Proposal to list and award market share for various wound care products in DHBs





Introduction

PHARMAC is seeking feedback on a proposal to list and award market share for various wound care products in DHBs, as a result of a request for proposals issued on 15 September 2015 and the subsequent amendment issued on 7 October 2015.

This is the first time PHARMAC is proposing to award market share in a hospital medical devices category since PHARMAC started managing hospital medical devices in 2012. This proposal follows consultation, feedback and engagement with the sector on PHARMAC's proposed approach to market share procurement for hospital medical devices. We proposed wound care would be the first category considered for market share procurement.

The proposed market share agreements are different to current PHARMAC hospital medical devices agreements. Market share agreements guarantee suppliers a portion of the DHB market in return for competitive pricing and quality products. This means that any DHB that uses the types of products for which a market share agreement has been awarded would be subject to certain restrictions.

We are proposing to introduce market share agreements to DHBs for a small group of relatively low risk clinical products. This will allow DHBs to start to benefit from some savings while setting the foundations for similar activity in other medical device categories that may offer greater savings.

Please give us your feedback on the proposal by **29 July 2016** to help us make the best possible decisions.

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Proposal summary

This proposal would result in **listing and awarding Hospital Supply Status,** to a single supplier for each of the six wound care sub-categories listed below. If approved, this means that DHBs **must** only purchase brands of wound care products from suppliers outlined in Table 1 below, with allowance for discretionary purchasing with a specified discretionary variance (DV) Limit.

In summary, this proposal would result in:

Hospital Supply Status

Listing and awarding Hospital Supply Status (HSS) for the following wound care sub-categories in DHBs, are listed in **Table 1 below.**

List date: 1 October 2016

HSS start date: 1 April 2017

HSS end date: 30 June 2020

The list date would be the date at which the HSS Supplier's brand(s) of wound care products would be available for purchase by DHBs at the new price. The HSS start date would be the date at which DHBs must only purchase the HSS brand of wound care product, with some allowance for discretionary purchasing.

Estimated total DHB savings

It is estimated the proposal would save DHBs approximately \$3.2 million over 5 years (NPV, 8%) or \$640,000 per annum across the six HSS Sub-categories. This represents approximate savings of 20%.

DV Limits

Discretionary purchasing for each HSS Sub-category would have a defined limit referred to as the DV Limit (discretionary variance limit). The proposed applicable DV Limit for each HSS Sub-category is included in **Table 1 below**.

The proposed scope of each HSS Sub-category is set out in <u>Appendix 1</u>. If the proposal is implemented, DHBs **must not** purchase non-HSS Products that fall within the scope of an HSS Sub-category (DV Medical Devices), unless allowed within the applicable DV Limits.

Transition timeframe

The proposal includes a transition period of six months from 1 October 2016 to allow DHBs to make the necessary product switches, before the market share provisions are effective and compliance with DV Limits is required.

Table 1. Suppliers and brands of wound care Sub-categories proposed for Hospital Supply Status

HSS Sub-category	DV Limit	HSS Brand(s) ¹	HSS Supplier	Estimated % savings ²
IV pressure pads	20%	Chushavan Cesablic	Defries Industries New Zealand Limited	9%
Low adherent dressings with adhesive border	20%	Asguard Flex +	Protec Solutions Limited	37%
Combine dressings (non-sterile)	20%	Bamford	W.M. Bamford & Co Ltd	57%
Combine dressings (sterile)	20%	Bamford	W.M. Bamford & Co Ltd	45%
Foam adhesive dressings (with and without border)	25%	Mepilex	Mölnlycke Health Care Pty Limited	11%
Foam non-adhesive dressings	20%	PolyMem Biatain	Universal Specialities Limited	42%

¹Details of the proposed individual line items and product codes can be found in the HSS Sub-category specific information provided in <u>Appendix 1</u>. ²Estimated % savings based on current expenditure versus proposed expenditure under HSS agreements.

Your feedback

Meaningful engagement with, and feedback from, a wide range of external stakeholders has played a major role in the development of this proposal. We want your feedback on the details of the proposal to ensure we make decisions on the basis of all relevant information.

Please provide your feedback on this proposal by **Friday, 29 July 2016.** Send to:

Denise Mundy Device Category Manager PHARMAC PO Box 10 254 Wellington 6143

Email: <u>woundcareconsult@pharmac.govt.nz</u> Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal. Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Background

RFP for various wound care products

A Request for Proposals (RFP) for various wound care products was issued in September 2015 for the following types of wound care products:

- Combine dressings
- IV pressure pads
- Low adherent dressings with adhesive border
- Foam dressings
- Laparotomy sponges
- Compression bandages
- Securement bandages

The RFP closed in October 2015 and a large number of proposals were received and evaluated by PHARMAC.

The evaluation process took into account supplier and product specifications, clinical advice and financial impacts for DHBs, including the cost of change.

For some of the sub-categories included in the RFP, the value offered in the proposals did not clearly exceed the potential cost to DHBs of implementation. For this reason PHARMAC decided not to award any market share agreements in the following sub-categories:

- Compression bandages
- Foam dressings (shaped)
- Laparotomy sponges
- Securement bandages

These sub-categories are not part of this proposal and DHBs can continue to choose which products they purchase in these sub-categories.

The HSS Sub-categories included in this proposal are listed in Table 1 (page 1) and Table 2 (page 4).

Clinical advice

PHARMAC has had significant clinical input from a range of sources regarding market share procurement in general, and in July 2014, established the Wound Care Advisory Group (WCAG) to provide clinical advice as part of its consideration of wound care procurement opportunities.

The WCAG is made up of practicing Wound Care Specialists who work for DHBs and was established through a formal process, where PHARMAC sought nominations from the New Zealand Wound Care Society, the Royal Australian College of Surgeons and the New Zealand Nurses' Organisation.

The WCAG has met regularly since the RFP closed to review proposals, provide clinical advice to PHARMAC and to recommend when clinical advice from other sources was required.

The WCAG advised PHARMAC of the interchangeability of products and sizes to inform PHARMAC's financial analysis.

Proposals were then short-listed for further advice where the WCAG considered:

- Patient needs across a range of DHB clinical settings, including the needs of patients with complex, long-term conditions (eg. Epidermolysis Bullosa)
- Clinical benefits and risks of products
- Cost effectiveness, including consideration of cost of change
- Product support, education and training requirements
- Information provided by the supplier including product specifications, conformance with relevant standards and regulatory requirements
- Evidence for clinically relevant outcomes.

The WCAG also completed side by side desk-top evaluations of product samples against the product specifications included in the RFP.

On completion of the clinical product evaluations WCAG made recommendations about which products would be suitable for single, dual or multiple supplier options in DHBs. PHARMAC's Evaluation Committee then took the WCAG's advice into account when evaluating the proposals in accordance with Schedule 2, clause 3, of the RFP document.

Appendix 2 provides detail of where and when clinical advice has been received throughout the process and further information about the Wound Care Advisory Group.

Question 1: What, if any, patient clinical needs are not met by the proposed range of HSS Products in each HSS Sub-category?

Background documents

Background documents including PHARMAC's approach to market share procurement consultation and feedback, the wound care RFP and WCAG minutes are available on the PHARMAC website.

The minutes of the WCAG meetings held after the RFP had closed have not been published because they include commercially sensitive information in the context of the RFP evaluation process.

Hospital Supply Status

The proposal is to award Hospital Supply Status (HSS) in DHBs to a single supplier for each of six wound care Sub-categories as laid out in **Table 2 below**.

Table 2. HSS Sub-category details

HSS Sub-category	HSS Brand(s)	HSS Supplier
IV pressure pads	Chushavan Cesablic	Defries Industries New Zealand Limited
Low adherent dressings with adhesive border	Asguard Flex +	Protec Solutions Limited
Combine dressings (non-sterile)	Bamford	W.M. Bamford & Co Ltd
Combine dressings (sterile)	Bamford	W.M. Bamford & Co Ltd
Foam adhesive dressings (with and without border)	Mepilex	Mölnlycke Health Care Pty Limited
Foam non-adhesive dressings	PolyMem Biatain	Universal Specialities Limited

This would involve listing the HSS Supplier's products for each HSS Sub-category in Part III of Section H Pharmaceutical Schedule from 1 October 2016, with HSS being effective from 1 April 2017.

Not all proposed HSS Sub-categories would involve a product switch for DHBs. However, for most HSS Subcategories, at least a partial change would be required to meet market share obligations. All of the proposed HSS Suppliers have existing national contracts with PHARMAC.

Detailed HSS Sub-category information is provided in **Appendix 1** and includes:

- The HSS Sub-category scope
- The proposed range of wound care products from the HSS Supplier to be listed on the Pharmaceutical Schedule, including product sizes, pack size and price for each product
- Examples of DV Medical Devices for the HSS Sub-category

Each HSS Sub-category scope has been defined following clinical advice and is specific to the market share opportunities provided through the RFP. We understand that the definitions may not align with other definitions used by DHBs or how products are currently listed in the Pharmaceutical Schedule. Subject to consultation feedback, PHARMAC proposes to amend the Pharmaceutical Schedule to include the relevant HSS Sub-category definitions and listing details.

Question 2: When considering the detail provided in Appendix 1 what, if any, other information would DHBs find useful to understand what is in and out of scope of the HSS Sub-categories?

Benefits and impacts

PHARMAC expects that the benefits of the proposed changes will outweigh the cost of change. A summary of the expected benefits and impacts of this proposal are set out below:

Benefits

- Continued access to high-quality wound care products and support, from reputable suppliers
- Estimated savings to DHBs of \$3.2 million over 5 years (5yr, 8% NPV)
- Limited change impact that involves relatively low-risk products
- Provision for some discretion for DHBs to purchase from non-HSS Suppliers

Impacts

- Depending on current usage, DHBs may need to change products requiring resource commitment during the transition period to ensure clinical staff understand the change, and that it is implemented in the internal DHB supply chain
- DHBs would need to manage purchasing within the DV Limits to avoid supplier compensation claims

Question 3: What, if any, other benefits or impacts should PHARMAC take into account when making decisions about the proposed changes?

Transition period

The proposal includes a transition period of six months from 1 October 2016 to 31 March 2017. This is a longer period than DHBs suggested during previous consultation feedback. The longer transition period is proposed to account for the wide range of DHB care settings that could be impacted by any changes and for any reduction in services during the December and January holiday periods.

During the transition period, the DV Limit would not apply, however PHARMAC expects to liaise regularly with the DHB Change Managers on progress so that DHBs are in a good position to be compliant with DV Limits for the duration of the HSS period.

PHARMAC would provide each DHB with a report prior to and following the transition period, detailing their position against the DV Limit requirements. DV Limit compliance would be applicable following the end of the transition period.

Question 4: Is the six month transition period appropriate when considering any product changes and staff training and education? If not, what time period would be suitable and why?

DV Limits

The purpose of the DV Limit is to allow DHBs to purchase a small proportion of products within the HSS Sub-category from non-HSS Suppliers, while setting a limit on this so that the DHBs' market share obligations to the HSS Supplier are met.

The DV Limit would be the maximum percentage of the total HSS Sub-category market allowed for discretionary purchasing. DHBs may like to consider a full switch to the HSS products and to develop an in-house exceptions process to manage purchases of DV Medical Devices where this is clinically required.

Throughout the HSS Period (1 April 2017 to 30 June 2020) the DV Limit compliance would apply.

DV Limit compliance would be calculated for the periods set out below with individualised reports provided to each DHB and each HSS Supplier as soon as practicable after the period:

- 1 April 2017 to 30 June 2018
- 1 July 2018 to 30 June 2019
- 1 July 2019 to 30 June 2020

In addition, PHARMAC would provide DHBs with a report following the first six months of the first DV Limit compliance period detailing their position against the DV Limit requirements.

PHARMAC's aim would be to ensure that DV Limit compliance is achieved and maintained. PHARMAC would work directly with DHB Change Managers if a DHB seemed at risk of non-compliance so that the necessary steps could be taken to ensure the HSS Supplier would get the market share they are entitled to, when averaged over the full period.

DV Limit compliance would be calculated at the HSS Subcategory level. DHB Change Managers would be provided with the calculation methodology and tools and resources that DHBs could use for in-house monitoring.

If DHBs are compliant with an HSS Sub-category DV Limit at a national level, PHARMAC would take no further action.

If DHBs are non-compliant with an HSS Sub-category DV Limit at a national level, the HSS Supplier would be entitled to seek compensation from any non-compliant DHBs.

The aim of the financial compensation is to compensate the HSS Supplier for their actual losses as the result of the DHB's non-compliance. PHARMAC would calculate the compensation the HSS Supplier would be entitled to seek, taking into account:

- The degree of the DV Limit non-compliance
- The price of the relevant HSS Products that the DHB should have purchased instead of purchasing a non-HSS product; and
- The fact that the HSS Supplier did not actually have to supply the product

Question 5: What else, if anything, should PHARMAC consider when calculating DV Limit compliance and any compensation a supplier may seek for non-compliance?

Delivery and supply

Contract management

It is expected that DHBs would continue to engage directly with suppliers to raise and resolve day to day operational matters. PHARMAC expects to be involved where there is an issue that affects many DHBs, as described for supply issues below, and where DHBs have information relevant to supplier performance monitoring.

The draft DHB Procurement Plan for 2016/17 includes a strategic project to develop a Contract Management Framework. PHARMAC would engage with DHBs in this context to clarify in more detail the contract management activities that need to be undertaken across the activity within PHARMAC's scope, and relevant responsibilities for these.

Delivery

The standard delivery timeframe would be within three business days. There would be minimum order requirements and there may be fees for urgent delivery or very small orders.

Management of supply and supply issues

HSS Suppliers would have a minimum stock holding in New Zealand of two months stock based on normal sales to be available for supply to DHBs at any given time, and as a contingency for any interruption in deliveries or problems with supply.

Under the proposal, if an HSS Supplier has any reason to think they will go below the minimum stock level or for any other reason think they may fail to supply, they would have to inform PHARMAC and work with PHARMAC and/or DHBs (depending on the type and duration of any potential issue) to agree an approach to managing the issue.

The responsibility for managing risks and finding suitable alternative products would be with the HSS Supplier and PHARMAC would work with them to ensure timely action is taken, and DHBs are kept informed.

If an alternative product is provided, the HSS Supplier would be expected to provide this at the same price and if they are unable to arrange for an alternative they may be required to cover the costs for an alternative arranged by PHARMAC or the DHB. Alternative products purchased due to a supply failure would not be counted as DV Medical Devices for DV Limit compliance calculations.

Where feasible, DHBs should check with PHARMAC before arranging for alternative products, however PHARMAC understands that there will be some situations where this is impractical.

Specific delivery, stock holdings and supply requirements are included in each of the provisional agreements and these would be provided to DHB Change Managers prior to implementation.

Question 6: What else, if anything, should PHARMAC expect from HSS Suppliers regarding stock holding and management of supply issues?

Implementation

The HSS Suppliers' products are proposed to be listed on the Pharmaceutical Schedule from 1 October 2016 and implementation activities would be structured around what is required to support DHBs to make any necessary changes by the end of the six month transition period.

A post implementation review would commence in April 2017, with on-going liaison between DHBs, HSS Suppliers and PHARMAC.

A high-level timeline with proposed key activities that would be required by DHBs, HSS Suppliers and PHARMAC is included in **Appendix 3**.

DHB requirements

Section H of the Pharmaceutical Schedule includes what PHARMAC requires from DHBs in relation to medical devices. The listing in Part III of Section H would include the HSS details for the relevant HSS Sub-categories.

The degree of change required, and how any change is managed, would differ between HSS Sub-categories and between DHBs.

In order to make the necessary product switches before the end of the transition period, it would be important for each DHB to:

- understand the HSS Sub-category scope and what this means for their purchasing decisions
- liaise with the HSS Supplier on stock requirements and any necessary training and education requirements
- identify how they will use or adapt their existing systems and processes to measure and manage DV Limit compliance
- identify a DHB Change Manager to manage the wound care change processes and liaise with PHARMAC and the HSS Supplier

Supplier requirements

Implementation support from the HSS Supplier would be expected to be tailored to the needs of each DHB and could include provision of:

- Analysis of current product use and cross referencing of codes
- Supplier contact person to assist with any queries arising from the changes
- Detailed information about the products
- Detailed information about the supply and distribution chain

The HSS Supplier would contact the DHB Change Manager or other DHB nominated change manager to discuss requirements for stock, product information and any training and education requirements for both the transition period, and on-going.

HSS Suppliers would also provide PHARMAC with regular reports on progress with transition, so that PHARMAC can provide additional support to DHBs if needed.

PHARMAC support

PHARMAC would contact each DHB Change Manager prior to 1 October 2016 to discuss their DHB's support needs and would also regularly liaise with them to work through any issues that arise during implementation.

Each DHB Change Manager would be provided with an implementation pack that could include:

- Supplier contact details
- PHARMAC contact details
- Details of products to be listed on the Pharmaceutical Schedule
- HSS Sub-category definitions and examples of DV Medical Devices
- Details of how DV Limits are calculated
- A tool that DHBs could use for internal monitoring and forecasting of DV Limit compliance
- Information about the DHB's baseline position in relation to DV Limit compliance
- A checklist of things DHBs should consider during implementation, particularly in regard to the market share requirements
- The full terms and conditions of each market share agreement

PHARMAC would provide opportunities for DHB Change Managers or other relevant DHB personnel to collectively discuss emerging issues in relation to the market share agreements or areas where clarification is needed. PHARMAC could do this by providing regular teleconferences or by participating in previously established teleconferences.

In addition, PHARMAC would engage with the Procurement Operations Advisory Group, established as part of the DHB Procurement Strategy, regarding implementation issues that are not specific to an individual DHB.

Question 7: What other implementation support would DHBs need to manage the change?

Summary of questions

Please provide your feedback on this proposal by **Friday, 29 July 2016** to:

Denise Mundy Device Category Manager PHARMAC PO Box 10 254 Wellington 6143

Email: woundcareconsult@pharmac.govt.nz Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

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Question 5: What else, if anything, should PHARMAC consider when calculating DV Limit compliance and any compensation a supplier may seek for non-compliance?	Pg 6			
Question 6: What else, if anything, should PHARMAC expect from HSS Suppliers regarding stock holding and management of supply issues?	Pg 6			
Question 7: What other implementation support would DHBs need to manage the change?	Pg 7			
Question 8: Are you aware of any reason why PHARMAC should not list and award market share to the proposed HSS Suppliers for their brand(s) of wound care products? If so, what is the reason?				

Question 9: Do you have any other comments with respect to the proposal to list and award market share for the six Sub-categories in DHBs?

Glossary

DHB means a District Health Board, and includes a DHB's hospital(s) and/or associated health services that are provided by a DHB and for which that DHB purchases wound care products.

DHB Change Manager means the person responsible for managing the wound care change process within each DHB. This person may be a Procurement Manager or Clinical Product Coordinator or any other person designated by the DHB.

DV Limit means, for each of the relevant HSS Sub-categories, the relevant discretionary variance limit. The DV Limit is the maximum percentage of the total HSS Sub-category market allowed for discretionary purchasing of DV Medical Devices.

DV Medical Devices means non-HSS Products that are within the scope of the relevant HSS Sub-category.

Hospital Supply Status (HHS) means the status of being the only supplier of products within a Sub-category under a listing agreement with PHARMAC which DHBs are obliged to purchase from when purchasing from within that Sub-category, subject to any DV Limit.

HSS Brand means the brand of products supplied by the HSS Supplier under a listing agreement with PHARMAC.

HSS Products means the products supplied by the HSS Supplier within an HSS Sub-category under a listing with PHARMAC.

HSS Sub-category means a grouping of products within a defined scope as agreed between PHARMAC and the relevant HSS Supplier. An HSS Sub-category scope includes both HSS Products and non-HSS Products.

HSS Supplier means the supplier with Hospital Supply Status within an HSS Sub-category.

NPV means net present value. NPV calculations take into account the expected value of money over a period of time. PHARMAC typically calculates NPV savings over a 5 year period and includes an 8% discount rate each year after the first year.

Pharmaceutical Schedule means the pharmaceutical schedule produced by PHARMAC pursuant to section 48(a) of the New Zealand Public Health and Disability Act 2000.

RFP means Request for Proposals.

WCAG means the Wound Care Advisory Group established by PHARMAC to provide objective clinical advice as part of its consideration of wound care procurement opportunities.

PHARMAC Pharmaceutical Management Agency

Proposal to list and award market share for various wound care products in DHBs

PHARMAC proposes that Hospital Supply Status (HSS) is awarded for the following wound care sub-categories:

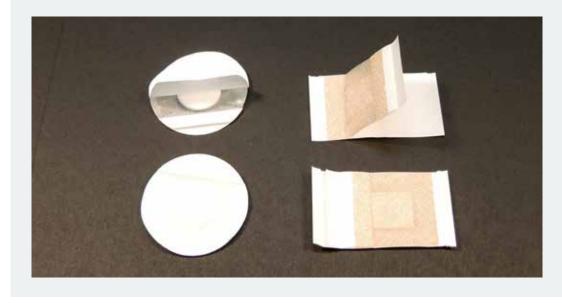
- IV pressure pads
- Low adherent dressings with adhesive border
- Combine dressings (sterile)
- Combine dressings (non-sterile)
- Foam adhesive dressings (with and without border)
- Foam non-adhesive dressings

This would mean that if a DHB purchases products within the scope of any of these HSS Sub-categories, they would have to purchase them from the relevant HSS Supplier's range, with some allowance for discretionary purchasing.

If a DHB purchases products within the scope of any of these HSS Sub-categories from a supplier other than the HSS Supplier, these purchases would be included in the DV Limit calculations. Any purchases over the DV Limit could result in the DHB having to pay compensation to the relevant HSS Supplier.

Details of each of the HSS Sub-categories, is set out on the following pages.

IV pressure pads



An example of the types of products within this Sub-category

HSS Supplier: Defries Industries New Zealand Limited (Defries)

DV Limit: 20%

HSS Sub-category scope

Would include:

- small, sterile, adhesive dressings with absorbent haemostatic pads that are normally used following removal of an IV, drawing blood, or needle injection, and
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- arterial pressure pads, and
- any other products determined by PHARMAC to be out of scope of the HSS Sub-category, following appropriate clinical advice

Proposed Defries HSS Products (to be listed on the Pharmaceutical Schedule from 1 October 2016)

Manufacturer	Brand	Description	Product code		Pack price
Nichiban	Cesablic	Dressing with Adhesive Border, 36mm round	DEF929	100	\$20.00
Nichiban	Chushavan	Dressings with Adhesive Border, 27mm x 27mm (8)*	DEF1250	60	\$96.00
*each pack contains 60 strips of 8 dressings					

About the proposed products

The Cesablic brand of IV pressure pads has a 3mm thick haemostatic pad and is currently supplied to DHBs. The Chushavan brand would be new to DHBs and has 1mm thick haemostatic pad with a beige backing.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings.

If you would like more information about the products, you can contact:

Wayne Titmus NZ Sales Manager & Product Manager Defries Industries New Zealand Limited Phone: +61 448 043 275 Free phone: 0800 511 740 Email: wayne.titmus@defries.com.au

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

An example of a DV Medical Device for this HSS Subcategory would be Asguard Flex+ Haemoplast.

This would not be the only DV Medical Device. Any product that fits the HSS Sub-category definition and is not one of the Defries HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

Low adherent dressings with adhesive border



An example of the types of products within this Sub-category

HSS Supplier: Protec Solutions Limited (Protec)

DV Limit: 20%

HSS Sub-category scope

Would include:

- simple, conformable island dressings and dressing rolls with a low adherent wound contact layer, over an absorbent pad, and with a breathable, non-woven, adhesive backing, and
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- highly absorbent dressings with adhesive borders
- antimicrobial dressings with adhesive borders
- transparent film island dressing
- IV pressure pads
- island dressings with foam pads, and
- any other products determined by PHARMAC to be out of scope of this HSS Sub-category, following appropriate clinical advice

Proposed Protec HSS Products (to be listed on the Pharmaceutical Schedule from 1 October 2016)

Manufacturer	Brand	Description	Product code	Pack size	Pack price
Sentry Medical	AsGuard Flex +	Dressing, 7.5cm x 5cm	SZ-ISD001	50	\$5.10
Sentry Medical	AsGuard Flex +	Dressing, 8cm x 10cm	SZ-ISD002	50	\$9.20
Sentry Medical	AsGuard Flex +	Dressing, 15cm x 10cm	SZ-ISD003	20	\$6.70
Sentry Medical	AsGuard Flex +	Dressing, 20cm x 10cm	SZ-ISD004	20	\$8.00
Sentry Medical	AsGuard Flex +	Dressing, 25cm x 10cm	SZ-ISD006	25	\$10.70
Sentry Medical	AsGuard Flex +	Dressing, 30cm x 10cm	SZ-ISD008	25	\$12.70
Sentry Medical	AsGuard Flex +	Dressing, 8.25cm x 6cm	SZ-ISD030	50	\$6.20
Sentry Medical	AsGuard Flex +	Dressing Roll, 5cm x 10M	SZ-ISD011	1	\$6.10
Sentry Medical	AsGuard Flex +	Dressing Roll, 7.5cm x 10M	SZ-ISD012	1	\$8.80
Sentry Medical	AsGuard Flex +	Dressing Roll, 10cm x 10M	SZ-ISD013	1	\$11.60

About the proposed products

The AsGuard Flex + brand of island dressings and dressing rolls are not currently supplied to DHBs however are currently supplied to hospitals in Australia.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings and that the range of sizes would be appropriate.

If you would like more information about the products, you can contact:

Phil Cumiskey National Sales Manager – Medical Protec Solutions Limited Phone: 04 380 7231 Mobile: 021 190 4077 Email: pcumiskey@protecsolutions.co.nz

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

DV Medical Devices for this HSS Sub-category would include: Cutiplast, Cosmopor, Mepore and Primapore island dressings, and Cutiplast Rolls and Mepore Rolls.

This is not an exhaustive list. Any product that fits the HSS Sub-category definition and is not one of the Protec HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

Combine dressings (non-sterile)



An example of the types of products within this Sub-category

HSS Supplier: : WM Bamford & Co Ltd (Bamford)

DV Limit: 20%

HSS Sub-category scope

Would include:

- simple, non-adhesive, thick, fleece, non-sterile dressings and dressing rolls, covered in a soft, non-woven or gauze fabric (where the dressings have soft-seal ends)
- non-sterile Gamgee dressings and dressing rolls
- non-sterile combine and Gamgee dressings and dressing rolls, as described above, with or without a moisture repellent layer on the external surface of the dressings or rolls, and
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- non-sterile combine or Gamgee dressings and dressing rolls containing super-absorbent polymers, gel forming agents or anti-shear layers
- non-sterile combine or Gamgee dressing rolls with a length of five metres or more, and
- any other products determined by PHARMAC to be out of scope of this HSS Sub-category, following appropriate clinical advice



Proposed Bamford HSS Products (to be listed on the Pharmaceutical Schedule from 1 October 2016)

Manufacturer	Brand	Description	Product code	Pack size	Pack price
Bamford	Bamford	Dressing, 9cm x 20cm	BAM054	2500	\$146.52
Bamford	Bamford	Dressing, 9cm x 10cm	BAM055	4000	\$188.36
Bamford	Bamford	Dressing Roll, 10cm x 3M	BAM057	1	\$19.81
Bamford	Bamford	Dressing Roll, 15cm x 3M	BAM058	1	\$23.23
Bamford	Bamford	Dressing, 20cm x 20cm	BAM059	1300	\$110.64
Bamford	Bamford	Dressing, 20cm x 30cm	BAM060	1200	\$134.92
Bamford	Bamford	Gamgee Roll, 500g 45cm wide	BAM061	1	\$5.04
Bamford	Bamford	Dressing, 9cm x 20cm	BAM065	250	\$17.10
Bamford	Bamford	Dressing, 9cm x 10cm	BAM066	250	\$13.85
Bamford	Bamford	Dressing, 20cm x 20cm	BAM067	250	\$24.25
Bamford	Bamford	Dressing, 20cm x 30cm	BAM068	250	\$31.50

About the proposed products

The Bamford brand of non-sterile combine dressings are not currently supplied to DHBs however the Bamford brand of sterile combine dressings are.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings and that the range of sizes would be appropriate.

If you would like more information about the product, you can contact:

Katherine Venn-Brown Business Development Manager WM Bamford & Co Ltd Mobile: 027 442 1014 Email: katherine@bamford.co.nz

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

DV Medical Devices for this HSS Sub-category would include: BSN and Sentry Medical non-sterile combine dressings and dressing rolls.

This is not an exhaustive list. Any product that fits the HSS Sub-category definition and is not one of the Bamford HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

Combine dressings (sterile)



An example of the types of products within this Sub-category

HSS Supplier: : WM Bamford & Co Ltd (Bamford)

DV Limit: 20%

HSS Sub-category scope

Would include:

- simple, non-adhesive, thick, fleece, sterile dressings and dressing rolls, covered in soft, non-woven or gauze fabric (where the dressings have soft seal ends)
- sterile Gamgee dressings and dressing rolls
- sterile combine and Gamgee dressings rolls as described above with or without a moisture repellent layer on the external surface of the dressings
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- sterile combine or Gamgee dressings and dressing rolls containing super-absorbent polymers, gel forming agents or anti-shear layers
- sterile combine or Gamgee dressing rolls with a length of five metres or more, and
- any other products determined by PHARMAC to be out of scope of this HSS Sub-category, following appropriate clinical advice

Manufacturer	Brand	Description	Product code	Pack size	Pack price
Bamford	Bamford	Dressing, 10cm x 10cm	BAM004	1	\$0.14
Bamford	Bamford	Dressing, 10cm x 20cm	BAM022	1	\$0.17
Bamford	Bamford	Dressing, 10cm x 30cm	BAM062	1	\$0.18
Bamford	Bamford	Dressing, 20cm x 10cm	BAM063	1	\$0.17
Bamford	Bamford	Dressing, 20cm x 20cm	BAM005	1	\$0.14
Bamford	Bamford	Dressing, 20cm x 30cm	BAM023	1	\$0.17
Bamford	Bamford	Dressing, 45cm x 45cm	BAM064	1	\$0.77
Bamford	Bamford	Dressing, 10cm x 10cm	BAM086	1	\$0.14
Bamford	Bamford	Dressing, 10cm x 20cm	BAM087	1	\$0.16
Bamford	Bamford	Dressing, 10cm x 30cm	BAM088	1	\$0.17
Bamford	Bamford	Dressing, 20cm x 10cm	BAM089	1	\$0.16
Bamford	Bamford	Dressing, 20cm x 20cm	BAM090	1	\$0.23
Bamford	Bamford	Dressing, 20cm x 30cm	BAM091	1	\$0.28
Bamford	Bamford	Dressing, 45cm x 45cm	BAM092	1	\$0.63
Bamford	Bamford	Gamgee Roll, 45cm x 95cm	BAM069	1	\$2.79
Bamford	Bamford	Dressing, 9 x 10cm (5)*	BAM036	1	\$0.35
Bamford	Bamford	Dressing, 9 x 20cm (2)*	BAM037	1	\$0.27
Bamford	Bamford	Dressing, 9 x 20cm (6)*	BAM038	1	\$0.54

* Multiple dressings per pouch

About the proposed products

Bamford sterile combine dressings are currently supplied to DHBs.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings and that the range of sizes would be appropriate.

If you would like more information about the product, you can contact:

Katherine Venn-Brown Business Development Manager WM Bamford & Co Ltd Mobile: 027 442 1014 Email: katherine@bamford.co.nz

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

DV Medical Devices for this HSS Sub-category would include: Propax, Sentry Medical and Zetuvit sterile combine dressings and dressing rolls.

This is not an exhaustive list. Any product that fits the HSS Sub-category definition and is not one of the Bamford HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

Foam adhesive dressings (with and without border)



An example of the types of products within this Sub-category

HSS Supplier: Mölnlycke Health Care Pty Limited (Mölnlycke)

DV Limit: 25%

HSS Sub-category scope

Would include:

- square or rectangular, highly absorbent, conformable, polyurethane adhesive foam dressings and dressing rolls with a surface that allows exudate to pass through and with a structure that holds fluid within the dressings, or transfers fluid into a secondary dressing
- foam dressings as described above:
 - that have any level of self-adhesion, regardless of whether or not a secondary fixation dressing is required
 - with or without an adhesive border
 - of various thicknesses, densities and levels of exudate management ability, and
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- antimicrobial foam dressings
- charcoal impregnated foam dressings
- foam dressings used as part of the structural components of a negative pressure wound therapy system
- composite foam dressings, which includes foam dressings with gel forming layers
- adhesive shaped dressings including sacral, heel, digit, circle, oval, multi-site, multi-lobe, fenestrated and other shaped foam dressings for use on difficult body contours, and
- any other products determined by PHARMAC to be out of scope of this HSS Sub-category, following appropriate clinical advice



Proposed Mölnlycke HSS Products (to be listed on the Pharmaceutical Schedule from 1 October 2016)

Manufacturer	Brand	Description	Product code	Pack size	Pack price
Mölnlycke	Mepilex Border Lite	Dressing with adhesive border, 4cm x 5cm	281000	10	\$13.50
Mölnlycke	Mepilex Border Lite	Dressing with adhesive border, 5cm x 12.5cm	281100	5	\$14.55
Mölnlycke	Mepilex Border Lite	Dressing with adhesive border, 7.5 x 7.5cm	281200	5	\$13.70
Mölnlycke	Mepilex Border Lite	Dressing with adhesive border, 10cm x 10cm	281300	5	\$16.95
Mölnlycke	Mepilex Border Lite	Dressing with adhesive border, 15cm x 15 cm	281500	5	\$43.35
Mölnlycke	Mepilex Border	Dressing with adhesive border, 7.5cm x 7.5cm	295200	5	\$15.50
Mölnlycke	Mepilex Border	Dressing with adhesive border, 10cm x 10 cm	295300	5	\$17.50
Mölnlycke	Mepilex Border	Dressing with adhesive border, 15cm x 15 cm	295400	5	\$30.75
Mölnlycke	Mepilex Border	Dressing with adhesive border, 15cm x 20 cm	295600	5	\$56.10
Mölnlycke	Mepilex Border	Dressing with adhesive border, 10cm x 20 cm	295800	5	\$46.30
Mölnlycke	Mepilex Border	Dressing with adhesive border, 10cm x 25cm	295850	5	\$51.65
Mölnlycke	Mepilex Border	Dressing with adhesive border, 10cm x 30 cm	295900	5	\$58.90
Mölnlycke	Mepilex XT	Dressing, 10cm x 10 cm	211100	5	\$20.85
Mölnlycke	Mepilex XT	Dressing, 10cm x 20 cm	211200	5	\$47.20
Mölnlycke	Mepilex XT	Dressing, 15cm x 15 cm	211300	5	\$57.30
Mölnlycke	Mepilex XT	Dressing, 20cm x 20 cm	211400	5	\$89.95
Mölnlycke	Mepilex Lite	Dressing, 6cm x 8.5 cm	284000	5	\$13.85
Mölnlycke	Mepilex Lite	Dressing, 10cm x 10 cm	284100	5	\$20.50
Mölnlycke	Mepilex Lite	Dressing, 15cm x 15cm	284300	5	\$49.00
Mölnlycke	Mepilex Lite	Dressing, 20cm x 50 cm	284500	4	\$215.80
Mölnlycke	Mepilex	Dressing, 5cm x 5cm	294015	5	\$16.40
Mölnlycke	Mepilex	Dressing, 10cm x 10 cm	294100	5	\$18.95
Mölnlycke	Mepilex	Dressing, 10cm x 20cm	294200	5	\$42.90
Mölnlycke	Mepilex	Dressing, 15cm x 15cm	294300	5	\$52.10
Mölnlycke	Mepilex	Dressing, 20cm x 20cm	294400	5	\$81.75
Mölnlycke	Mepilex	Dressing, 20cm x 50cm	294500	2	\$83.96
Mölnlycke	Mepilex Transfer	Dressing, 7.5cm x 8.5cm	294600	5	\$23.55
Mölnlycke	Mepilex Transfer	Dressing, 10cm x 12cm	294700	5	\$46.60
Mölnlycke	Mepilex Transfer	Dressing, 15cm x 20cm	294800	5	\$97.05
Mölnlycke	Mepilex Transfer	Dressing, 20cm x 50cm	294502	4	\$175.80

About the proposed products

The Mepilex range of brands of foam dressings listed above are currently supplied to DHBs with the exception of Mepilex XT which would be new to DHBs.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings and that the range of sizes would be appropriate.

If you would like more information about the product, you can contact:

Brad Green Marketing Manager – Wound Care Mölnlycke Health Care Pty Limited Mobile: +61 409 463 881 Email: brad.green@molnlycke.com

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

DV Medical Devices for this HSS Sub-category would include: PolyMem, Allevyn, Tegaderm and Advazorb adhesive foam dressings.

This is not an exhaustive list. Any product that fits the HSS Sub-category definition and is not one of the Mölnlycke HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

Foam non-adhesive dressings



An example of the types of products within this Sub-category

HSS Supplier: Universal Specialities Limited (USL)

DV Limit: 20%

HSS Sub-category scope

Would include:

- square or rectangular, highly absorbent, conformable, polyurethane non-adhesive foam dressings and dressing rolls with a surface that allows exudate to pass through and with a structure that holds fluid within the dressing, or transfers fluid into a secondary dressing
- foam dressings as described above of various thicknesses, densities and levels of exudate management ability, and
- any other products determined by PHARMAC to be within the scope of this HSS Sub-category, following appropriate clinical advice

Would not include:

- antimicrobial foam dressings
- charcoal impregnated foam dressings
- foam cavity dressings
- composite foam dressings which includes foam dressings with gel forming layers
- foam dressings that form part of the structural components of a negative pressure wound therapy system
- foam dressings with any level of self-adhesion or tackiness prior to application
- polyurethane membranes
- non-adhesive shaped foam dressings including sacral, heel, digit, circle, oval, multi-site, multi-lobe, fenestrated and other shaped foam dressings for use on difficult body contours, and
- any other products determined by PHARMAC to be out of scope of this HSS Sub-category, following appropriate clinical advice



Proposed USL HSS Products (to be listed on the Pharmaceutical Schedule from 1 October 2016)

Manufacturer	Brand	Description	Product code	Pack size	Pack price
Coloplast Pty Ltd	Biatain	Dressing, 5cm x 7cm	13276	10	\$24.80
Coloplast Pty Ltd	Biatain	Dressing, 10cm x 10cm	13277	10	\$28.90
Coloplast Pty Ltd	Biatain	Dressing, 10cm x 20cm	13278	5	\$30.50
Coloplast Pty Ltd	Biatain	Dressing, 15cm x 15cm	13279	5	\$33.80
Coloplast Pty Ltd	Biatain	Dressing, 20cm x 20cm	13280	5	\$45.10
Ferris	PolyMem	Dressing, 4.7cm x 4.7cm	10485	20	\$43.97
Ferris	PolyMem	Dressing, 8cm x 8cm	8013	15	\$55.09
Ferris	PolyMem	Dressing, 10cm x 10cm	8014	15	\$67.41
Ferris	PolyMem	Dressing, 13cm x 13cm	8015	15	\$115.61
Ferris	PolyMem	Dressing Roll, 10cm x 32cm	8017A	1	\$21.39
Ferris	PolyMem	Dressing Roll, 10cm x 32cm	8017	12	\$254.51
Ferris	PolyMem	Dressing Roll, 10cm x 61cm	8018A	1	\$34.97
Ferris	PolyMem	Dressing Roll, 10cm x 61cm	8018	4	\$132.80
Ferris	PolyMem	Dressing Roll, 20cm x 60cm	10943	2	\$140.00
Ferris	PolyMax	Dressing, 11cm x 11cm	8027	10	\$79.01
Ferris	PolyMax	Dressing, 20cm x 20cm	90163	5	\$125.23

About the proposed products

The PolyMem and PolyMax brands of foam dressings are currently supplied to DHBs. The Biatain brand of nonadhesive foam dressings is not currently supplied to DHBs however is well established overseas.

The Wound Care Advisory Group has advised that these products would be suitable for use in DHB settings and that the range of sizes would be appropriate.

If you would like more information about the product, you can contact:

Mel Dodds

Woundcare Product Manager Universal Specialities Limited Phone: 09 815 7750 Mobile: 021 770 536 Email: melanie.dodds@uslmedical.co.nz

DV Medical Devices

DV (discretionary variance) Medical Devices would be non-HSS Products that fall within the HSS Sub-category scope that DHBs **must not** purchase, unless within the applicable DV Limits.

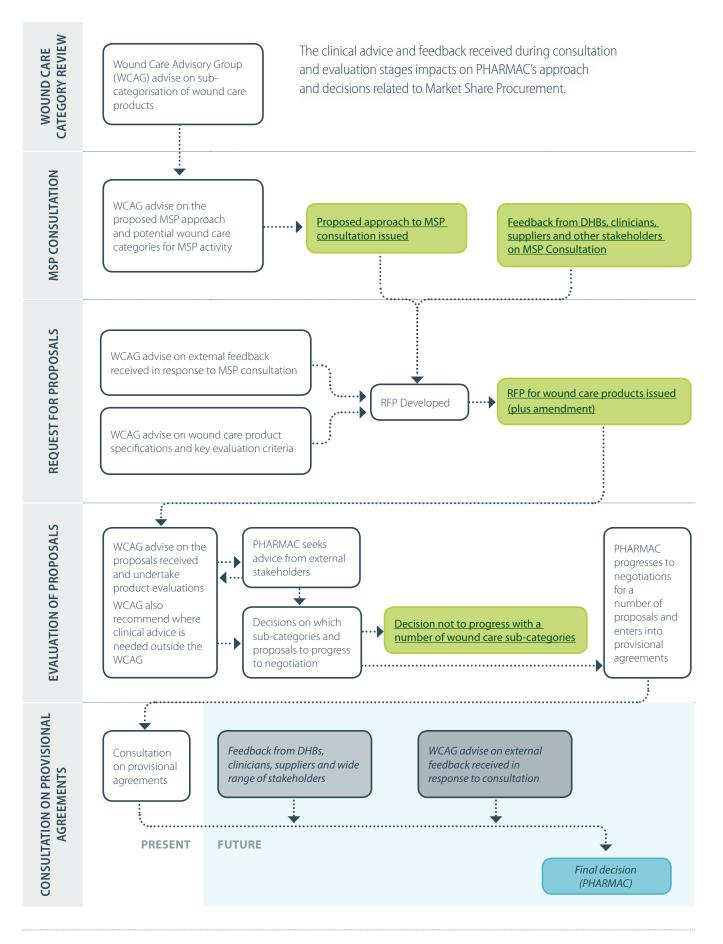
DV Medical Devices for this HSS Sub-category would include: Allevyn, Advazorb, and Kendall Copa non-adhesive foam dressings.

This is not an exhaustive list. Any product that fits the HSS Sub-category definition and is not one of the USL HSS Products would be considered a DV Medical Device. If a DHB is unsure if a product would be a DV Medical Device or not, they can contact PHARMAC for advice.

APPENDIX TWO

PHARMAC Pharmaceutical Management Agency

Clinical input into the Market Share Procurement (MSP) process



24 Proposal to list and award market share for various wound care products in DHBs.

PHARMAC Pharmaceutical Management Agency

About the Wound Care Advisory Group (WCAG)

PHARMAC established a Wound Care Advisory Group in July 2014 to provide clinical advice as part of its consideration of wound care procurement opportunities.

The WCAG was established through a formal nominations process, where PHARMAC sought nominations from the New Zealand Wound Care Society, the Royal Australasian College of Surgeons and the New Zealand Nurses' Organisation.

Role

The role of the WCAG has been to:

- provide objective advice to PHARMAC on the possible approaches for standardisation and rationalisation of wound care products nationally
- assist with defining requirements and specifications that require consideration in relation to each wound care subcategory
- review clinical evidence and appropriateness of new wound care products and/or new technology offered by wound care supplier
- help ensure that products are fit for purpose, clinically appropriate and meet the needs of patients at a sustainable cost, and
- consider, make recommendations or report to PHARMAC and/or PTAC on any other matters that may be referred to it by PHARMAC

Members

The WCAG is made up of practising wound care specialists working for DHBs. The WCAG members are listed below:

Name	Position	District Health Board
Julie Betts (Chair)	Wound Care Nurse Practitioner	Waikato DHB
Alan Shackleton	Nurse Consultant - Wound Care Service Clinical Lead	Counties Manukau DHB
Amanda Pagan	Wound Care Specialist Nurse	Southern DHB
Catherine Hammond	Wound Care Clinical Nurse Specialist & Educator	Nurse Maude (Community Nursing Provider for Canterbury DHB)
Emil Schmidt	Nurse Specialist Wound Care	Southern DHB
Jonathan Heather	Plastic Surgeon	Counties Manukau DHB
Susie Wendelborn	Specialty Clinical Nurse Wound Care	Nelson-Marlborough DHB
Wendy Mildon	Clinical Nurse Specialist Wound Care	Hawke's Bay DHB



PHARMAC Pharmaceutical Management Agency

Proposed implementation activities and timeline

	Pre-Implementation 1 - 30 September 2016	Transition period 1 Oct 2016 - 31 March 2017	Post-Implementation 1 April 2017 onwards
DHBs	 Nominate DHB Change Manager Liaise with HSS Supplier and PHARMAC regarding any specific implementation support needs and stock requirements Identify any system and process adaptations needed to manage DV Limit compliance Use PHARMAC implementation pack as needed to support change activities 	 Adapt systems and processes as required to manage DV Limit compliance Upload local systems with any new product or supplier information Ongoing liaison with HSS Suppliers on product changes and delivery of training and education Advise PHARMAC of any implementation issues and/or where any additional support or information is needed Work with HSS Supplier to implement any product changes and deliver any required training and education 	 Continue to manage DV Limit compliance Provide PHARMAC with feedback on HSS Supplier performance and any issues with DV Limit management Liaison with HSS Supplier on day to day requirements and issues
HSS Suppliers	 Contact DHB Change Managers to discuss implementation and stock requirements and provide relevant set-up details Begin any product change processes Ensure stock available to support transition and ongoing requirements 	 Continue with any product change processes and support including delivery of any required training and education Provide PHARMAC with regular transition progress reports 	 Ongoing supply and product support to DHBs Regular reports to PHARMAC Early notification of any potential supply issues
PHARMAC	 Notify decision and update Pharmaceutical Schedule Contact DHB Change Managers to provide implementation pack and copies of contract, and to discuss specific support requirements Identify opportunities for collective discussions with DHB Change Managers and other relevant groups Complete the development of tools and resources for DHBs to manage DV Limit compliance 	 Ongoing liaison with DHB Change Manager Participate in or arrange collective discussions with DHB Change Managers and other relevant groups Provide DHB Change Managers with tools, resources and reports to support DV Limit compliance Provide additional support and information to DHBs as needed Engage with Procurement Operations Advisory Group regarding implementation issues Manage any HSS Supplier related implementation issues 	 Post implementation review Ongoing support to DHBs to ensure DV Limit compliance maintained Ongoing contract management including managing HSS Supplier performance

The timing of activities provided by the HSS suppliers may vary between DHBs as to whether it occurs pre-implementation or during the transition period.

