

PHARMAC
PO Box 10-254
Wellington

30 March 2010

Re: Consultation/discussion document for possible expansion of PHARMAC's role

To whom it may concern

The New Zealand Wound Care Society (NZWCS) is the only national body for health care professionals with an interest in wound management in New Zealand. The Society currently represents over 400 members including Nurse Practitioners™, Nurse Specialists, Registered Nurses in both primary, secondary and aged care, Podiatrists and Surgeons, as well as commercial companies involved in wound management. As such, the NZWCS National Committee, along with our members, are very disappointed that we were not included in PHARMAC's original consultation list. Our members represent those most intimately involved in wound management and are a group whose clinical practice could be significantly impacted on by this proposal. This oversight has resulted in us having less time to prepare a submission on the proposal to expand the role of PHARMAC, as we only became aware of the proposal in mid March.

The NZWCS applauds PHARMAC's wish to implement recommendations from the 2009 MRG report in order to contain health expenditure. However, within the fine balancing act of juggling financial constraints within the Health Sector and implementing best evidence-based wound management practice (including the discerning selection of wound consumables), the Society holds a number of reservations about PHARMAC undertaking the assessment, prioritisation and procurement of wound management products.

A chief concern of the NZWCS is that if this proposal is enacted it has the potential to significantly affect market competition. New Zealand has a relatively small market for wound management products and if only select products are funded it would most likely result in a number of companies withdrawing from the New Zealand market. This has already been seen with some medicines when the revenue from sales becomes too small or the potential financial gain for the company is minimal. A significant risk of such an anti-competitive market is domination by one or two companies who can then command whatever price they wish as there will be no competitor for the products they offer. Already in New Zealand we have limited access to the full range of wound management products available internationally simply because of the small market size; we do not want to see this reduced even further. An anti-competitive market and subsequent reduction in product availability *will seriously and adversely impact on clinician choice and treatment options leading to poorer patient outcomes.*

While different manufacturers produce dressings of the same category, the performance, and therefore application, of products within the same category can vary depending on the product components and the wound characteristics. Therefore, clinicians require appropriate access to a range of products in order to meet the diverse and changing needs of patients in order to deliver best care. Restriction on choice of products will impact on options for clinical care and may also affect access to new products. Already DHBs and collaborative buying groups provide an avenue for product assessment and procurement at acceptable pricing levels, and these processes are guided by local wound care experts. We therefore believe that a national procurement approach is not needed or warranted for wound management products.

In any instance where national consistency, procurement and price negotiation would be beneficial, then a process that has already been undertaken by DHBNZ could be followed, which includes input from an expert advisory group, as well as clinical and laboratory evaluation. This approach was used successfully over 2008-2009 for the assessment and procurement, on a national basis, of a replacement syringe driver for palliative care. It included not just DHBs but also hospices and aged residential care facilities. Where national consistency would be desirable for any wound management product, this process could be adopted.

In addition to the potential loss of product range, New Zealand health care professionals could stand to lose opportunities for commercial sponsorship and value added services such as clinical education; this is especially important for nursing and podiatry groups. This prospect is of great concern to the NZWCS, as we rely on commercial sponsorship to provide education and professional development opportunities for members and non-members through seminars, study days and conferences.

We are also concerned about the process by which wound management products may be assessed and prioritised by PHARMAC, as wound management products are not related to the current business of PHARMAC. We are not aware that PHARMAC has the requisite expertise to undertake this role in relation to wound management products and as such are concerned about how decisions will be made. There is a great deal more to wound management than simply the dressing or irrigating fluid and any assessment of clinical benefits and cost-effectiveness must also consider the broader components of wound management. These include, but are not limited to, health care professional time, frequency of dressing change requirements, other consumables, length of time to healing, place of care (predominantly wound care is undertaken in community settings) and patient quality of life. All of these factors are cost drivers, not just the cost of the initial dressing or device. Economic evaluation becomes more complex in the case of chronic or non-healing wounds, or when the aim of care is symptom control and comfort, as may be the case with palliative care patients.

Any approach that focuses predominantly on product cost will result in misleading cost-effectiveness data, as some 'expensive' dressings/devices result in a much shorter time to complete healing resulting in a net cost saving or equivalence to simple or traditional products that take considerably longer to produce healing. The impact of this on the patient cannot be underestimated, as quality of life is substantially improved once a wound is healed and the patient can more quickly resume normal activities, including return to work.

NZWCS responses to specific questions from PHARMAC, with particular reference to wound management products.

- a. Should there be a fixed budget for hospital medicines and for the medical devices identified above? If so, how should these operate? Should they be combined or separate from existing budgets? Should it be set, as with PHARMAC's existing activity, through negotiation between PHARMAC and DHBs?

The NZWCS does not believe a fixed budget is appropriate for wound management products. If there were extraordinary events in one year, such as a major disaster resulting in multiple injured people, the budget may be exhausted. Or, if there were more than expected numbers of burns in a year it would impact on dressing product expenditure and potentially reduce the budget for other patients.

Within a fixed budget there may be limited or no ability to access new innovations in wound management if they fall outside of the allocated budget or once the budget has been set for the financial year.

In addition, DHBs already manage budgets for wound management products within acceptable limits and purchase products that have been assessed by specialists in the field to meet the needs of their patient population.

We do not believe current expenditure of wound management products contributes greatly to health care spending compared to other high cost treatments or medical devices.

- b. How can clinical choice with regard to hospital medicines and the medical devices identified above be balanced with national consistency and good resource management?

The NZWCS considers that wound management products are already being used in a resource conscious way and that access is consistent nationally, albeit products may be supplied by different manufacturers or distributors. Many DHBs have a wound management product guide in place that supports best practice and guides clinician choice. This approach ensures appropriate product use and good resource management. The most important aspect of this point is that almost every DHB has a wound care specialist who is able to assess patient need for more expensive wound management products, so choice is based on clinical expertise and patient need. This is also the case for podiatrists who practice wound management for diabetic foot ulcers.

It is very important that wound management products are not selected based on cost alone, as clinical effectiveness is more important to achieve desired patient outcomes and usually a more expensive, often more contemporary, product will achieve faster healing.

- c. PHARMAC manages Exceptional Circumstances Schemes to offer access to medicines which are not otherwise currently funded. Would a specific scheme be required for hospital medicines? How might it operate?

If this proposal were to be enacted and an EC scheme put in place for wound management products, the EC process would need to be available to nurses and podiatrists, as they are the key health professionals making decisions about wound management products.

- d. What challenges do the differences in how medicines are prescribed and dispensed in hospital and community settings (including information systems) present to the implementation of this proposal? How might these challenges be overcome?

Although wound management products are generally not prescribed in hospitals, there is a potential issue in relation to funding of hospital supplied products. Hospitals are required to keep certain stock levels of wound management products for urgent or ongoing use, or for changes in dressing regimens based on clinical assessment, rather than allocate them to specific patients based on a prescription. This could present issues with funding and reimbursement and may require extensive review of hospital processes and prescribing practices for wound management products.

- e. What lessons from PHARMAC's expansion into the management of hospital cancer medicines should be considered in deciding how PHARMAC's role should be expanded into all hospital medicines?

The use of cancer medicines as a political gambit should serve to dissuade PHARMAC from this approach to medical devices, as it will only encourage consumer dissatisfaction, political lobbying and potentially unsound political decisions that may not be based on best available evidence. PHARMAC took on funding cancer medicines to control cost of these expensive medicines and to try and ensure national equity of access. These issues are not present in relation to wound management products within DHBs. There are however, issues of access in primary care and the NZWCS would encourage PHARMAC to consider subsidising, but not limiting, access to wound management products in this setting.

- f. What categories of medical devices should PHARMAC be responsible for managing the prioritisation and procurement of? What categories of devices do not lend themselves to being managed by PHARMAC? Please provide reasoning.

The NZWCS does not believe that wound management products lend themselves to prioritisation and procurement by PHARMAC. This is for several reasons; we do not believe PHARMAC has the requisite expertise to be able to undertake assessment and prioritisation of wound management products. There would need to be an expert advisory group established for this purpose if this proposal were to be progressed. Perhaps a bigger issue is the assessment of wound management products from an economic perspective. Firstly because the wound management product itself equates to only a portion of the whole wound care cost, as noted earlier. If the wound is not expected to heal due to patient factors, then this is an additional complicating factor. Second, the evidence available for many commonly used wound care products is not in the same league as the vast randomised controlled trials conducted for medicines. Although research does demonstrate effectiveness of products in clinical practice and improved clinical outcomes, this limited evidence may prove inadequate for PHARMAC's current assessment processes.

In relation to procurement, there are already good processes in place in all DHBs. Most DHBs being part of larger buying groups enabling them to achieve better pricing and rebate schedules, for example the Lower North Island Buying Group and Otago and Southland DHBs. Their range of available products has been evaluated by experts in the field of wound management and is based on available evidence, cost and appropriateness to meet local population need.

- g. PHARMAC's decision-making criteria and processes have been designed to guide decision-making with respect to medicines and may not be suitable for managing the prioritisation and procurement of medical devices. What specific additional criteria need to be considered in making decisions about medical devices? Are there any criteria PHARMAC currently use that would not be relevant to medical devices?

The NZWCS considers the current Decision Criteria to be more focused on medicines and revised criteria may need to be developed should medical devices be included. We note with interest that PHARMAC may, at its own discretion, ignore these criteria or add others, which is of concern given PHARMAC's role of providing a consistent approach to assessment and prioritisation.

- h. Would an Exceptional Circumstances Scheme be required for medical devices? How might it operate? Would it need to be separate from a hospital scheme for medicines?

As noted above if this proposal were to be enacted the EC process would need to be available to nurses and podiatrists as they are the key health professions making decisions about wound management products. An EC Scheme would potentially be necessary for those patients deemed to require high cost treatment, which would likely include many people with chronic wounds who require long term treatment, including venous leg ulcers, diabetic foot ulcers and epidermolysis bullosa, as well as large acute wounds such as major burns. It is also possible that there may be restricted access to high cost products, such as growth factors and dermal substitutes that would require funding under an EC Scheme. Such a scheme would need to be separate from a medicines scheme and would require appropriate experts on any decision making body.

In addition to the above comments, the NZWCS would welcome improved management of medical devices in New Zealand, as the current WAND database is reliant on voluntary notification by manufacturers/importers, and there are limited mechanisms for control of medical device marketing and sales, and reporting of adverse events related to medical devices is minimal. As suggested in the MRG report, Medsafe's activities could be extended to cover the regulation and safety of medical devices.

We would also like to encourage PHARMAC to consider funding special dietary supplements to aid wound healing, which can result in faster healing and therefore reduced costs related to wound treatment.

Representatives of the NZWCS would be very happy to meet with Dr Sage and Ministry of Health staff to discuss our concerns further and provide expert advice on this proposal.

On behalf of the New Zealand Wound Care Society.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Wayne Naylor', written in a cursive style.

Wayne Naylor
President
The New Zealand Wound Care Society Inc.

Correspondence can be sent to:
NZWCS
C/o 23 Dimock Street
Titahi Bay
Porirua 5022

E-mail: wayne_cheryl@xtra.co.nz
Phone: 021 201 1249