



26 October 2007

Mr Richard Waddel
Chairman
PHARMAC Board
PO Box 10-254
Wellington

Dear Mr Waddel

Submission on the PHARMAC 2007/08 Tender Consultation (Suppliers Version)

Thank you for the opportunity to comment on the Alternative Brand Access proposal in the 2007/08 Draft Invitation to Tender.

General Comments

The RMI is pleased that PHARMAC now acknowledges that there are serious problems emanating from Sole Subsidised Supply contracts. In the case of pharmaceuticals, "one size does not fit all".

The RMI does not support Sole Subsidised Supply and it must be stressed that this submission on the Alternative Brand Access proposal does not in any way imply RMI support for Sole Subsidised Supply.

The RMI does see a role for procurement through tendering provided the molecule is off-patent and there is more than one supplier contracted as a result of the tendering process.

The RMI is concerned about the feasibility of the Alternative Brand Access proposal and is disappointed that PHARMAC did not seek input from stakeholders such as the RMI when developing the proposal.

Specific Concerns of the RMI

1. PHARMAC appears to have only considered the ramifications of the proposal from the perspective of the sole supplier and not from the alternative supplier, prescriber or patient. The proposed criteria, which require that a patient can only seek access to the alternative brand once defined clinical criteria are met, will be impractical for many affected patients. Many of these patients may receive sub-optimal treatment during the qualifying period.

2. It is proposed that PTAC and/or a relevant sub-committee will identify where there is a need for inclusion of an Authorised Allowance in a Sole Subsidised Supply contract. The criteria for deciding whether an Authorised Allowance is included are not provided. It is important that there is transparency around decision making to include an Authorised Allowance, and the size of that allowance.
3. PHARMAC is proposing that “an allowance in the region of 0.2% -1% may be appropriate” but the basis for this range is not specified. A number of questions therefore arise:
 - Was this simply an arbitrary figure chosen to ensure the sole subsidised supply agreements remain attractive to the supplier?
 - Was it based on CARM data? If it was, then this is of concern because CARM data is based on a voluntary reporting system which captures very few brand-switch related events (it is estimated that less than 5% of adverse events are reported to CARM).
 - What happens if demand for Alternative Brand Access exceeds the authorised allowance? Will it be a case of first in first served? If so, where is the equity of access?
4. From the perspective of an Alternative Brand Supplier, the restriction to, at best, 1% of a market is not a commercially viable proposition. Of the 400+ line items in the 2007/08 tender, only around 10% have annual sales exceeding \$500,000. Therefore, at 1% of the market, only 10% of the alternative brands could return more than \$5,000 annually. Conversely, 90% of items would return less than \$5,000 annually.

There are significant costs associated with having a pharmaceutical available in the market. For example, regulatory fees to maintain an up-to-date dossier (changes in manufacturing, etc) can be in the order of \$3,200 for one change. These costs alone could far exceed the product's annual sales under the proposal. Additional costs are incurred where suppliers must purchase a minimum amount with subsequent wastage through expiry of stock.

5. No information has been provided about how pricing will be agreed between PHARMAC and the Alternative Brand Supplier. Would PHARMAC be prepared to pay the real cost of supplying the market? The RMI is also concerned about the additional cost to PHARMAC of administering the proposal, particularly the impact on the pharmaceutical budget and how this will affect PHARMAC's ability to fund new investments.

PHARMAC also proposes that funding could be provided even if the product had to be sourced from overseas (i.e. the local supplier had discontinued supply). This raises a range of issues:

- Firstly, the potential for parallel importing. Parallel importing is illegal – for good reason. Parallel imported and section 29 medicines are usually imported without the Certificates of Analysis from the supplier presenting a potential problem in the event of a recall in the market of origin

- Product being supplied under Section 29 which has labelling or accompanying product information with different dosages and/or contraindications, indications etc compared to what is approved in New Zealand potentially risks patient safety.
 - If the source of the imported product is not the manufacturer/ sponsor there is the potential for counterfeit product to be supplied putting patient safety at risk.
6. PHARMAC already has the tools to address the problem and provide a more practical and effective solution.

The RMI notes that the funding of alternative molecules in many therapeutic sub-groups in the Pharmaceutical Schedule is severely limited (despite these products having consent to market). The funding of a wider range of alternative molecules from within not only the same but different classes would overcome the need for Alternative Brand Access and would provide New Zealanders access to medicines that is comparable to citizens in other OECD countries.

Conclusion

You will note from the comments above that the RMI has serious misgivings over the practicability of the Alternative Brand Access proposal from a commercial perspective. We are most concerned with the serious difficulties emanating from the existing sole subsidised supply contracts and agree that change is necessary and urgent. This PHARMAC Alternative Brand Access proposal fails to provide a workable solution to these problems.

The RMI would be pleased to meet with PHARMAC to discuss these matters further.

Yours sincerely

A handwritten signature in black ink, appearing to read "Ken Shirley". The signature is written in a cursive, flowing style.

Ken Shirley
Chief Executive Officer