Summary of consultation feedback

PHARMAC's proposed approach to market share procurement for hospital medical devices

August 2015

SUMMARY OF KEY THEMES

1. The key themes from PHARMAC's April 2015 discussion document *PHARMAC's proposed approach to market share procurement for hospital medical devices* are presented here. PHARMAC received 23 submissions: ten clinical submitters, seven device suppliers and one device supplier group, three District Health Boards (DHBs), DHB Chief Executive Group (CEs representing all 20 DHBs) and a national product evaluators group (PEHNZ). Responses from DHBs, DHB Chief Executive Group and PEHNZ have been grouped together due to the nature of the respondents (representing DHB views) and the high degree of feedback alignment.

Q1: What other market share models should PHARMAC consider and why?

2. The majority of respondents across submitter groups supported a multiple supplier or a percentage of market share model. Some suppliers preferred a dual supplier model as long as both suppliers had a comprehensive range of products. One device supplier proposed an open market model, in which suppliers that meet mandatory technical specifications are eligible to supply the market. A clinical respondent suggested that the type of market share model should depend on the seriousness of the safety issues associated with the device in question (eg categories 1, 2a, 2b and 3). An age and price banding model was suggested by a clinical respondent for larger orthopaedic devices.

Q2: What risks/benefits are there for these models?

3. Submitters across groups suggested numerous risks and benefits for all models, had a number of questions about the implementation of particular models, and commented on many factors that should be taken into account. With reference to the percentage of market share model, a large number of respondents pointed out that it would be difficult to administer and implement (eg measuring and enforcing compliance). Dual supply may offer lower prices and a degree of standardisation but carried the risk of others withdrawing from the market, a lack of flexibility, and limited access to new technology. Suppliers considered that with a sole supplier model there was likely to be greater savings achieved and a greater likelihood of standardisation; however, submitters across groups noted that sole supply had a number of risks associated with it, such as:
    - low quality product
    - reduction of services provided
    - supply risks
    - stifling of innovation and local competition
    - lack of clinical choice and inability to use new and innovative technology.

Q3: How do DHBs weigh up the costs of changing suppliers?

4. Weighing the cost of change is a difficult task, and carried out differently depending on the item in question. The majority of respondents noted a multi-factorial approach to weighing up the cost of change. DHBs may use formal evaluation committees; however, one respondent noted a DHB that does not use scientific methods (eg health technology assessment (HTA)) in making the decisions around change in the majority of cases.

Q4: What are the key issues wound care suppliers identify with the proposed approach to market share procurement for the wound care category?

5. Device suppliers challenged the assumption there is a high level of interchangeability between wound care brands. Suppliers considered medical devices including wound care products to be inherently different to pharmaceuticals. Issues include: suppliers ceasing to provide products where there is no commercial benefit, and the proposed model affecting a company's ability to address issues relating to dressing performance. Additionally, some suppliers stated that it would be important for PHARMAC contracts to include opportunities to introduce new technology. Clinical submitters suggested that the

function of the wound care device needs to be clarified. DHBs want good information and education on how to implement products. Access to alternative products may be needed for some patients. There must be a process in place for reviewing new products so the suppliers do not go directly to the DHBs, and the work of the Wound Care Advisory Group (WCAG) needs to be made available to DHBs as part of the change process

Q5: How appropriate are the wound care subcategories proposed for market share procurement?

6. Most respondents agreed that the wound care subcategories selected were narrow, but appropriate for market share procurement. However, clinical submitters considered the list needs refining as it is currently a mix of suppliers and actual dressing products. It was suggested that dressing functions may be a more useful way of sorting out subcategories. Device suppliers also considered that the categorisation of wound care should be aligned with the indication or condition.

Q6: What would be the preferred market share model for the wound care subcategories and why?

7. The majority of suppliers recommended having two or three suppliers per category. This was on the basis of as much standardisation as practicable, without risking supply issues. DHBs considered that the model would depend on the product – a single provider could be used in most cases; however there is a need to consider occasions where different products are clinically indicated. A monopoly supply should be avoided. There was some preference for 80/20 market share contracts. Nationally, there would need to be a panel of suppliers (minimum of three) as DHBs have different views on what is fit for purpose. Clinical submitters' views varied: one supported dual suppliers as long as they have a comprehensive range of products; the other suggested multiple suppliers in order to offer choices.

Q7& 8: What level of clinical choice (if any) is clinically appropriate for the wound care subcategories proposed for market share procurement? Why?

8. Submitters supported clinical choice being at the centre of product selection; however, the level of clinical choice would vary, depending on the nature of the product being considered. There was some submitter agreement that choice for low risk products should be limited. Some submitters detailed the level of clinical choice that could apply in various scenarios.

Q9: How do DHBs currently balance the need for clinical choice and the benefits of some market exclusivity for suppliers in the wound care subcategories?

9. Most respondents noted that there was an evaluation committee that made a decision on any changes to clinical suppliers. Decisions were made considering a number of factors including cost, clinical outcomes, supply chain considerations, impact on existing assets (if appropriate) and consistency across the organisation.

Q10: What other wound care subcategories should PHARMAC consider progressing to market share procurement? Why?

10. A number of respondents across submitter groups suggested other subcategories such as: alginates, occlusive dressings, negative pressure wound therapy, castings, securement tapes, calcium alginate dressings, tubular bandages on a roll, gels, absorbent pads, hydrocolloids, swabs (sterile and non-sterile) and tapes, antimicrobial dressings, and chemical debriding agents. Several submitters considered that including further subcategories should be driven by consultation with the sector.

Q11: What other key issues or properties should PHARMAC consider when evaluating products in the subcategories?

11. Submitters across groups suggested a wide range of key issues that PHARMAC should consider when evaluating products in the subcategories. These issues encompassed general principles relating to the evidence base use, having broad input, costing change, cost effectiveness, patient outcomes, and the ability to introduce new technologies; as well as very specific suggestions related to particular wound care products.

Q12: Who would you consider important to have on a wound care user testing panel for the products?

12. Submitters across groups suggested that representatives should be involved from across the product use spectrum, from a full range of clinical specialities, and a representative cross section of DHBs throughout New Zealand. Stakeholders include clinicians, other DHB staff, and frequent patient users. One DHB submitter suggested that a table top evaluation may be suitable initially to assess the products due to the interchangeability they have. Another submitter noted that user testing is not currently a means of obtaining good quality comparative data.

Q13: What other ways should be considered to approach user testing, taking into account the limited time and resources DHBs and PHARMAC might have available?

13. Submitters across groups suggested using available information such as the HTA information on wound care products already available in the Cochrane Database. Clinical submitters and DHBs stated that user testing should be as short as possible; using the team with the best coverage. One clinical submitter suggested on the job testing and fast feedback from the operating table and recovery rooms are the best places to receive feedback. Submitters across groups considered that user testing could be done at a regional level – specified DHBs could be nominated evaluation sites for defined subcategories to create efficiency with regard to user testing. It was also suggested that user testing could be an intrinsic part of the contract, and noted that the approach to user testing depends on what size panel is offered.

Q14: What kind of support do DHBs require to implement a change for the wound care subcategories?

14. Submitters considered that the support required would depend on the product. DHBs and clinicians suggested a number of areas for support including: time to use up old stock, a thorough user guide explaining outcomes, and an implementation pack that includes a listing of product details. Support for staff using the equipment and support to collate feedback may also be needed. In some DHBs there will be implementation champions who are available for questions and support. A clinical submitter noted that many services that use medical devices have no ability, currently, to capture and record data about device usage – this is a serious threat to monitoring implementation and conformity. It was suggested that the need for support will be reduced if relevant clinicians are offered the opportunity to be involved in the specification and testing group.

15. Device suppliers noted that DHBs generally require detailed product information, impact data, product education and clinical support provided in the form of expert supplier staff on-site in the DHB before and during product trials and conversions. DHB and PHARMAC implementation results may vary depending on the product and supplier attempting the conversion.

Q15: Would a change in any of the wound care subcategories listed above require additional resourcing? If yes, what are the resources required and why are they needed?

16. Clinical submitters considered additional resourcing would not be required except in the case of more specialised dressings. It was noted that categorising dressings by function would be more useful to the end user, and that more work is required in specifics for subcategories. Most DHB submitters identified several areas for additional resourcing, depending on the nature of the change and the timeframe required before compliance was required. These areas included a wound formulary for DHBs to guide staff in purchasing, supplier support to provide education regarding the changes (if relating to a totally new application technique) and potentially educator support to provide this within DHBs. Suppliers considered that a supportive change management process included: education, training and in-service support to ensure appropriate product selection and use and to realise any cost savings; implementation planning and assistance; stock management planning; and personnel and financial support.

Q16: Regarding market share procurement for products in the wound care subcategories, what other implementation issues are important for PHARMAC to take into account for your DHB?

17. Clinical and DHB submitters requested clear communication and timelines. DHBs want to have enough time to run down old stock and to have an adequate supply of product and be able to notify supply departments to ensure imprest item changes are updated and coded in departments. Submitters also queried what would become of existing stock, and whether there was potential for buy back of other product.

18. Device suppliers identified implementation issues around identifying which products are to be used in which areas, stock management, adherence to individualised implementation plans in consultation with key people from each DHB and suppliers, and sufficient time allocated for training on the products. One device supplier provided an extensive list of the broader issues around implementation and the key factors that may determine whether an implementation of a market share decision is successful.

Q17: What are the transition timeframes, training, resources and other support DHBs require to introduce new wound care products?

19. Clinical and DHB submitters suggested that the timeframe, training, and resources required depended on product function and the size of the change. For a simple product such as absorbent dressings – two to three weeks; for more specialised products such as silver antimicrobials – four to six weeks. More time may be required for a more complex transition for some products given the wide diversity of departments using them and distribution methods. Submitters suggested that as a general rule, DHBs need at least two to three months' notice to implement, and use existing stock.

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INTRODUCTION

20. This report presents a summary of submissions received by PHARMAC in response to its 2015 consultation *PHARMAC's proposed approach to market share procurement for hospital medical devices*. PHARMAC received 23 submissions: 10 clinical submitters, seven device suppliers and one device supplier group, three DHBs and DHB Chief Executive Group (representing all 20 DHBs) and a national product evaluators group (PEHNZ). Responses from DHBs, DHB Chief Executive Group and PEHNZ have been grouped together due to the nature of the respondents (representing DHB views) and the high degree of feedback alignment.

Background to the discussion document

21. The Government determined in 2010 that to control cost growth, PHARMAC will assume responsibility for managing the assessment, prioritisation, and procurement of medical devices on behalf of DHBs. This was part of Cabinet's response to the recommendations of the Ministerial Review Group. In 2012, the Government asked PHARMAC to work towards a phased plan to progressively take on the management of hospital medical devices, while also undertaking some immediate interim procurement activity. This follows PHARMAC's successful management of the combined pharmaceutical budget, and PHARMAC's role in managing hospital medicines and vaccines.

22. PHARMAC started the development of this process in 2012 with the first of six consultations. We have consulted on how we would obtain clinical input, what sorts of information we needed to consider, our decision criteria, and how to best apply the PHARMAC model to take on management of hospital medical devices.

23. PHARMAC's management of hospital medical devices will increase over time. As part of our initial activity, PHARMAC has been negotiating national contracts in five medical device categories, with seven others in development. Our first national contracts for hospital medical devices took effect in February 2014. As of 1 May 2015, PHARMAC has negotiated contracts for about 14,000 medical devices, covering approximately $47 million of expenditure. The savings to DHBs from PHARMAC's contracted medical devices are estimated at $13.2 million over five years.

24. The purpose of our discussion document summarised here was to seek feedback from stakeholders to inform PHARMAC's thinking on any issues submitters considered relevant to PHARMAC moving its hospital medical devices activity from national contracting to market share procurement. The consultation was open from 13 April 2015 to 7 May 2015.

25. This discussion document represents our sixth consultation with the sector about our work in medical devices. PHARMAC has received a lot of valuable feedback from these consultations and has engaged with a wide range of stakeholders. This discussion document was built on the earlier feedback we've received and is a continuation of our commitment to transparency and open dialogue.

26. PHARMAC will use the information from the feedback summarised here, and from previous consultations, to help develop and refine our approach to market share procurement for hospital medical devices.

ANALYSIS OF FEEDBACK

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

Q1: What models should PHARMAC consider and why?

28. In the discussion document, PHARMAC described a number of market share models and asked submitters what other market share models PHARMAC should consider and why? Sixteen submitters responded: four clinical, six device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

29. Clinical submitters had a range of views.

30. One clinical submitter considered that the market share model chosen should depend on the safety issues associated with the device in question. With category 2b and 3 devices, the determination of preferred device(s) ought to precede the choice of a market share model. The more expensive the device and the more serious the potential adverse consequences of getting the decision wrong, the more select the suppliers ought to be.

31. Another submitter noted particular considerations with orthopaedic devices relating to the holistic nature of the device delivery and use (a whole pack is required with multitudinous parts to it), the longevity of orthopaedic devices (the full range needs to be maintained), and the fact that orthopaedic surgeons use a wide variety of devices across the sector but individually become very good within a small range.

32. With reference to orthopaedic models, a submitter suggested that using the full-factorial attraction model for market share predictability would allow for precise estimation and predictability of market share while also allowing for new entrants to the market. Another appropriate model would be age and price banding for larger orthopaedic devices – this would leave market opportunities open but constrain medical technology companies to fit into a particular price bracket.

33. One submitter suggested PHARMAC consider dual suppliers as long as they have a comprehensive range of products.

34. One submitter wanted clarification as to whether a market share approach relates to a contract given to a supplier (and their whole range), or a subcategory heading, and the supplier's range under that heading.

DHBs, DHB Chief Executive Group and PEHNZ

35. Submitters considered that having multiple suppliers is appropriate for the wound care category while one preferred dual suppliers each with a percentage of the total. One submitter questioned whether PHARMAC would look at DHB specific market share models or sector wide market share models, noting that there are pros and cons for each of these. Another submitter noted that as experience and expertise develops, there may be opportunities to use other models such as growth share, with an emphasis on price markdown to compensate for excess supply.

Device suppliers

36. Two suppliers noted that the PHARMAC discussion document adequately reflected the variety of market share models in existence.

37. Several device suppliers suggested pricing models. One suggested PHARMAC consider pricing by each individual DHB's commitment to a supplier's product by market share. This submitter noted that previously 80 percent was considered commitment, with purchases outside this level acceptable because of individual patient specific requirements. This model reduces any need for analysis.

38. In relation to market share procurement with a percentage guaranteed portion, one submitter asked what happens if:
    - the percentage is not achieved and the pricing the goods were sold at was in a different band to the percentage reached?
    - there is a change in practice such that the product group is no longer used?

39. One supplier suggested the open market model be considered. In this model, providing suppliers meet the mandatory technical specification requirements, they are eligible to supply the market. The market share they win would be determined by the market (on a 'value for money' basis). This submitter suggested that the benefits of this model are that competition drives innovation in product design and supply chain efficiencies providing increased 'value for money' medical devices. It was noted that an open market model needs to be balanced against the benefits of device standardisation, cost of change and long term after sales service provision where a device has a long life cycle. It was also noted that in most medical device categories, the 'open market' model would condense to a small number of core suppliers given the size of the New Zealand market.

40. Two suppliers stated that the multiple suppliers' model is likely to be the most effective across the broadest range of scenarios in the procurement of hospital medical devices. Within this model basic dressings would typically require less choice and more sophisticated, advanced wound care systems would require more choice and flexibility to meet clinical needs. Submitters noted that a multiple supplier model can be flexible and capable of introducing innovation. It was suggested that PHARMAC should consider a ring fenced share allocated for innovative offerings. The risk of other supply models (such as sole or dual supply) subjects the New Zealand healthcare system to significant risks that are outside of the company's control (eg, United States' port closures).

41. One device supplier suggested multi-category supply.

42. Another device supplier suggested that a national procurement system should align with patient-centric and value for money concepts. These concepts require consideration of the following:
    - clinical and societal merits such as improved clinical outcomes, hospital efficiency gains, patient safety and manufacturer innovation, reliability and service capacity
    - cost-related factors extend beyond the initial purchase price
    - innovation and industry participation.

43. Another device supplier suggested that due to the complexities involved, the ideal procurement model would allow for negotiation in order to encompass measurable patient outcomes, full indication based value measurement, fostering innovation and avoiding an exaggerated focus on commodity purchasing.

Summary

44. The majority of respondents across submitter groups supported a multiple supplier or a percentage of market share model. Some suppliers preferred a dual supplier model as long as both suppliers had a comprehensive range of products. One device supplier proposed an open market model, in which suppliers that meet mandatory technical specifications are eligible to supply the market. A clinical respondent suggested that the type of market share model should depend on the seriousness of the

safety issues associated with the device in question (eg categories 1, 2a, 2b and 3). An age and price banding model was suggested for larger orthopaedic devices.

Q2: What risks/benefits are there for these models?

45. Eighteen submitters commented on the risks and benefits of market share models: five clinical, seven device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

46. Clinical submitters listed the benefits of market share procurement as:
    - Greater savings and financial predictability for a period of time provides sustainability for the DHB and supports budgeting models
    - standardisation and rationalisation will bring continuity of product use, reducing confusion, lessening the need for education, and freeing up storage space.
    - less wastage.

47. Clinical submitters saw failure of supply as the key risk, along with the risk of losing access to products used to treat different patient groups.

48. Several clinical submitters raised further considerations:
    - If using an 80:20 type of contract, the 20 percent needs to be free range access to alternative suppliers and not limited to one or two others.
    - Market share models also need to incorporate access to new products which come to the market.
    - One submitter reiterated that the orthopaedic device market is different from others. This submitter further noted opposition to any rebates to companies for large purchases. Such rebates would 'drive DHB ordering behaviour and will ultimately mean surgeons are not able to use the devices they are used to, productive with and have low revision rates from.'
    - Choosing a market model prior to understanding the range of suitable devices that ought to be available could result in the irreversible loss of suppliers or, conversely, the unwelcome persistence of a supplier of inferior devices.

DHBs, DHB Executive Group and PEHNZ

49. Submitters considered that, overall, the benefits of market share procurement may include: simplification of choice, lower pricing, and standardisation (though the link to standardised clinical practice needs to be actively promoted).

50. The general risks were considered to be:
    - impact on security and continuity of supply
    - increased costs to the DHBs if they do not fully understand the current market share being achieved by DHBs and cost of change
    - PHARMAC not committing enough time to ensure DHBs understand how PHARMAC's market for goods and services are structured and the type of product based activities it is planning to undertake.

51. Submitters generally commented on the benefits and risks of market share procurement in terms of the various models, as shown in the table below.

Table 1 DHBs, DHB Executive Group and PEHNZ views of benefits & risks of models

Model	Benefits	Risks
Percentage of market share	Better prices for guaranteed share of	Difficult to control at national level, easier to control at DHB level. Difficult to get compliance as clinician

Model	Benefits	Risks
	market.	preference varies across the country. Difficult to enforce when there is a wide range and large number of end users. It is much more feasible in a specialist unit. Requires close oversight and monitoring to ensure compliance.
		Issues with recalls and stock availability with no other NZ supplier, shortage of product related to potential shipping/freighting issues nationally or internationally.
		Sole supply can destroy competition by driving competition out of the market and will be a huge issue in the next stages.
		If a panel is in place but all or substantially all of the DHBs opt for a single supplier then the same risks exist as for selecting a single supplier as some panel suppliers may decide to withdraw from the arrangement.
		When the monopoly is created, suppliers retreat from NZ and long term prices do not bring the anticipated benefit. In addition risks associated with lowest price offered.
		Suppliers cut the price then have to reduce other services previously offered.
		Supplier management of customer needs, ongoing support with education, availability in clinical support situations – theatre procedures etc.
Dual suppliers		Opportunity for potential for price collusion between suppliers.
		Market share may result in withdrawal of suppliers from the market leading to lack of choice of product that fits consumers' needs.
		Not being able to move to more advanced technology as it is introduced due to the length of the contract.
Sole supply	Large savings at outset.	Risk of creating monopoly and retreat of suppliers from NZ market.
		Long term prices may not always benefit DHBs.
Multiple suppliers	Provides a more complex wound range and clinical choice.	The choice of product may be restricted if good clinical input is not provided.
	Better prices for guaranteed share of market.	Need to protect continuity of supply with a national contract.
	Ability to maintain multiple suppliers to ensure competition and innovation.	Chosen supplier(s) unable to deliver on promised capacity or specification.
	Great for competition and maintains honesty with supply prices.	Failure to properly engage clinicians who then complain about restricted clinical freedom.
		Appears to assume that all suppliers offer all the products clinically required. This is not so, especially in the wound care market.

52. Submitters also noted several general considerations:

- the cost of measuring market share commitments to ensure the benefits are worthwhile must be included in total cost of the initiative
- impact on supply chain costs for DHBs and third party logistics need to be included in the total cost of the initiative otherwise DHBs may not receive as high a benefit as expected
- DHBs need flexibility in contract terms as populations are not static

- there is a need for information about how new technology, new techniques and new evidence are assessed and managed within the contract environment
- the clinical stakeholders PHARMAC intends seeking advice from need to be identified at the outset of a device/range contracting process
- the agreements may not be used by the DHBs if there is insufficient clinical engagement and a clear new product process is not put in place.

53. One submitter suggested a need for more detail about what benefits market share procurement could bring to the overall supply chain especially in the areas of:
    - product life, which is continually getting shorter
    - alignment to proposed future national and regional distribution
    - buying behaviour – those DHBs who follow a regular and predictable buying pattern should be invited to participate in collaborative programs where a supplier and DHBs share supply and demand forecasts in order to reduce demand variability.

Questions

54. One submitter asked questions about procurement strategies and how they can support and align to market share models:
    - How will PHARMAC and the health sector become suitably informed on the state of the supplier market in creating effective procurement strategies?
    - How will PHARMAC determine the right model and/or procurement strategy for individual and/or groups of suppliers?
    - Will PHARMAC and DHBs be better informed on supplier work programmes and information about what they can provide to allow PHARMAC and subsequently DHBs to make fully informed decisions about the best approach to obtain value for money?
    - How strong will the analysis be to support long-term views on how PHARMAC will achieve market sustainability, and encourage efficient and competitive markets, remove barriers and foster supplier entry or growth?
    - Market conditions can change during the tenure of a contract – how will these changes be met and overcome?

Device suppliers

55. Device suppliers cited general benefits of market share procurement as:
    - enhanced user choice and cost savings
    - maintaining a competitive local supplier base
    - certainty of price/volume allowing improved planning and resourcing for the supplier.

56. Device suppliers considered that the risks of market share procurement were:
    - DHBs do not have systems in place to monitor compliance, leading to the inability to enforce market share agreements
    - increased burden for PHARMAC to administer the appropriate data required to guarantee suppliers are accessing their entitled market share
    - innovation and local competition could be stifled as monopolies could be created or maintained
    - supplier churn will increase for no net long term benefit considering PHARMAC and users costs to assess alternatives
    - lack of supply should a single supplier be unable to meet demand peaks and troughs in exceptional circumstances
    - reduced competition could push price upwards in the long term

- limited product availability with potential impacts on clinical effectiveness and patient well-being (some dressings are used outside the usually considered wound situation, eg Mepitel film is used in radiation oncology as a skin protectant, not a wound dressing)
- compromise of appropriate clinical choice, impacting patient outcomes and overall health expenditure
- required increase in training/re-training will affect face-to-face patient time
- companies will not invest in innovation if it becomes a battle of product on price line by line – they will be forced to supply the cheapest product with minimal training or support
- once a supplier has exited the market, it is very difficult to get them to return – New Zealand will suffer with technology introductions and it could encourage clinicians to leave New Zealand to advance their learning
- the investment in training of doctors and nurses would be affected and the health system would need to fund these costs moving forward.

57. Suppliers also commented on risks and benefits in relation to particular models, as listed in the table below.

Table 2 Suppliers' views of benefits & risks of models

Models	Benefits	Risks
Percentage of market share (with a guaranteed portion of the market)	Certainty of price/volume allows improved planning and resourcing for the supplier. Provides suppliers with the confidence to invest in infrastructure – providing this market share is of appropriate size.	A guaranteed portion of the market could potentially slow down innovation in product design and supply chain efficiencies.
	A degree of standardisation provides efficiencies to DHBs with staff training and device servicing.	The best 'value for money' supplier would be limited to their guaranteed share of the market (and what they could win of the open portion) instead of winning as much as possible of the market.
		Potentially some cost of change risks to DHBs.
		Companies not awarded share exiting the market.
Sole supplier	Theoretically the successful sole supplier should provide the best 'value for money' possible to DHBs due to the security provided by the sole supplier position.	The incentive to innovate could be significantly reduced and DHBs are unlikely to receive the benefits provided by state of the art devices in the industry.
	The highest degree of standardisation is achieved with a sole supplier.	Other suppliers may exit NZ. This may limit the choice of suppliers next time around.
		Service levels may deteriorate without competition – can be mitigated with performance clauses audited regularly.
		The cost of change could be significant if the supplier is effectively new to the market.
Dual suppliers	Limiting the market to two suppliers improves the economics for these suppliers and this should translate to lower device prices.	Innovation will be limited to the innovation provided by the two suppliers; this may not be the current state of the art in the industry.
	A high degree of standardisation is achieved.	Unsuccessful suppliers may exit NZ as sustaining infrastructure until the next contract round may not be viable. This may limit the choice of suppliers next

Models	Benefits	Risks
		time around.
		If supplier pricing is fixed for the contract term; the anticipated competition between the two suppliers may not occur if there are significant price differences. This can be overcome by allowing each supplier to run special pricing offers for a nominated time period.
		The cost of change could be significant if either supplier is effectively new to the market.
		Risk of inadequate flexibility to meet clinical needs for more complex wounds.
Multiple suppliers	Limiting the number of suppliers provides an increased degree of confidence to those suppliers on the panel.	There is a risk of having too many suppliers on the panel for the size of the NZ market – mitigate by limiting the number of suppliers on the panel.
	Increased competition for the business (no guaranteed portion of the market) incentivises innovation.	If supplier pricing is fixed for the contract term; the anticipated competition between the suppliers may not occur if there are significant price differences – overcome by allowing suppliers to run special pricing offers for a nominated time period.
	A degree of standardisation is achieved if there are not too many suppliers on the panel.	Long term contracts can prevent DHBs benefiting from new technology that has been introduced after the contract – can be mitigated by allowing suppliers on the panel contract to introduce new technology at regular intervals.
		Potentially some cost of change risks to DHBs.

Further considerations

58. Device suppliers raised a number of further considerations:
    - PHARMAC and the DHBs may find it more challenging than anticipated to successfully agree, implement and monitor market share contracts. Further, national contracts may not actually deliver the level of savings that individual DHBs could achieve by looking at their overall requirement rather than category specific national panel style or market share agreements.
    - If medical devices are selected by PHARMAC for inclusion in national contracts with too much emphasis on lowest price and less emphasis on clinical efficacy, clinical choice, quality of supply and supplier, clinicians may break proposed market share commitments to provide an appropriate product for patients.
    - PHARMAC would need to undertake detailed sector consultation prior to engaging in any market share procurement within a category.

59. One supplier also noted that market share procurement based on dollar sales is not necessarily a true indicator of use of product for wound care (eg hospitals purchasing foam products not for standard wound care use, but for patients suffering epidermolysis bullosa).

Questions

60. Device suppliers asked:
    - Whether it would be the responsibility of the DHBs to monitor and enforce compliance?
    - What guarantees will there be that this will happen and will this be transparent to the supplier?
    - What are all of the risks which PHARMAC recognises and will consider in this regard?

Summary

61. Submitters across groups suggested numerous risks and benefits for all models, had a number of questions about the implementation of particular models, and commented on many factors that should be taken into account. With reference to the percentage of market share model, a large number of respondents pointed out that it would be difficult to administer and implement (eg measuring and enforcing compliance). Dual supply may offer lower prices and a degree of standardisation but carried the risk of others withdrawing from the market, a lack of flexibility, and limited access to new technology. Suppliers considered that with a sole supplier model there was likely to be greater savings achieved and a greater likelihood of standardisation; however, submitters across groups noted that sole supply had a number of risks associated with it, such as:
    - low quality product
    - reduction of services provided
    - supply risks
    - stifling of innovation and local competition
    - lack of clinical choice and inability to use new and innovative technology.

Q3: How do DHBs weigh up the costs of changing suppliers?

62. Submitters were asked to comment on how their DHBs currently weigh up the costs and benefits to decide when it is favourable to make a change? Twenty-one submitters responded to this question: eight clinical, seven device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

63. In general, submitters stated that DHBs look at cost, clinical benefits and risks. Trials with clinicians may also be done. Cost/benefit analysis is done particularly when new products rather than replacement products are evaluated. Consultation with key stakeholders is carried out, particularly if major changes in practice are necessary.

64. Several submitters commented specifically on wound care products. The decision to evaluate new products, and/or consider a change of provider, comes about following feedback of current product performance, patients' changing needs, and evidence of better performing products becoming available. Dressings are scrutinised based on suitability and performance and rated compared with previous product price. One stated that changes to dressing products are processed by the Tissue Viability Service Clinical Nurse Specialists.

65. One submitter noted that surgeon autonomy for orthopaedic device choice is the main way devices are purchased. Savings have been made in some DHBs where orthopaedic surgeons agree to use a small range of devices but are able to go outside of this parameter after agreement with their colleagues.

66. One submitter that there was currently a lot of freedom in their DHB. Another submitter stated that the drivers of choice about suppliers appear "not to be scientific in the vast majority of cases". "At best, such choices are made by committees that do not use HTA techniques but depend on experience and the

oratory skills of proponents. At worst, such choices are expedient ones based on hastily made, poorly-informed decisions perhaps based loosely on costs."

DHBs, DHB Executive Group and PEHNZ

67. Submitters noted that the cost of change is very hard to assess and needs to be treated on a case by case basis. Submitters provided extensive lists of considerations that may be involved when considering the total cost of ownership. As part of the total cost submitters consider the following factors:
    - The robustness of the supply chain, and the time and effort required for supply chain changes.
    - Staff costs:
        - Training, time, acceptance, ease of use, any issues identified by staff and/or departments to consider if another line is deleted as a result of this decision.
        - Level of difficulty of becoming familiar with replacement product, how emotionally attached are the end users and who are the key stakeholders as some are more powerful and influential than others.
        - The anticipated level of resistance to change due to previous historical negative experiences.
    - Placing system alerts (if identified as specialised product) requiring specialist advice only to use.
    - Ensuring that clinical best practice will be met if the change is pursued.
    - Patient need and the delivery of care needed to meet this.
    - Focussed product evaluations to assess clinical effectiveness compared to current product used.
    - Consumer feedback on the product via evaluations.

68. Submitters asked who does the user testing and when this is decided. It was noted that the acceptance processes and evaluation need to be structured ('not a random disorganised approach'). Additionally, analysis needs to compare the cost of what is currently used to the cost of a new product, and related costs such as other items needed to complete a package of care, any associated consumables or hardware needed to make the device work as intended, and the costs of wastage.

69. Submitters noted that making a change with more complex products requires a great deal more energy and time. The resources involved could outweigh the available savings.

Device suppliers

70. Suppliers suggested that DHBs could reduce the time taken to implement change at DHB level and increase the transparency with which PHARMAC and DHBs are aligned in achieving change in medical device procurement. Additionally PHARMAC should ensure sufficient and appropriate resources are allocated to DHBs to assist them to implement change.

71. It was also considered that the cost of implementing change in supply is underestimated by DHBs – there is considerable investment by suppliers to support change in treatment with education and training. Also, there needs to be very good communication at all levels within the DHB, to ensure that all parties understand a contract – what it means to the DHB and the benefits to them.

Summary

72. Weighing and measuring up the cost of change is a difficult task, done in various ways depending on the item in question. The majority of respondents noted a multi-factorial approach to weighing up the cost of change. DHBs may use formal evaluation committees however one respondent noted a DHB that does not use scientific methods (eg HTA) in making the decisions around change in the majority of cases. Suppliers noted that the cost of implementing change in supply is underestimated by DHBs.

Q4: What are the key issues wound care suppliers identify with the proposed approach to market share procurement for the wound care category?

73. Submitters were asked about the key issues wound care suppliers identify with the proposed approach to market share procurement. Thirteen submitters responded: three clinical, six device suppliers and one device supplier group, two DHBs and DHB Chief Executive Group.

Clinical submitters

74. Clinical submitters suggested that the function of the wound care device needs to be clarified. Although the dressing range between suppliers seems comparable there are differences between the products, and evaluation will be required before implementing. Percentage allowances for market share could be variable between 'simple' dressing ranges and 'complex' dressing ranges.

75. One submitter noted that wound care in orthopaedics requires very specific procurement as deep tissue infection and surgical site infection can mean a long slow recovery process.

DHBs, DHB Executive Group and PEHNZ

76. Submitters raised several issues in response to this question. DHBs need to obtain clinician buy-in and consult well across all users. They need good information and education on how to implement products. Access to alternative products may be needed for some patients. There must be a process in place for reviewing new products so the suppliers do not go directly to the DHBs.

77. A submitter also considered that the work of the WCAG needs to be made available to DHBs as part of the change process.

78. Another submitter noted possible difficulties with product standardisation and supplier rationalisation should the market share panel be too extensive, and shortage of strategy and parameters to support clinicians to start making non brand driven choices.

Device suppliers

79. Device suppliers identified a number of issues with the proposed approach to market share procurement.

80. Device suppliers challenged the assumption that there is a high level of interchangeability between wound care brands. It was noted that, in general, with many wound care products, there is a clear benefit/cost trade-off. Lower priced products tend to have lower performance, higher overall treatment costs and less clinical testing/evidence to support their usage.

81. Submitters also considered medical devices, including wound care products, to be inherently different to pharmaceuticals. Development lead times are shorter, as are product life cycles. The actual cost to produce a particular device (excluding all development costs) is a far greater percentage of the finished price than occurs with pharmaceuticals. Supply chain costs (freight) are also much greater.

82. One submitter considered that a high degree of rationalisation of this category and awarding to multiple suppliers puts the New Zealand healthcare market and DHBs at risk due to suppliers' reduced ability to effectively manage supply chain efficiencies, procure the best price and manage demand fluctuations for all customers. Additionally, the model would affect a company's ability to address any issues of dressing performance. However, another submitter stated that having multiple suppliers in any category allows for a critical manufacturing or delivery problem to occur without damaging total supply.

83. Suppliers agreed that having a new technology clause will be important in any new contract with the ability to review and potentially add new products regularly.

84. It was noted that suppliers will cease to provide products where there is no commercial benefit. The subsequent reduction in choice may reduce clinical efficacy, particularly in niche areas. Reduced competition will also result in less education and training, less support at third party clinical meetings and less company education forums.

85. Device suppliers asked that accurate figures for the total market size are made available during the procurement process so that realistic pricing can be offered by any respondent.

Summary

86. Clinical submitters suggested that the function of the wound care device needs to be clarified. DHBs want good information and education on how to implement products. Access to alternative products may be needed for some patients. There must be a process in place for reviewing new products so the suppliers do not go directly to the DHBs, and the work of the WCAG needs to be made available to DHBs as part of the change process

87. Device suppliers challenged the assumption there is a high level of interchangeability between wound care brands. Suppliers considered medical devices, including wound care products, to be inherently different to pharmaceuticals. It was noted that suppliers will cease to provide products where there is no commercial benefit, and that a new technology clause must be added to contracts. Device suppliers asked that accurate figures for the total market size are made available during the procurement process so that realistic pricing can be offered by any respondent. Issues raised include the proposed model affecting a company's ability to address issues relating to dressing performance

Q5: How appropriate are the wound care subcategories proposed for market share procurement?

88. The discussion paper asked about the appropriateness of the wound care subcategories proposed for market share procurement. Thirteen submitters responded: two clinical, five device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

89. Clinical submitters considered that the current subcategory list is incomplete, for example, it does not include high cost products. The list needs a lot more refining as it is currently a mix of suppliers and actual dressing products. Dressing functions may be a more useful way of sorting out subcategories, for example, how they manage moisture, bacteria, or fragile skin.

DHBs, DHB Executive Group and PEHNZ

90. Submitters agreed that the wound care subcategories proposed for market share procurement are appropriate. It was noted by two submitters that the subcategories are relatively narrow; however, this was acceptable to these submitters if sole supply was avoided. Several submitters noted that the list of subcategories was not exhaustive and gave examples of some that were missing, for example, hydrocolloids, and alginates. It was suggested by several submitters that more work was required in this area, including further clinical input.

Device suppliers

91. Device suppliers considered that the categorisation of wound care should be aligned with the indication or condition.

92. Some suppliers agreed that the products listed on the table in the discussion document are simple, low-risk products that are appropriate, with an agreed high level of interchangeability – the less technologically advanced products are much more suitable for any market share procurement. It was noted, however, that not all subcategories in wound care would fit this approach. There is a big difference in likely change in technology between something as basic as a wound dressing pack and foam dressings that would currently be considered the most advanced wound dressing category.

93. These submitters suggested that PHARMAC should consult with the sector around proposed subcategorisation within categories.

Summary

94. Most respondents agreed that the wound care subcategories selected were narrow, but appropriate for market share procurement. However clinical submitters considered the list needs refining as it is currently a mix of suppliers and actual dressing products. It was suggested that dressing functions may be a more useful way of sorting out subcategories. Device suppliers also considered that the categorisation of wound care should be aligned with the indication or condition.

Q6: What would be the preferred market share model for the subcategories and why?

95. The discussion paper asked respondents what the preferred market share model for the subcategories would be and why. Fourteen submitters responded to this question: three clinical, five device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

96. Clinical submitters' views varied. One supported dual suppliers as long as they have a comprehensive range of products; the other suggested multiple suppliers in order to offer choices when patient needs are outside of the norm, and to ensure patients with allergies have timely access to alternative products. This submitter also raised the need to consider cheaper options for other providers such as aged residential care, and the need to consider ACC and alignment to the range of products they supply. Another submitter noted that the preferred market share model would be different for different care settings and the percentages required within the categories may vary.

DHBs, DHB Executive Group and PEHNZ

97. Submitters stated that the model would depend on the product. At the local DHB level and for some basic products (such as low adherent dressings, securement bandages and wound dressing packs), a single provider could be used in most cases; however, there is a need to consider occasions where different products are clinically indicated.

98. Two submitters noted that monopoly supply should be avoided. Amongst DHBs there was some preference for 80/20 market share contracts. One submitter suggested a volume based percentage market share inclusive of financial rebates if a DHB maintains its confirmed volume and increased pricing for those that do not (with a more accountable approach to how contracts are entered into and managed).

99. It was also submitted that nationally there would need to be a panel (with a minimum of three suppliers) as DHBs have different views on what is 'fit for purpose.' DHB submitters reiterated that foam dressings have different presentations and should have multiple suppliers (ie, more than two). One submitter stated they were open to seeing what the tender process shows as the best savings for the sector when considering the total cost of change.

Device suppliers

100. Several device suppliers noted that the preferred market share model would vary depending on the category (and should be the result of PHARMAC consultation with the sector before beginning market share activities within any given category). Submitters accepted that market share procurement models could be applied to commodity product categories. However, advanced wound dressings such as foams would be better assessed and purchased through the efficiency-based purchase-provider model.

101. Categories should be aligned with indications for clearer differentiation between simple wound care products and the more complex – in which case, dual or single supplier models may work for the simpler offerings. It was noted by one submitter that there is no evidence of such a differentiation in use locally or internationally.

102. One submitter suggested pricing by each individual DHB's commitment to a supplier's product by market share. Another submitter suggested that multiple suppliers could reduce risk for DHBs (of availability or product failure). Dual or multiple market share was considered preferable because the products appear in almost every ward in every DHB, putting these products into a high risk category due to volume and breadth of use. Another submitter also suggested having two or three suppliers per category because of the need for standardisation as far as practically possible, and to mitigate against the risk of supply issues arising. However one device supplier considered that given the nature of the products, a sole or dual market share model should not be considered due to significant risks.

Summary

103. The majority of suppliers recommended having two or three suppliers per category. This was on the basis of as much standardisation as practicable, without risking supply issues. DHBs considered that the model would depend on the product – a single provider could be used in most cases; however there is a need to consider occasions where different products are clinically indicated. A monopoly supply should be avoided. There was some preference for 80/20 market share contracts. Nationally, there would need to be a panel of suppliers (minimum of three) as DHBs have different views on what is fit for purpose. Clinical submitters' views varied: one supported dual suppliers as long as they have a comprehensive range of products; the other suggested multiple suppliers in order to offer choices.

Q7& 8: What level of clinical choice (if any) is clinically appropriate for the wound care subcategories proposed for market share procurement? Why?

104. The discussion document asked respondents what level of clinical choice (if any) they would consider clinically appropriate for the wound care subcategories proposed for market share procurement. Sixteen submitters responded: four clinical, five device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

105. Clinical submitters' views varied. One submitter considered that if the dual supplier model was applied to each subcategory this would give clinicians enough choice.

106. One submitter stated that subcategories should be chosen by function, and by clinicians with a working knowledge of wound care and wound products (preferably those who specialise in this field, or spend a considerable part of their time working with patients with wounds.) Similarly, another submitter considered that clinical choice is of the utmost importance, noting that the cost of surgical site infections outweigh any benefit from any low price for market exclusivity.

107. One submitter considered that further clarification was needed around the products that sat under various wound care headings (eg combine dressings). Patient needs vary across the care continuum and therefore an appropriate range of products needs to be available. The same submitter stated that foam dressings should not be considered for market share procurement.

108. Clinicians were considered more likely to have the benefit of greater hands-on experience and evaluation of product usage, suitability and user friendliness, with a wider range of products

109. One submitter detailed the level of clinical choice that should apply in various scenarios:
    - the exception device is superior in terms of patient outcomes but costs more – an incremental cost-effectiveness ratio should be calculated by PHARMAC and used by PHARMAC and or the DHB wishing to use it about inclusion and/or affordability
    - the exception device is superior in terms of patient outcome but costs the same or less – PHARMAC should move to change the preferred device
    - the exception device is non-inferior but costs more – purchase should be mandated against at PHARMAC and DHB levels
    - the exception device is non-inferior and costs the same – PHARMAC may agree to include the device and allow its purchase (discretionary)
    - the exception device is non-inferior and costs less – PHARMAC should move to change the preferred device
    - the exception device is inferior in terms of patient outcomes – purchase should be mandated against at PHARMAC and DHB levels.

DHBs, DHB Executive Group and PEHNZ

110. Submitters agreed that patient outcomes are the priority and clinical choice provides the opportunity to scale patient care up and down if necessary. The more complex the product the more clinical input is needed. The level of clinical choice must be dependent on patient related factors and having enough flexibility in available products to allow for patient reactions (more likely to be an issue with low adherent dressings with adhesive border, securement bandages and foams).

111. One submitter suggested that for any product type (in this subcategory) there should be a maximum of four, and a minimum of two suppliers, that is, some choice but high standardisation. It was further noted that at a local level a DHB may decide on one supplier although experience nationally suggested that 'one product doesn't always fit all'.

112. Another submitter agreed that choice for such general or low risk products (as cited in the discussion document) should be limited. Another submitter suggested the following degree of choice:
    - combine dressings – 1 range
    - low adherent dressings – 2 ranges
    - securement bandages – 2 ranges
    - wound care dressing packs – 1 range
    - foam dressings – 2 ranges.

Device suppliers

113. Device suppliers supported clinical choice being at the centre of product selection; however, the level of clinical choice would vary depending on the nature of the product being considered. Advanced and more complex wound care requirements need significantly more clinical involvement and product choices.

114. The level of clinical choice needs to accommodate a range of end uses and levels of technical competency required for correct application.

115. Additionally, the level of detail appropriate for wound care subcategories would need to be chosen without excluding those suppliers that have small but niche product ranges.

116. It was also noted by one submitter that DHBs currently make very different procurement decisions even though they have similar product and pricing information.

117. Overall suppliers considered that clinical choice is essential due to a wide variety of factors such as patient type, skin type, allergy, wound type, wound response and healing time with expert wound care practitioners needing all tools available to them. It was also noted that the frequency and complexity of change regimes can have a profound effect on the overall cost of treatment. Clinicians were considered to be best placed to make the clinical choices about the appropriate device for a patient and situation. One supplier noted that products are always designed and created with the assumption that clinical choice will drive the best possible patient outcome.

118. Additionally, limitation of the surgeon's choice has significant implications for training and technique which is likely to have an impact on patient outcomes. Further to this, access to the current 'gold standard' medical technologies as well as to new and innovative technology is an important factor when attracting and maintaining a high quality public health sector workforce.

Summary

119. Submitters supported clinical choice being at the centre of product selection; however, the level of clinical choice would vary, depending on the nature of the product being considered. There was some submitter agreement that choice for low risk products should be limited. Some submitters detailed the level of clinical choice that could apply in various scenarios.

Q9: How do DHBs currently balance the need for clinical choice and the benefits of some market exclusivity for suppliers in the wound care subcategories?

120. The discussion paper asked respondents how DHBs currently balance the need for clinical choices and the benefits of some market exclusivity for suppliers in the wound care subcategories. Ten submitters responded: two clinical, two device suppliers, a device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

121. Clinical submitters stated that their DHBs currently balance the need for clinical choice and the benefits of some market exclusivity for suppliers through their procurement service and product evaluation committees. These committees facilitate trial and approval of wound care product and undertake cost/benefit analysis with each new product submitted.

DHBs, DHB Executive Group and PEHNZ

122. Submitters stated that the processes vary between DHBs and products; however, patient outcomes are the priority. One submitter commented on the need to build a foundation of trust with clinicians by demonstrating that procurement is listening to them and want to come to a collaborative decision in the best interests of patients and the DHB. Examples of processes were:
    - working very closely with clinical staff during the evaluation and selection process to gain agreement on items selected
    - any changes to clinical supplies are required to go through the product evaluation committee for a decision that balances a number of factors including cost, clinical outcomes, supply chain considerations, impact on existing assets (if appropriate) and consistency across the organisation

- analysis of benefits and risks of the various products on offer as well as historic and current use – if the benefit of market exclusivity is supported from a clinical and cost perspective then it would be considered.

123. One submitter noted that with a high level of interchangeability of the listed products, and a significant focus on cost savings, it is likely cost benefit could be weighed more heavily.

Device supplier

124. One device supplier noted that to achieve standardisation a very robust testing programme would need to be developed and agreed nationally with binding hospital-wide buy-in.

Summary

125. Most respondents noted that there was an evaluation committee that made a decision on any changes to clinical suppliers. Decisions were balanced on a number of factors including cost, clinical outcomes, supply chain considerations, impact on existing assets (if appropriate) and consistency across the organisation.

Q10: What other wound care subcategories should PHARMAC consider progressing to market share procurement? Why?

126. The discussion paper asked what other wound care subcategories PHARMAC should consider progressing to market share procurement, and why. Twelve submitters responded: two clinical, four device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

127. Clinical submitters listed the following wound care subcategories:
    - gauze
    - tapes
    - padding for use under or as part of support and compression bandages, and under plaster of Paris casts
    - tubular bandages for retention, support, protection, and as part of wet wraps treatment for skin conditions
    - negative pressure wound therapy, antimicrobial dressings, chemical debriding agents.

DHBs, DHB Executive Group and PEHNZ

128. Submitters had various views. One considered there was a need for feedback from the advisory group; another stated that no more subcategories were required. Suggestions for other subcategories were:
    - alginates – as there are several suppliers of this product, and silver as a dressing is now provided by multiple companies in different strengths with a consequent concern for overuse and bacterial resistance
    - including occlusive dressings in low adherent dressings
    - negative pressure wound therapy as it has a large spend and only two major suppliers
    - castings
    - securement tapes
    - calcium alginate dressings (non-antimicrobial)
    - tubular bandages on a roll
    - gels (non-antimicrobial)
    - adhesive dressing
    - antimicrobial dressings

- dressing tapes
- compression dressings
- absorbent pads (high absorbency) and hydrocolloids as these products are generally standard and do not vary as greatly in properties as other products such as foams.

Device suppliers

129. One device supplier suggested that PHARMAC measure and review the entire episode of care where wound products are used and record the variation and ultimate effectiveness of each episode as a whole. This submitter stated that the following wound care subcategories could be considered: swabs (sterile and non-sterile) and tapes as these subcategories meet the criteria outlined in the discussion paper.

130. Other device suppliers suggested that the subcategorisation should be driven by consultation with the sector as well as specific input from clinicians. A third submitter considered that from a category perspective, PHARMAC is best placed to make that judgement.

Summary

131. A number of respondents across submitter groups suggested other subcategories such as: alginates, occlusive dressings, negative pressure wound therapy, castings, securement tapes, calcium alginate dressings, tubular bandages on a roll, gels, absorbent pads, hydrocolloids, swabs (sterile and non-sterile) and tapes, antimicrobial dressings, and chemical debriding agents. Several submitters considered that including further subcategories should be driven by consultation with the sector.

Q11: What other key issues or properties should PHARMAC consider when evaluating products in the subcategories?

132. The discussion paper asked what other key issues or properties PHARMAC should consider when evaluating products in the subcategories. Fifteen submitters responded: three clinical, six device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

133. Clinical submitters suggested the following issues:
    - different settings
    - specific functions
    - size of product
    - practicality of packaging and multi packs.

134. One submitter noted that there is a great deal of HTA information available on wound care products, especially in the Cochrane database. It was suggested that this information be considered before decisions are made about preferred providers and product ranges.

DHBs, DHB Executive Group and PEHNZ

135. Submitters offered a number of specific points for PHARMAC to consider. Generally, PHARMAC should consider best practice and evidence based research articles, patient comfort and acceptability, and environmental sustainability. Cost efficiency must include wear time, noting that fewer dressing changes saves on the cost of nurses' time, freight, minimal order levels – the whole cost of accessing these products.

136. Specifically related to particular wound care products, PHARMAC should consider:

- hypoallergenic properties, while maintaining adhesive properties in low adherent dressings with adhesive borders
- length (metres) and quality of bandages for securement – since smaller length bandages require the use of two bandages rather than one, and poor quality bandages can cause limb constriction or poor support.
- wound dressing packs – forceps that do not snap
- waterproof field to use if needed (ie, field around the tray)
- depth of tray
- choice of gauze balls and gauze swab
- foam dressings: absorption, silicone interface available for fragile, vulnerable skin
- securement bandages (non-sterile/sterile) crepe bandage – consideration needs to be given to ensure that it is definitely non-linting
- adhesive border – considering the range of shapes and sizes, need a wide variety.

137. Relating to input, DHB submitters stated that there is a need to consider feedback from a range of departments including community and supply chain as wound care affects many departments. It was noted that wound care is an area where there is a lot of clinical preference, so it is important to select the correct people for the evaluation teams and have thorough scrutiny for conflict of interest of members. Clinical advice needs to be balanced by commercial advice in all matters (this means a mix of clinicians and DHB commercial skills working together).

Device suppliers

138. Device suppliers stated that issues or properties PHARMAC should consider when evaluating products in the subcategories included:
    - patient outcomes
    - cost effectiveness
    - health economics
    - clinical evidence
    - clinician feedback
    - adverse reactions, side effects
    - cost of change
    - ability to introduce new products/technologies
    - product linting and absorbency performance
    - the potential for allergenic response
    - supplier performance with respect to continuity of supply
    - the lead times required for ramping up and down of product supply in volume.

139. Relating to input, device suppliers submitted that the WCAG expertise will be useful in identifying clinical risks; however without knowledge of the non-clinical aspects of the product true risk may not be identified. Formal steps in relation to product decisions must include clinical advice, outcomes, supply, quality, quality systems, implementation, training and support.

140. Submitters considered that the product evaluation process and criteria needs to be very broad and should include DHBs and hospitals across varying clinical specialties and applications covering the medical spectrum. The scope and execution must be clear and representative of the proposed breadth of implementation and use. If national decisions are to be made from evaluation data then PHARMAC and the DHBs must ensure these processes are fair, transparent, relevant and accountable.

141. It was further suggested that a more robust trial process needs to be implemented. Suppliers proposed that PHARMAC partner with credible suppliers to develop a process that compares and analyses the vast amount of manufacturers' product data in a structured way. PHARMAC should consider the international experience of *Coverage with Evidence Development* as promoted by the University of York.

Summary

142. Submitters across groups suggested a wide range of key issues that PHARMAC should consider when evaluating products in the subcategories. These issues encompassed general principles relating to the evidence base used, having broad input, costing change, cost effectiveness, patient outcomes, and the ability to introduce new technologies, as well as very specific suggestions related to particular wound care products.

Q12: Who would you consider important to have on a wound care user testing panel for the products?

143. The discussion paper asked submitters who they would consider important to have on a wound care user testing panel for the products. Fifteen submitters responded: four clinical, five device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

144. Clinical submitters suggested clinical users from a variety of clinical settings, including surgical & medical inpatient, specialty (emergency department, operating theatre, IV therapy clinical nurse specialists, tissue viability clinical nurse specialists), district nursing, practice nursing, podiatrists, and aged residential care.

145. One submitter stated that orthopaedic surgeons are willing to be involved in wound care testing, and that on the job testing and fast feedback from the operating table and recovery rooms are the best places to receive feedback from.

146. Another submitter noted that 'user testing' is not a means of obtaining good quality comparative data: rather it is 'a euphemism for 'trying a few out' and rendering an unstructured opinion about one's personal preferences.'

DHBs, DHB Executive Group and PEHNZ

147. One submitter suggested that a table top evaluation may be suitable initially to assess the products due to the interchangeability they have (foam dressings excluded).

148. Submitters suggested a number of people for user testing panels – with representatives from a good cross section of DHBs throughout New Zealand (not just the Auckland DHBs):
    - high users of current products such as ward nurses, district nurses, operating theatre nurses, wound specialists for more complex dressings (consider specialised areas such as burns, radiotherapy, epidermolysis bullosa nurses)
    - wound care viability nurses along with general clinical staff (users) – balanced with good commercial advice
    - users at the coal face to complete the user testing
    - theatre staff in regards to swabs, as well as logistics
    - stores representative to assist with ordering, package sizes, storage of bulk orders.

149. Submitters noted that advice should be obtained from the WCAG on what items might be contentious to ensure more vigorous testing.

Device suppliers

150. Device suppliers suggested
    - appropriate clinical representation covering geography and clinical indications
    - experienced wound care nurse/specialist(s), physician(s) and financial/business analysts
    - wound care specialists
    - representatives from across product use spectrum: paediatric, geriatric, burns, A&E, surgical
    - frontline care staff that manage dressing regimes, eg wound clinical nurse consultants, educators, patients or their advocates, district nurses.

151. For most categories suppliers would expect a panel to include:
    - a cross section of clinicians from a several DHBs – for example from regional DHBs, large city DHBs and a tertiary teaching DHB, and a geographical cross section also
    - representatives of the relevant surgical speciality or colleges
    - representatives of the national and local clinical product co-ordinators groups
    - cross-discipline representatives.

152. One supplier suggested the creation of a cross-disciplinary team that would provide opportunity for the development of guidelines applicable across multiple DHB wound care environments, and ensure appropriate clinical input and products are provided. It was noted that a wound care testing panel must have agreement on testing protocols and buy-in on outcomes measurement standardised across all DHBs. Additionally, there needs to be a more robust set of testing to develop better documentation to assist in appropriate clinical decisions.

Summary

153. Submitters across groups suggested that representatives should be involved from across the product use spectrum and clinical indications, and a good cross-section of DHBs throughout New Zealand. Stakeholders include clinicians, and other DHB staff, and should include frequent patient users. One DHB submitter suggested that a table top evaluation may be suitable initially to assess the products due to the interchangeability they have. Another submitter noted that 'user testing' is not currently a means of obtaining good quality comparative data.

Q13: What other ways should be considered to approach user testing, taking into account the limited time and resources DHBs and PHARMAC might have available?

154. The discussion paper asked what other ways should be considered to approach user testing, taking into account the limited time and resources DHBs and PHARMAC might have available. Fourteen submitters responded: Four clinical, four device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

155. A clinical submitter suggested that the HTA information on wound care products already available, for example, in the Cochrane database could be used. One submitter noted 'extreme' scepticism about user testing assessments' for wound care products.

DHBs, DHB Executive Group and PEHNZ

156. Submitters expressed a range of views: One considered that the user testing as described is acceptable. If it is an established product then very little testing is required; if it is a new item then a full evaluation and patient testing is the only way to establish that the product works.

157. Another submitter noted that, in general, user testing should be as short as possible; it should utilise the best team with the best coverage. This submitter noted that infrequently used types of equipment ("where we only use 12 in a year") should not be tested; rather teams that can cover a large number of patients of a wide variety should report on the product. Potentially user testing could be done at a regional level, for example, with a tertiary DHB leading and smaller DHBs providing support and input also. User testing could also incorporate recent pre-project DHB clinical trial information for the same products.

158. For complex wounds management, one submitter suggested the best team might be District Nursing Service staff who do a large number of relevant types of wounds/dressings each day for the item being assessed for acceptance. They also have good relationships with their patients, which contributes to the quality of the feedback. For something like a dressing pack, a high use area assessment would be helpful, but is often dependant on resource constraints when seeking feedback.

159. It was also suggested that user testing be an intrinsic part of the contract: choose the supplier(s) who will all be current suppliers (with a track record), then use the user panel (who devised the original specifications) to set clear criteria for objective and (possibly) subjective/sampled patient experience evaluation on an improving trajectory to be embedded in the contract and contract refresh process.

160. One submitter noted that the approach to user testing depends on what size panel is offered. Sole supply would require everyone to agree they will be happy to purchase but if a panel of three or more was offered then there is a higher likelihood one of the products will meet the needs.

Device suppliers

161. Device suppliers also suggested using available information such as
    - existing clinical papers and studies
    - best practice guidelines and international guidelines
    - evaluating successful local protocols and practices where products are currently being widely used
    - requesting end user reference sites from Australia and New Zealand.

162. Suppliers may be able to provide efficacy data to demonstrate that the product can achieve the desired clinical outcome; this should be admissible with appropriate local clinical review of the data presented.

163. Further possibilities suggested included: clinical trials if available, data on file, key opinion leader experience, formal evaluations, and protocols from DHBs. These could be considered and reviewed by an expert committee.

164. Two submitters suggested that specified DHBs could be nominated evaluation sites for subcategories to create efficiency with regard to user testing, considering the provision of DHB level of treatment (tertiary/secondary). Relevant centres need to have the appropriate expertise and resources and they must commit to undertake the work, be engaged and appropriately resourced. This is an area where centres of excellence could work well. Specifically chosen sites that have a broad product use and application (eg Middlemore Hospital) could provide extensive opportunities for product testing within a single site.

165. It was also submitted that if resources are severely constrained a portion of the overall cost savings could be invested in testing. The converse being if savings are not significant then resources to pursue marginal cost benefit should be denied.

Summary

166. Submitters across groups suggested using available information such as the HTA information on wound care products already available in the Cochrane Database. Clinical submitters and DHBs stated that user testing should be as short as possible; it should utilise the best team for it with the best coverage. Submitters across groups considered that user testing could be done at a regional level – specified DHBs could be nominated evaluation sites for subcategories to create efficiency with regard to user testing. It was also suggested that user testing could be an intrinsic part of the contract and noted that the approach to user testing depends on what size panel is offered.

Q14: What kind of support do DHBs require to implement a change for the wound care subcategories?

167. The discussion paper asked what kind of support DHBs require to implement a change for the wound care subcategories. Twelve submitters responded: three clinical, three device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

168. One clinical submitter specified the need for information on:
    - the range of sizes available on the schedule
    - in-service education
    - standardised classification/title for distribution centres across DHBs
    - time to use up old stock.

169. Another requested discussion with procurement staff.

170. One submitter noted PHARMAC's offer to assist with internal databases and software assumed that such databases for medical devices already exist. This submitter considered there are many services that use medical devices without any ability, currently, to capture and record data about device usage. This is a serious threat to ongoing efforts at monitoring implementation and conformity.

DHBs, DHB Executive Group and PEHNZ

171. Submitters considered that the support required would depend on the product. A basic product may require no support apart from alerting staff to the change; for more complex products, support may be needed to identify product change (pictorial of past and new product) and use.

172. It was noted that in some DHBs there will be implementation champions or other support available. Where change processes are well established, DHBs could handle the change in-house. Keeping DHBs informed and engaged as the RFP progresses is a necessary part of the change process – other than this the need for support would be minimal.

173. It was also suggested that support would not be required if all relevant clinicians were offered the opportunity to be involved in the specification and testing group, and the process was well communicated before, during and after, supplier and product selection.

174. Another submitter suggested support with:
    - clear lists of products codes
    - pricing
    - minimum quantity purchase etc to update and change individual DHB catalogues
    - a thorough user guide explaining outcomes and an implementation pack that includes in EXCEL a listing of product details

- support for staff using the equipment (often this is a simple training in-service, and the ability for a company rep to be available by phone, especially when a senior nurse team is involved).

175. Support to collate the feedback will also be important. If a national feedback tool is developed, a simple spread sheet or something similar centralised to view regional variations, role delineation variations etc. would be helpful

Device suppliers

176. Device suppliers noted that DHBs typically require detailed product information, impact data, product education and clinical support provided in the form of expert supplier staff on-site in the DHB before and during product trials and conversions. It was noted that not all suppliers are either able or willing to provide this level of DHB support and therefore DHB and PHARMAC implementation results may vary depending on the product and supplier attempting the conversion.

177. A submitter also observed that hospitals do not factor their change costs as part of their considerations (the costs of change and implementation are grossly underestimated as they are seldom measured or considered).

178. Device suppliers questioned the level of review that actually happens 12 months following the business case decision to determine actual effectiveness compared to the plan.

Summary

179. Submitters considered that the support required would depend on the product. DHBs and clinicians suggested a number of areas for support including: time to use up old stock, a thorough user guide explaining outcomes, and an implementation pack that includes a listing of product details. Support for staff using the equipment and support to collate feedback may also be needed. In some DHBs there will be implementation champions who are available for questions and support. A clinical submitter noted that many services that use medical devices have no ability, currently, to capture and record data about device usage – this is a serious threat to monitoring implementation and conformity. It was suggested that the need for support will be reduced if relevant clinicians are offered the opportunity to be involved in the specification and testing group.

Q15: Would a change in any of the wound care subcategories listed above require additional resourcing? If yes, what are the resources required and why are they needed?

180. The discussion paper asked whether a change in any of the wound care subcategories listed above would require additional resourcing, and if so what the resources required are and why are they needed. Eleven submitters responded: three clinical, two device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

181. One clinical submitter considered additional resourcing would not be required except in the case of more specialised dressings. One submitter noted that there needed to be adequate resourcing from the industry for education and training during changeovers. Another submitter proposed categorising dressings by function, which would be more useful to the end user. It was noted that many dressings now are composites and are difficult to categorise. One clinical submitter considered that more work is required in specifics for subcategories.

DHBs, DHB Executive Group and PEHNZ

182. One submitter stated that no additional resources would be needed. Other submitters identified several areas for additional resourcing, depending on the nature of the change and the timeframe required before compliance was required. In some DHBs transition would be managed by clinical product coordinators. DHBs would need a reasonable length of time to roll out changes and line up supply chain. Submitters suggested that PHARMAC consider a staged approach if large changes are made so DHBs can cope with existing FTE or increase resources to handle the additional workload. A wound formulary for DHBs to guide staff in purchasing and use could be very helpful. Support to provide education regarding the changes, if a totally new application technique is involved would also be required.

Device suppliers

183. Device suppliers noted that to ensure a successful transition and implementation of any new products within the DHB environment, there needs to be a supportive change management process that includes the following factors:
    - education, training and in-service
    - implementation planning and assistance
    - stock management planning
    - personnel and financial support.

184. Submitters noted that experience has shown separating product cost from service, training, and education has often led to the loss of expected cost savings.

Summary

185. Clinical submitters considered additional resourcing would not be required except in the case of more specialised dressings. Adequate resourcing from the industry could be required for training and education during changeover. It was noted that categorising dressings by function would be more useful to the end user, and that more work is required in specifics for subcategories. Most DHB submitters identified several areas for additional resourcing, depending on the nature of the change and the timeframe required before compliance was required. These areas included a wound formulary for DHBs to guide staff in purchasing, supplier support to provide education regarding the changes (if relating to a totally new application technique) and potentially educator support to provide this within DHBs. Suppliers considered that a supportive change management process included: education, training and in-service to ensure appropriate product selection and use and to realise any cost savings; implementation planning and assistance; stock management planning; and personnel and financial support.

Q16: Regarding market share procurement for products in the wound care subcategories, what other implementation issues are important for PHARMAC to take into account for your DHB?

186. The discussion paper asked what other implementation issues are important for PHARMAC to take into account for DHBs. Eleven submitters responded: two clinical, three device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitter

187. A clinical submitter suggested PHARMAC take into account the need for clear communication and timelines. Another submitter suggested that PHARMAC and clinical staff would need to agree on the content of the subcategories as “some products looked like an apple but don’t act or taste like one” and considered that this process needed to be transparent.

DHBs, DHB Executive Group and PEHNZ

188. Submitters stated that good communication was critical. One submitter stated that all communications must come directly to the CE of the DHB and should not be disseminated through the wider organisation.

189. Submitters wanted a user guide and implementation pack to ensure adequate information, ie supplier information (code, description, pack size, dimensions, delivery options, lead times etc). It was noted that multiple change of commonly used items may require changing 200 - 300 barcodes in most hospitals.

190. Submitters also wanted a date to change. There were several considerations associated with this:
    - having enough time to run down old stock (timeframes depend on product turnover and usage, some items would turn over very quickly and some not)
    - having an adequate supply of product so that there is no disruption to supply for the DHB
    - notifying supply departments to ensure imprest item changes are updated and coded in departments.

191. Submitters also queried what would become of existing stock, and whether there was potential for buy back of other product.

Device suppliers

192. One device supplier identified the following implementation issues:
    - product rationalisation – identifying which products are to be used in which areas
    - stock management is a critical component of the implementation process
    - use of and adherence to individualised implementation plans in consultation with key people from each DHB and suppliers
    - sufficient time allocated for training on the products.

193. Another device supplier provided an extensive list of the broader issues around implementation and the key factors that may determine whether an implementation of a market share decision is successful:

    Supplier
    - support and services offered, including technical training of surgeons and clinical staff, ongoing professional education, and in-theatre support where required.

    The ability of the medical device supplier to support:
    - education and training
    - track record of quality products
    - track record of supply chain consistency and reliability
    - management and support during product recalls
    - clinical support to clinicians
    - management of stock in theatre environments where applicable
    - length-of-time operating within the New Zealand market
    - footprint and employment within New Zealand
    - financial stability
    - disaster management and ability to supply in such an event
    - credibility of the supplier and their clinical and product support staff.

    Product
    - quality and performance of the medical device
    - suitable global regulatory approval
    - registry data where applicable
    - education and trials/clinical evaluation

- heritage of the manufacturer relating to current/prior products
- current usage within New Zealand
- regulatory approval with recognised regulatory authorities.

Manufacturer

- trust and reliability of supplier/manufacturer
- recourse for product quality or safety issues
- ethics and integrity to continue to supply a high-quality product
- reliably report adverse events
- cooperate with regulatory authorities as required
- rapid assessment and resolution of issues.

Summary

194. Clinical and DHB submitters stated a need for clear communication and timelines. DHBs want to have enough time to run down old stock and to have an adequate supply of product and be able to notify supply departments to ensure imprest item changes are updated and coded in departments. Submitters also queried what would become of existing stock, and whether there was potential for buy back of other product.

195. Device suppliers identified implementation issues around identifying which products are to be used in which areas, stock management, adherence to individualised implementation plans in consultation with key people from each DHB and suppliers, and sufficient time allocated for training on the products. One device supplier provided an extensive list of the broader issues around implementation and the key factors that may determine whether an implementation of a market share decision is successful.

Q17: What sort of transition timeframes, training, resources and other support do DHBs require to introduce new wound care products?

196. The discussion paper asked what sort of transition timeframe, training, resources and other support DHBs require to introduce new wound care products. Eleven submitters responded: three clinical, two device suppliers and one device supplier group, three DHBs, DHB Chief Executive Group and PEHNZ.

Clinical submitters

197. Clinical submitters suggested that the timeframe, training, and resources required depended on product function.

198. One submitter noted that transitions needed to be planned carefully with all key stakeholders, if not in agreement than at least with an understanding of the rationale. The same submitter noted that there are high stresses in the health sector and that if changes were to occur, they needed to do it at once.

199. In relation to resources, the company should be represented throughout the DHB to ensure good understanding of product action and use. The more complex dressings should have available coloured brochures, charts or websites on their use.

200. Timeframes required depend on the complexity of the product. For a simple product such as absorbent dressings – two to three weeks; for more specialised products such as silver antimicrobials – four to six weeks will be needed to allow all areas to be targeted. One submitter commented that it was difficult to determine transition periods

201. Training depends on product function and where it is used. For example a simple absorbent pad needs no training, just notification of product. However, some of the more complex dressings (especially

antimicrobials) need to be taught on appropriate usage. Suppliers need to provide education wherever it is needed, on a regular basis.

DHBs, DHB Executive Group and PEHNZ

202. Submitters considered what was required would depend on the size of the change. For example, whether it requires a practice change (such as a different application or removal technique) or how far they are rationalising the known against introducing the new. If the latter then the supplier would need to train and support change.

203. In relation to timeframes, most submitters suggested as a general rule DHBs need at least two to three months' notice to implement, and use up existing stock to allow a seamless introduction of the new product. One submitter noted that they like to phase old product out and then introduce the new product so this could take time depending on department usage levels.

204. Another submitter noted that if training is not needed and the stock keeping unit level is manageable, implementation is usually very quick once any old stock is wound down. If training is needed then the process is far longer and normally staged and in-line with training schedules.

205. Submitters generally noted that any required staff in-service training needs to be considered. More time may be required for a more complex transition for some products given the wide diversity of departments using different products and distribution methods.

206. One submitter suggested that there was a need to ensure adequate supply chain input from the sector, and proposed that a supply chain representative could be included in the WCAG.

Device suppliers

207. One device supplier suggested the following resources and education:
    - training offered across various mediums, ie, web, CD, face to face
    - training guides
    - user manuals
    - in-service posters
    - application guides
    - material safety data sheets
    - clinical papers
    - brochures.

Summary

208. Clinical and DHB submitters suggested that the timeframe, training and resources required depended on product function and the size of the change. A simple product such as absorbent dressings may take two to three weeks; for more specialised products such as silver antimicrobials, four to six weeks. More time may be required for a more complex transition for some products given the wide diversity of departments using them and distribution methods. Submitters suggested as a general rule DHBs need at least two to three months' notice to implement, and use up existing stock.

LIST OF SUBMITTERS

3M
Australian & New Zealand College of Anaesthetists (ANZCA)
Beavis, Vanessa (Auckland DHB)
Capital and Coast DHB
DHB Chief Executive Group (CEs representing all 20 DHBs)
EBOS Healthcare
Howard Wright Care
Johnson, Desley (MidCentral DHB)
Johnson & Johnson
Medical Technology Association of New Zealand (MTANZ)
Mölnlycke Health Care
Munn, Professor Stephen (ADHB)
New Zealand Medical Association (NZMA)
New Zealand Nurses Organisation (NZNO)
New Zealand Orthopaedic Association (NZOA)
New Zealand Society of Anaesthetists (NZSA)
Pamela Mitchell (Canterbury DHB)
Product Evaluation Health New Zealand (PEHNZ)
Protec Solutions Limited
Ridley, Sandra (Hawkes Bay DHB)
Smith & Nephew
Southern DHB
Waikato DHB