Wound Care Advisory Group

Meeting held 30 June 2015

(Minutes for web publishing)

The role of the Wound Care Advisory Group (WCAG) is 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 suppliers,
- 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.

Note that this document is not necessarily a complete record of the WCAG meeting; only the relevant portions of the minutes relating to WCAG discussions regarding recommendations and categorisations are generally published. Numbering has been updated to reflect this.

1. Review of feedback to Discussion Document on PHARMAC's proposed approach to MSP

1.1. The Group reviewed the summary of feedback to the Discussion Document on PHARMAC's proposed approach to MSP.

1.2. The Group noted that in response to question 5 of the Discussion Document, a suggestion was made to PHARMAC that dressing function may be a more useful way to categorise the different wound care products. The Group noted that this option had initially been discussed at the start of the categorisation process but had been discarded because the majority of wound care products had multiple functions, which made them difficult to list and difficult to implement.

1.3. PHARMAC staff stated that it was possible to develop a separate document, similar to a wound care formulary available in other jurisdictions to assist PHARMAC, wound care specialists and DHB hospital staff.

1.4. The majority of WCAG members commented that a national wound care formulary, similar to the one presented to the WCAG (Wound Management Product Formulary – Version: CLCH2014, NHS) could be useful, as it could allow comparisons between different wound care treatments, costs and could promote good practice around product selection.

1.5. A WCAG member noted that the lack of high-quality evidence (eg large, objective RCTs) around the use of different wound care products could limit the credibility of a formulary that was too prescriptive.

1.6. A WCAG member noted that one option for a formulary was to refer to the basic characteristics of a wound (eg exudate level, wound depth, infection) as opposed to specific wound descriptions.

2. Review of Product Specifications for RFP

2.1. Prior to the meeting, the Group was asked to review product specifications, requirements and features for various wound care products selected for market share procurement. The Group were asked general questions relating to all selected wound care subcategories and specific questions relating to each wound care subcategory.

2.2. The Group advised that the following items should be mandatory requirements for any proposals received for wound care products selected for MSP:

Product requirements

2.2.1. Clear and easy to read labelling for wound care products, including:

(a) expiry dates (including on individual packages);

(b) brand names that allow distinction between different types of products;

(c) materials used in construction (eg adhesive and preservatives)

2.2.2. Minimum of two year shelf-life upon delivery.

2.2.3. Product information pamphlets, or alternatively links where this information can be found.

2.2.4. Information on the requirement to use secondary dressings (if applicable).

Regulatory requirements

2.2.5. Completed Product Evaluation Health New Zealand (PEHNZ) form.

2.2.6. Suppliers must provide risk classification of medical device as outlined on Medsafe's website.

Supplier requirements

2.2.7. Suppliers must outline customer support, training and educational resources that will be available during any major switchover (if applicable) and throughout the life of the contract.

2.2.8. Suppliers must outline current/ proposed ordering, supply chain management processes (eg 3PL) and risk management strategies to prevent out of stock situation (eg ring-fencing stock in other jurisdictions, real-time stock monitoring systems).

2.2.9. Suppliers must outline product complaint management processes and reporting ability.

Evidence requirements

2.2.10. Suppliers must provide evidence for clinically relevant outcomes for each product. High-quality randomized controlled trials (RCTs) with clinically relevant outcomes preferred. Other levels of evidence will be considered (eg prospective cohort study, expert opinion, case study).

2.2.11. Where claims are being made regarding superiority versus comparable products, a cost benefit analysis and evidence to support its claim must be provided.

2.3. The Group recommended that a template or algorithm to compare the cost-effectiveness of different wound care products could be useful to assist with product comparisons.

2.4. The Group noted that while there was greater awareness of costs around the use of different treatment, clinicians had limited ability to accurately evaluate and compare the cost of different treatments.

2.5. The Group advised that some of the key factors to consider when assessing the cost of different wound care treatments, include:

2.5.1. Frequency of dressing changes

2.5.2. Rate of healing

2.5.3. Level of pain and trauma on application/removal

2.6. The Group noted that it was difficult to assess claims made around different characteristics/properties of wound care products due to the lack of any internationally recognised standards and/or lack of compliance with those standards where they exist.

2.7. The Group recommended that in the event of a three supplier model being progressed, a 1% DV limit should still apply to allow for clinical choice outside of the three suppliers.

Combine dressings (sterile and non-sterile) specifications, requirements and features

2.8. The Group considered that the types of proposals being sought for combine dressings (sterile and non-sterile) as outlined in the WCAG paper were appropriate.

2.9. The Group considered that the specifications, requirements and features for combine dressings as outlined in the WCAG paper were appropriate, but recommended the following:

2.9.1. Description used for products in this range should be amended to “simple cotton based dressings with absorbent middle layer with soft non-woven fabric cover and soft end seals”.

2.9.2. High level of absorbency requirement should be amended to state “supplier to specify level of absorbency (low, medium, high).

2.10. The Group advised that PHARMAC could clarify the products it is seeking by listing the items currently under national contracts with PHARMAC.

Compression bandages and kits specifications, requirements and features

2.11. The Group considered that the types of proposals being sought for compression bandages and kits as outlined in the WCAG paper were appropriate.

2.12. The Group recommended that the term “compression kits” should be amended to “compression bandage kits” to distinguish it from kits that included the use of compression hosiery.

2.13. The Group advised that it would appropriate to seek proposals for a two layer compression bandage kit system that would cover the entire compression bandage kit market, as long as there was a 5% DV limit so that other compression bandage kits could be used.

2.14. The Group advised that if a 3 – 4 layer compression layer system was clinically required, it would be possible to create this system using the various compression bandages or using the 5% DV limit for the compression bandage kits.

2.15. The Group stated that it should be made clear that PHARMAC is not seeking proposals for compression systems that include compression hosiery.

2.16. The Group recommended that Coban Natural should remain listed under the compression bandage category.

2.17. The Group considered that the specifications, requirements and features for compression bandages and kits as outlined in the WCAG paper were appropriate, but recommended the following:

Compression bandage kits

2.17.1. Amend the Low ABPI description to state "between 0.5 – 0.8".

2.17.2. Amend "must specify level of compression (mmHg) that can be achieved" requirement to "must specify level of compression (mmHg) that can be achieved at rest".

2.17.3. Amend requirement for "Highly conforming – all shapes and sizes" to "Highly conforming – all leg shapes and sizes".

2.17.4. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

Compression bandages

2.17.5. As per recommendation 8.18 (b) -(d) above

2.17.6. Amend "durable product preferred" requirement to "information on durability must be specified, including maximum wear time".

2.17.7. Add requirement for suppliers to "specify whether product is reusable/washable".

Foam dressings specifications, requirements and features

2.18. The Group advised that the types of proposals being sought for foam dressings as outlined in the WCAG paper were appropriate.

2.19. The Group advised that it would be preferable to select a small number of suppliers that had a wide range of sizes and shapes of foam dressings to reduce

the confusion arising from multiple suppliers with different sized/shaped foam dressings.

2.20. The Group advised that the specifications, requirements and features for foam dressings as outlined in the WCAG paper were appropriate, but recommended the following:

Foam adhesive and non-adhesive dressings

2.20.1. Add requirement for suppliers to provide information around properties and function of foam dressing under pressure (eg compressibility, moisture retention, absorption, wicking properties).

2.20.2. Amend requirement "various shapes and sizes preferred" to "various dressing shapes and sizes preferred".

2.20.3. Clarify that this subcategory excludes anti-microbial foam dressings that are listed under a different subcategory heading.

2.20.4. Clarify that the "cuttability" requirement only applies to foam dressings without adhesive border.

2.20.5. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

2.20.6. Add requirement for suppliers to provide information on maximum length of wear.

Laparotomy sponges specifications, requirements and features

2.21. The Group advised that the types of proposals being sought for laparotomy sponges as outlined in the WCAG paper were appropriate.

2.22. The Group advised that it would be appropriate to allow bundling of laparotomy sponges and swabs as they were used in similar areas and had similar suppliers.

2.23. The Group recommended PHARMAC investigate further as to whether laparotomy sponge with tape was actually required.

2.24. The Group advised that the specifications, requirements and features for laparotomy sponges as outlined in the WCAG paper were appropriate, but recommended the following:

2.24.1. Amend "must be non-linting" requirement to "must be low-linting"

2.24.2. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

Low adherent dressings with adhesive border specifications, requirements and features

2.25. The Group advised that the types of proposals being sought for low adherent dressings with adhesive border as outlined in the WCAG paper were appropriate.

2.26. The Group recommended that PHARMAC include absorbent low adherent dressing to the RFP to allow the option of bundling with low adherent dressings with adhesive border.

2.27. The Group advised that the specifications, requirements and features for low adherent dressings with adhesive border as outlined in the WCAG paper were appropriate, but recommended the following:

2.27.1. Clarify that this subcategory excludes anti-microbial low adherent dressings with adhesive border that are listed under a different subcategory heading.

2.27.2. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

2.27.3. Request from suppliers information around the sterility of the dressing and packaging.

Securement bandage specifications, requirements and features

2.28. The Group advised that the types of proposals being sought for securement bandages as outlined in the WCAG paper were appropriate.

2.29. The Group recommended that PHARMAC separate out the crepe and non-crepe securement bandages.

2.30. The Group advised that the specifications, requirements and features for securement bandages as outlined in the WCAG paper were appropriate, but recommended the following:

2.30.1. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

2.30.2. Amend "durable" requirement to "information on durability must be specified, including maximum wear time".

Swabs specifications, requirements and features

2.31. The Group advised that the types of proposals being sought for swabs as outlined in the WCAG paper were appropriate.

2.32. The Group noted that double ended swabs were very low use items and only used by a few DHBs. The Group recommended that PHARMAC investigate

whether there was a need to request for proposals for double ended swabs or whether it should be excluded for consideration.

2.33. The Group recommended that PHARMAC investigate further on the need for gauze swabs (sterile) in larger sizes (eg 1cm x 110cm, 10cm x 55cm) and consider further rationalisation if appropriate.

2.34. The Group recommended that Debrisoft should remain in the Other swabs subcategory.

2.35. The Group advised that the specifications, requirements and features for swabs as outlined in the WCAG paper were appropriate, but recommended the following:

Cotton tipped swabs

2.35.1. Exclude proposals for jumbo cotton tipped swabs.

2.35.2. Request that suppliers specify the swab size and pack-size.

Non-woven balls (sterile)

2.35.3. Amend "latex free/ hypoallergenic preferred" requirement to state "presence of latex or other allergens (eg rosin/colophony) must be specified".

Wound dressing packs specifications, requirements and features

2.36. The Group recommended that PHARMAC seek further information from DHBs to establish the use of different wound dressing packs and assess whether a standardised range of wound dressing packs could be established.

2.37. The Group advised that the specifications, requirements and features for wound dressing packs as outlined in the WCAG paper were appropriate, but recommended the following:

2.37.1. Amend the requirement for "high-quality tweezers and sterile guard" to state "high-quality forceps and sterile guard".

2.37.2. Clarify that wound dressing packs should not contain wool wipes.

3. Evaluation process – who, what, how, where and when

3.1 PHARMAC staff provided a high-level overview of the different evaluation processes that could take place for simple/low risk, moderately complex/moderate risk and highly complex/high risk wound care products.

3.2 The Group advised with the proposed high-level approach to evaluate various wound care products and advised that the process should depend on the level of complexity and risk associated with a medical device.

3.3 PHARMAC staff stated that the definition of risk was being used in its broadest sense, but could include:

3.3.1. Risks to patient

3.3.2. Risks to supply

3.3.3. Risks around implementation

3.3.4. Risks associated with change

3.4 A member of the Group asked whether there was a risk with the WCAG undertaking evaluation when the group was relatively homogenous in its views. PHARMAC staff stated that feedback received through consultation processes were expected to mitigate this risk and members were expected to provide objective advice based on the feedback.

3.5 PHARMAC staff noted that where a wound care product has a high risk profile, advice could also be sought from the Pharmaceutical Therapeutic Advisory Group (PTAC) and/or other subcommittees of PTAC.

3.6 PHARMAC staff also noted that where WCAG felt it did not have sufficient experience or knowledge around specific wound care products to provide objective clinical advice, PHARMAC could seek advice from other specialists or clinical groups.

3.7 Referring to a standard DHB product evaluation form, PHARMAC staff asked whether something similar would be useful in the event that product evaluations needed to be carried out in DHB hospitals.

3.8 The Group advised that it could be useful to have a product evaluation form, but considered that device category specific product evaluation forms could be more useful, with the ability to include other information, such as patient comfort and total number of patients the product was tested on.

3.9 PHARMAC staff stated that it was difficult to identify the cost of change and this was also shown through the feedback received through the discussion document. PHARMAC staff also noted that the cost of change was dependent on the subcategory and the scale of change.

4. Identifying indirect costs/benefits of change and implementation requirements

4.1 PHARMAC staff outlined a list of potential costs arising from a change decision and asked the Group how these costs might apply to the list of wound care subcategories selected for MSP.

4.2 The Group advised that ACC funded some items over $20 and had its own catalogue for billing purposes. The Group recommended that PHARMAC should consult with ACC.

4.3 The Group stated for the selected wound care products for MSP, the time required related more to the time required to use up old stock. PHARMAC staff noted that for the medicines tender process DHB hospitals had a standard transition period of 2 months, but this related more to the ability to purchase and did not impact on the use of remaining stock.

4.4 The Group advised the following regarding the list of potential costs for the wound care subcategories selected for MSP:

4.4.1. *Administrative cost (eg updating systems and pricing)* – scale of cost would be driven by how widely it is used in DHB hospitals. For example, foam dressings, low adherent dressings with adhesive border, securement dressings and swabs are used extensively in DHB hospitals and therefore would require more time and resources to change. Whereas compression kits/bandages and laparotomy sponges would have more limited spread of use and administrative costs could therefore be smaller.

4.4.2. *Training and education time* – training and education time for simple changes could require as little as 1 month for training and education, but for more complex and bigger changes, this could take up to 3 months or longer depending on the level of education and training required. Training and education could be a big issue if there were multiple changes at the same point in time and therefore a staggered transition for training and education may be more appropriate.

4.4.3. *Change to guidelines/ best practice* – this was not a major issue for the wound care products selected for MSP.

4.4.4. *Storage* – consideration should be given to the minimum order quantities as individual DHBs may have differing needs. Shelf space in operating theatres are a bigger issue as there is limited space, for example, big boxes of sponges of lap sponges may not be practical for the theatre storage.

4.5 The Group advised that other costs that may be associated with change included the following:

4.5.1. Staff resistance/ engagement issues.

4.5.2. Unexpected challenges with new device – eg difficult packaging, which can frustrate clinicians.

4.5.3. Change fatigue – too many changes.

4.5.4. Packaging wastage and other environmental factors.

4.6 PHARMAC staff asked the Group how PHARMAC could implement changes better and what it should consider not doing when introducing change. The Group advised the following:

4.6.1. Early notification and communication is critical and it is important that the right channels are used to communicate any changes (eg theatre charge nurse for any changes to products used in theatre use).

4.6.2. Use DHB procurement groups as a channel to inform clinicians and surgeons of change.

4.6.3. An outline of any planned transition would be a useful way to communicate change and prepare staff (eg training and education).

4.6.4. PHARMAC needs to make sure that change decisions are communicated effectively to the right people and can be distinguished from the standard communications that go out regularly.

4.6.5. Wound specialist would normally be the lead for most wound care products, unless the product was also used in other areas such as plastics.

4.7 PHARMAC staff asked for an example of a big change programme so that it could be used as a reference. Members of the Group advised that transitioning negative pressure wound therapy (NPWT) products in their DHB took approximately 6 months due to the complexity of the change (eg training and education).

4.8 The Group advised that a post evaluation process could help PHARMAC understand how its change decisions impact on DHBs and allow further refinement where requirement.