness of devices?

Preferred contract duration

17. In general – across all categories – suppliers suggested three-year agreements were preferable, with a right of renewal for another year or two. This period was preferred as it gives stability and enough time to effect and consolidate any major conversions, as well as ensuring staff become very familiar with the products, but allows for any significant changes in circumstances such as manufacturing costs. Exchange rate variation clauses in contracts were preferred.

Feedback on individual categories

18. In response to questions posed in the consultation documents, DHBs and suppliers provided the following feedback.

Anti-embolism stockings

19. DHBs use anti-embolism stockings variably across medical and surgical specialties. Some DHBs considered the use of anti-embolism stockings could decline in the future.
20. Changes in usage or clinical guidelines was noted by suppliers, including; the Development of the New Zealand Venous Thromboembolism Prevention National Policy Framework, an increase in double wrapping, and a move towards knee length products.
21. Other factors needing consideration
- Quality of product and range of sizes available/required to meet all patient needs.
 - Ease of use.
 - If product is able to be laundered what are the laundering requirements to maintain effectiveness and how many uses will the patient get.
 - Consideration that any data supporting a product's efficacy needs to be evidence based.

Disposable sterile instruments

22. DHBs described three main areas of disposable instrument use: basic ward instruments – scissors, dressing forceps; disposable instrument sets for small procedures in wards or departments; and some theatre instruments. It was identified as a definite need to use disposable sterile instruments and moves toward an increasing amount of disposables. Perception, sustainability, waste and recycling in this area was however considered a challenge.
23. Suppliers considered that both single-use and reusable instruments would be relevant in New Zealand medical practice for the foreseeable future, but that there was a movement toward single-use instruments in high-volume procedures. Where sustainability is considered a critical factor then reusable or reposable devices should be considered. It was observed that some disposable medical devices once used are highly contaminated and not suitable for any form of recycling. However, one supplier currently provided 'a collection and recycling service' at one DHB. Also noted that disposable items are consistently sharp as opposed to reusable devices which dull over time.
24. Other factors needing consideration:
- Having a mix of both reusable and disposable in clinical areas can create confusion and lead to incorrect product being reprocessed/discarded.
 - Disposables must be:
 - clearly identifiable.
 - Fit for purpose.
 - Purchase with consideration given to recycling/ sustainability. Only use if truly cost effective.

Hand hygiene

25. Antibacterial hand rubs are widely available in DHBs in public as well as clinical areas (a dispenser at each bed in many cases). DHBs had mixed views on the suitability of hand hygiene products for PHARMAC's initial medical device activity.
26. Other factors needing consideration:
- Products must have minimal irritation or damage to the user's skin as a consequence of frequent use.
 - Ward furnishings and hospital infrastructure is altered or arranged around the type of product use in relation to brackets required. Brackets also need to secure product to prevent loss.
 - Products need to have low toxicity in case of ingestion.
 - Consideration of different patient populations and the epidemiology of regional microbiology.
 - Supply and installation of dispensers and brackets needs to be considered when selecting product.
 - Storage considerations where products are alcohol based.

Interventional cardiology

27. The term 'interventional cardiology', to cover all cardiology services that use devices was acceptable to two of the DHBs that responded; however, a clinical group considered the approach would lead to confusion as this definition was at variance with clinical use of the term. The group recommended initially dividing cardiology into device therapy and electrophysiology. There were a number

of considerations for PHARMAC activity in this area: in particular, rapid technology changes, the degree of clinical consultation required, and the on-going high level of technical support required. DHBs saw potential for cost savings as the wide range of products in the category could be problematic.

28. Three DHBs provided some categorisation suggestions as below:
- a. Capital equipment.
 - b. Stents/Catheters
 - i. imaging
 - ii. electrophysiology,
 - iii. vascular/structural (including introducers (radial, femoral), balloons, stents, thrombus extraction devices, specialty wires and specialty catheters).
 - c. Medicines (including contrast, antiplatelet therapy).
29. Suppliers noted that electrophysiology should be a distinct category to consider separately (noting the degree of crossover in the delivery setting and in the clinicians). Electrophysiology represents a complex category with the highest ongoing support burden over the lifecycle of the product. Given the complexity of the products, the service requirements and the rapid evolution of the technology, cardiology is not a good area of focus for PHARMAC at this stage.
30. Challenges faced in this category were noted as:
- a. Area of rapidly changing technology - allocation of a portion of market share for new technology trials needs to be considered due to the short innovation cycles.
 - b. Clinicians need to have choice available.
 - c. High level of technical support is required.
 - d. Wide range of products could be problematic and reduction in number of providers could be achieved as long as this didn't cause a reduction in potential innovation.
 - e. Having several providers reduces the impact of product failure or recall.
 - f. Consideration of effects to the broader health system need to be considered when selecting products – use of some therapies can provide unquantifiable benefits to patients and the community.

Mechanical compression devices and consumables

31. The use of Mechanical compression devices in DHBs depends on risk assessment but the devices need to be available in any area where the patient may be going for surgery. In some specialties the devices are used pre, intra and post-operatively and follow the patients. Other services use the devices only intra-operatively. Three DHBs stated that the devices were a definite growth area due to prophylactic management of deep vein thrombosis, and using the devices for a much wider range of surgical procedures.
32. Other factors needing consideration
- a. An understanding of the different forms of mechanical compression and the consumable choices available.
 - b. How hardware is factored in to the solution.
 - c. How this fits with DHB protocols for prophylactic management of DVTs.

Orthopaedic implants – maximisation of suite of contracts

33. The major issue for DHBs with orthopaedic implants was getting agreement from clinicians on standardising ranges. The process for allowing new products and new technology into the hospital was a particular challenge identified by several DHBs. Most respondents considered there were opportunities for further savings with orthopaedic implants, albeit with challenges similar to those found with current contracts. Overall, DHBs considered that a better system for procuring orthopaedic implants could be achieved. Most DHBs reported slight savings from the current national suite of contracts on orthopaedic implants.
34. Suppliers generally doubted that a better system for procuring orthopaedic implants could be achieved. Taking into account the critically important support services suppliers provide was emphasised. One supplier observed that national contracts have allowed terms and conditions to be aligned across DHBs and have enabled standardised agreements based on share. However, these contracts do not accommodate national variances or acknowledge other value-added services that suppliers invest in each DHB. Suppliers believe the investment they make in supply chain systems for orthopaedic implants have been instrumental in the efficiencies and savings that have been achieved thus far.
35. Other factors needing consideration
- a. Product use is related to the products surgeons were trained on and familiar with.
 - b. Cost of accommodating multiple devices at a DHB needs consideration in relation to; training, storage, reciprocity with other devices.
 - c. Introduction of new devices should have the support of more than one surgeon.
 - d. Management of loan kits.
 - e. Requirement for long term supplier support in provision of product components.

Any age and price banding needs to consider long-term studies and take into account; implant survivorship, lifetime costs, impact on efficiency.

Sterile surgical gloves

36. Almost all DHBs and suppliers commented on the strong clinician preference for particular products, and it was commonly considered that attempts to gain agreement to standardise on one or two suppliers would be a challenge. Opportunities were identified by DHBs for consistent pricing across DHBs.
37. Suppliers similarly commented on the importance of pre-contract clinical consultation and evaluation, with choice of supplier and breadth of range a key consideration. Suppliers noted that double gloving is becoming standard practice for many procedures.
38. Other factors needing consideration are that products must;
- a. Meet National and International standards.
 - b. Meet the needs of all the various surgical specialties.
 - c. Have latex-free option available.
 - d. Be easy to use in relation to; accessing packaging, donning.

- e. Be compatible with hand hygiene products.

Sterilisation wrap, tray liners and associated consumables

39. Procedures for wrapping instruments in Sterile Services Departments were described in varying detail by DHBs. Both DHBs and suppliers commented extensively on the quality of sterilisation wrap, tray liners and associated consumables, and noted that changes to packaging materials require sterilisers to be revalidated – a labour intensive and costly process.
40. Suppliers also noted an increasing trend toward pre-packages for specialities based on common use. The extent of clinical and technical support offered by some suppliers should be a consideration in any PHARMAC process.
41. Other factors needing consideration:
 - a. Physical properties test methodology in relation to; bacterial filtration efficiency, grab tensile, resistance to linting, hydrostatic pressure and flammability.
 - b. Data should be supplied for steam sterilisation, ethylene oxide, and gas plasma, bacterial barrier filtration, maintenance of package integrity, shelf life study.
 - c. Appropriate documentation could include compliance to ISO 11607-1: 2006, FDA Documentation – Declaration of Conformity, EU – TGA ARTG listing, quality management systems and environmental compliance, material safety data sheet, and disposal guidelines.
 - d. With tray liners, manufacturers should provide data to support the absorbency, low linting properties, and colour fastness. Fabric should not be abrasive so that instruments are not damaged.
 - e. Guarantee of supply.
 - f. Recycling and waste management requirements.
 - g. Clinical and technical support offered.

Sutures

42. Distinct sub-categories of sutures were put forward by DHBs but it was noted that these classifications were not discrete. Several DHBs considered there were opportunities for consistent pricing across DHBs and rationalising stock. Challenges included resistance to change from end users, and correctly associating particular types of suture with the appropriate speciality to obtain informed comment.
43. Suppliers commented more extensively on the distinct sub-categories of sutures, noting that sutures are significantly differentiated based on the type of procedure, tissue and patient they are used in. Suture was considered a particularly high involvement product, making change comparatively difficult. On-going clinical training on suturing technique for all levels of health professionals with current and new sutures was considered critical for optimal outcomes. Suppliers make a significant investment to ensure DHBs rationalise stock holdings and avoid expired product, with inventory management being provided by companies.
44. Other factors needing consideration:
 - a. If change were required how conversions would be managed?
 - b. Factors influencing a surgeon's choice of materials.
 - c. Supplier managed inventory.
 - d. Clinical training offered.

Thermometers

45. DHBs listed a great variety of types of thermometers used. Opportunities were identified by DHBs and suppliers for standardisation and for guidelines relating to the standard of device. One DHB commented on procurement experience with thermometers, noting the importance of consultation with wide range of staff across all services.
46. One supplier considered thermometry a candidate for a Product Range Review, but given the complications of capital equipment, this would require significant work on first creating standards, and even then only procuring on new business with the expectation that it would take several procurement cycles before a level of national standardisation is achieved. It would be challenging to get agreement on one technology and then capital outlay to equip hospitals with the appropriate device and retraining. Suppliers also considered it may be difficult to get DHBs to look at such an 'insignificant' item. One supplier believed that current agreements, where capital equipment is provided free of charge and as long as consumables are used, should be considered beneficial for the DHB and supplier.
47. Other factors needing consideration:
 - a. Standardisation guidelines relating to the standard of devicerequired according to different clinical areas.
 - b. Cost of capital equipment that could be required.
 - c. Accuracy.
 - d. Ease of use.
 - e. Suitability for all age ranges.
 - f. Speed.
 - g. Durability.
 - h. Security (to prevent loss through theft).
 - i. Cleaning: able to withstand a sporicidal disinfectant.
 - j. Avoid any that look like they can be reused but are actually single use.

Wound care

48. Most DHBs considered that activity in wound care should be done in sub-categories rather than more comprehensively because of the sheer volume and complexity of products available. The sub-category approach was considered better from a procurement process and clinical evaluation perspective and also more likely to provide a more standardised contractual outcome. Sub-categorisation would be problematic due to the multi-functional properties of many products, and the multitude of products.
49. Varying ways of sub-categorising were offered; therapeutic use, physical properties of dressing, aetiology. Several DHBs saw definite opportunities for savings with wound care through reducing inventory stock, and minimising the overlapping of consumables. The opportunity with wound care activity to inform clinicians, and support better clinical decision making was generally thought to be significant. DHBs considered it essential, though, that the product range matches the range of health needs. Managing change amongst practitioners was considered a key challenge – the process to gain consensus could be extensive.
50. Suppliers also generally considered for reasons of

practicality that activity in wound care should be done in sub-categories. Suppliers' wound care categorisation suggestions varied in scope but several suggested layers of categories such as a sub-category of advanced products being further divided.

51. Most suppliers considered there was scope for national standardisation of wound care products, however, there would need to be some options within the categories used in different clinical situations. A few suppliers considered that there was not scope for standardisation because many products currently available have their own unique features and benefits and these should be made available. It was suggested instead by one of these suppliers that PHARMAC have a panel of providers for each class and set pricing parameters. Several suppliers opposed having sole-supply arrangements because wound care is considered a very diverse category, with no one supplier being able to meet all requirements; and to prevent market domination by just a few suppliers.
52. Suppliers considered that in relation to basic, commonly-used wound care products only limited expertise is required which is readily available within DHBs and from suppliers. Advanced wound care products required clinical expertise from those who use the products and suppliers. Advice should be sought in the first instance from wound management groups within DHBs.
53. Other factors needing consideration:
 - a. Shelf life/stability.
 - b. Access to mentoring and professional support/training.
 - c. Access to new technology.

LIST OF RESPONDENTS

Health providers
Auckland DHB
Capital & Coast DHB
Cardiac Society of Australia and NZ
Chris Black
College of Emergency Nurses NZ (NZNO)
College of Infection Prevention and Control Nurses (NZNO)
DEBRA NZ
Hawkes Bay DHB
Health Alliance
Hutt Valley DHB
Lakes DHB
MidCentral DHB
Middlemore Hospital
Nelson Marlborough DHB
Nicholas Cooper
Northern Cancer Network
Northland DHB
NZ Medical Association
NZ Society of Anaesthetists
NZ Nurses Organisation
Product Evaluation Health New Zealand
Rachel Stedman
Royal Australasian College of Surgeons
Southern DHB
Tairāwhiti DHB
Waitemata DHB
West Coast DHB
Medical device suppliers
3M New Zealand Ltd
Covidien NZ Ltd
EBOS Healthcare
Intermed Medical
InterPharma Pty Limited
Jackson Allison Medical & Surgical Ltd
Johnson & Johnson (NZ) Limited
Kimberly Clark
Medical Technology Association of NZ
Medtronic Australasia Pty Limited
Molnlycke Health Care
Nutricia
NZ Medical & Scientific
Obex Medical Limited
Omnigon Pty Limited
Protec Solutions
Smith and Nephew
Stryker, South Pacific