

14 September 2007

Consultation on potential changes to Sole Subsidised Supply to include access to funding for alternative brands

The consultation for this year's tender is released today. In this document we are highlighting one particular proposal (the full consultation including proposed product list and tender contract are available from our website www.pharmac.govt.nz).

Tendering for off-patent medicines has been a successful strategy that has served us well over the years. But while sole supply has overall benefits at a population level, at an individual patient level it can have drawbacks for small numbers of people that experience clinical difficulties in changing brands. The current system for providing access through Community Exceptional Circumstances may not be dealing with these situations in an optimal way.

In considering whether to make any change at all, consideration to the costs and benefits of the change need to be weighed up carefully. An ideal system would be able to retain the health outcomes from tendered pharmaceuticals, without impacting on the funds released through the tendering (which are then available for re-investment).

With that principle in mind we have drafted a proposal on possible changes to Sole Subsidised Supply to include access to funding for alternative brands in certain circumstances.

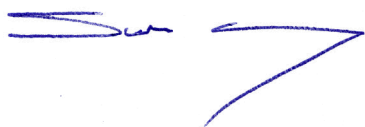
As well as welcoming comments on the general proposal and what the costs and benefits of it might be, we seek particular consideration of the following questions:

- Should we allow the provision of a subsidy for alternative brands and, if so, in what circumstances?
- What percentage allowance for alternative brands should be included within tender bids?

Further details on proposal are included in the attachment to this letter.

If you wish to make comments for the PHARMAC Board to consider when making its decision about the proposed tender changes, please forward them to PHARMAC, care of Mike Bignall (mike.bignall@pharmac.govt.nz or by fax or post) by **5pm 26 October 2007**. All comments submitted by this date will be considered.

Yours sincerely



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Consultation on potential changes to Sole Subsidised Supply - allowance for alternative brands to be funded in certain circumstances

At this time each year PHARMAC consults on its proposed product list and contract for its annual multi-product tender. The consultation for this year's tender is released today.

This year we are also consulting on adding an allowance within the contract for PHARMAC to provide funding for alternative brands of community pharmaceuticals (called Alternative Brand Access). This is a change from previous years' tenders, and if adopted would create a new mechanism for people to access brands of a medicine other than the one that wins the tender contract.

If the contractual allowance is adopted it would necessarily result in some changes to the manner in which Sole Subsidised Supply operates. There may also be changes to the contractual outcomes of requests for proposals (RFPs) involving Sole Subsidised Supply. A number of RFPs are currently out with suppliers.

Background

Between 1997 and 2007 over \$300 million that would otherwise have been unavailable has been reinvested in new pharmaceuticals and other health services as a result of sole-supply tenders.

Tenders and RFPs encourage competition so that the value from pharmaceuticals is maximised (including the costs of continuous supply being underwritten).

Sole Subsidised Supply for a defined period of time is often used to generate this competition. Once Sole Subsidised Supply is awarded all other brands of that pharmaceutical are delisted from the Pharmaceutical Schedule, and are no longer subsidised.

It may be desirable, where identified as a need by PTAC (and/or relevant subcommittee), to have greater flexibility under the sole supply policy for people to access other brands when the tender-winning brand is clinically unsuitable. Alternative Brand Access recognises that while most generic products will have established "bioequivalence" to the current market leader, in some circumstances a small number of patients may experience difficulties with the change.

Currently the mechanism available for funding of alternative brands, where one brand holds Sole Subsidised Supply, is through the Community Exceptional Circumstances (CEC) process. Given its specific criteria and purpose, the CEC process typically provides funding for alternative brands very infrequently.

Possible mechanism for implementation

To enable the proposed tender contractual changes to be developed, PHARMAC has considered possible mechanisms to apply an Alternative Brand Access. We are proposing the following mechanism:

- The product list (Schedule 2) would contain an Authorised Allowance which would be the amount of an Alternative Brand that could be subsidised without reimbursement to the tender winner for the reduced volume.
- An allowance in the region of 0.2 - 1% may be appropriate (where applied), although we welcome other views.
 - PHARMAC would seek advice from PTAC and/or its relevant subcommittee on whether to include an allowance in each case.
- The access to funding for the alternative brand would be through a Special Authority, on an “access by application” basis.
- Applications would be considered by a panel, using the following criteria, or similar:

Evidence is provided by the patient’s doctor that:

- a. The patient was adequately managed on a previously subsidised brand, and the subsidy for that brand is being removed as a result of Sole Subsidised Supply; and
- b. There are no other suitable alternative pharmaceuticals, or all the alternatives (including dose adjustment) have had an adequate trial and failed; and
- c. The Sole Subsidised Supply brand is considered to be unsuitable because of:
 - i. A serious adverse reaction has occurred to the Sole Subsidised Supply brand ;
or
 - ii. An excipient in the Sole Subsidised Supply brand that is contraindicated in the patient; or
 - iii. Lack of efficacy or intolerable side effects to the Sole Subsidised Supply brand demonstrated on challenge and re-challenge.

Approvals would not be given for issues related to features of the product that were considered as part of the tender evaluation (e.g. physical features of the product such as flavour, coatings etc.), and would not be given if the issue arose more than 6 months after the initiation of the Sole Subsidised Supply period.

- The funding for an alternative brand would be provided on a “Cost Brand Source” basis, meaning that funding could be provided even if the product had to be sourced from overseas (i.e. if the local supplier had discontinued supply).