

29 July 2004

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF NICOTINE REPLACEMENT THERAPY (NRT) PATCHES AND/OR GUM

PHARMAC invites proposals for the supply of Nicotine Replacement Therapy (NRT) transdermal patches and/or gum in New Zealand.

This request for proposals (**RFP**) letter incorporates the following schedules:

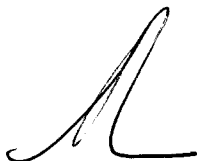
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceutical; and
- Schedule 4 contains the RFP form in which you are to provide details of your proposal.

If you wish to submit a proposal, you must submit it to PHARMAC no later than **12.00 midday on Friday 27 August 2004**.

If you have any questions about this RFP, please contact Hew Norris on (04) 916 7515 or Andrew Davies on (04) 916 7531.

We look forward to receiving your proposal.

Yours sincerely



Wayne McNee
Chief Executive

Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of:

- NRT transdermal patches; and/or
- NRT gum.

2. Background to RFP

The background to this RFP is as follows:

- The Ministry of Health has allocated \$2.5 million (excluding GST) per annum to continue to fund NRT patches and gum product as part of the national campaign for smoking cessation.
- The current contractual arrangements for sole subsidised supply of NRT patches and gum are due to expire on 31 December 2004.
- PHARMAC is looking to award sole subsidised supply for NRT patches and/or gum for the period from 1 January 2005 to 31 December 2007.
- If sole supply is awarded to brand(s) of NRT patches and/or gum other than the current sole supply brand (Nicotrol) PHARMAC would expect there to be a transition period from 1 January 2005 to 31 March 2005. During the transition period, both Nicotrol and the new brand(s) of NRT patches and/or gum would be subsidised.

3. Types of proposals sought

- PHARMAC seeks proposals from either current or potential suppliers for the sole subsidised supply of NRT patches and/or gum in the following strengths and presentations, for the period from 1 January 2005 to 31 December 2007 (subject to the above transition period):

Chemical and Presentation	Dose Level	Strength / hours coverage
NRT Patches	Low	5mg / 16 hours
		7mg / 24 hours
	Medium	10mg / 16 hours
		14mg / 24 hours
	High	15mg / 16 hours
		21mg / 24 hours
NRT Gum	Low – Medium	2mg
	Medium – High	4mg

- If, however, a supplier wishes to submit a proposal for a strength or release duration not listed in the table above, please provide evidence of comparative effectiveness in the low, medium and high dose range for NRT patches and low-medium and medium-high dose range for NRT gum.
- PHARMAC will fully subsidise (except for a patient co-payment) a maximum of one brand of each of the low, medium and high dose NRT patches and of each of the low-medium and medium-high dose NRT gums.
- The NRT patches and gum are to be listed on the Pharmaceutical Schedule with a restriction, that they will only be subsidised on presentation of a Quitline Exchange card, as follows:

Nicotine patches and gum are only available/subsidised on presentation of a Quitline Exchange Card.

- Proposals will be subject to the maintenance of the current co-payment and claiming arrangements.
- We note that this process of subsidisation may be extended to include other Ministry of Health and District Health Board initiated programs (such as the existing hospital and the Au Kati Kaupapa programs).
- PHARMAC is willing to consider proposals that include conditions. For example, suppliers may wish to offer price discounts if PHARMAC accepts their bids for all the dose levels of their product.
- Proposals must be limited to the supply of:
 - (a) NRT patches in low, medium and/or high dose; and
 - (b) NRT gum in low-medium and/or medium-high dose,

and may not include any other pharmaceuticals or related products or programmes.

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

Schedule 2: RFP process

The following is indicative of the process that PHARMAC expects to follow in relation to the RFP. PHARMAC expects to follow the process in the sequence set out below.

1. Submission

- (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.
- (b) Proposals must be in the form set out in Schedule 4.
- (c) Proposals must be submitted no later than **12.00 midday (New Zealand time) on Friday 27 August 2004**. Late proposals will only be considered at PHARMAC's discretion.
- (d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (e) All proposals must be submitted to PHARMAC at:

Level 14 Cigna House
40 Mercer Street
PO Box 10 254
Wellington 6001,

to the attention of Hew Norris, Therapeutic Group Manager, either by hand delivery, by courier or by post (and not by facsimile or email).

2. Evaluation

- (a) Following the deadline for submitting proposals PHARMAC will evaluate each proposal to select its preferred proposal(s). PHARMAC will seek any regulatory, legal, medical or other advice as it considers appropriate in assessing the proposals. PHARMAC may request any further information from a supplier in relation to their proposal. Any such request does not indicate acceptance of that proposal.
- (b) The matters to be taken into account by PHARMAC will include:
 - (i) the decision criteria set out in PHARMAC's then current Operating Policies and Procedures (**OPPs**), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable;
 - (ii) any clinical advice from the Ministry of Health, PTAC or its relevant sub-committee; and
 - (iii) any other matters that PHARMAC considers to be relevant,

provided that the basis on which PHARMAC will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are ultimately at the discretion of PHARMAC.

- (c) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.
- (d) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **Negotiation**

- (a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of one supplier's proposal would exclude acceptance of the other proposal(s).
- (b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, including relevant sole supply terms, which are available on request from PHARMAC, will apply.
- (c) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiation with you on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on the price.
- (d) PHARMAC may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.
- (e) If PHARMAC and the supplier(s) are unable to reach a provisional agreement within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

4. **Consultation and approval**

- (a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, and on Board approval (or approval by PHARMAC's Chief Executive under delegated authority).
- (b) PHARMAC will not consider any counter-offers received during consultation.
- (c) The provisional agreement and responses to consultation will be considered by PHARMAC's Board (or by PHARMAC's Chief Executive under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.
- (d) If the Board or the Chief Executive does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement with any other supplier(s).
- (e) The RFP process will be complete once PHARMAC has notified suppliers of either:
 - (i) the Board's or its Chief Executive's decision to accept a negotiated agreement; or

- (ii) the termination of the RFP process.

5. Miscellaneous

- (a) PHARMAC reserves the right:
 - (i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;
 - (ii) not to accept any proposal for some or all strengths of each product;
 - (iii) not to provide reasons for the acceptance or non-acceptance of any proposal;
 - (iv) to enter into an agreement or arrangement that differs in a material respect from that envisaged in this RFP letter;
 - (v) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit;
 - (vi) to readvertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.
- (c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or Chief Executive.
- (d) You must not at any time initiate any communication with:
 - (i) PHARMAC's directors or officers;
 - (ii) the Ministry of Health, the Minister of Health or District Health Boards;
 - (iii) any person or organisation contracted to provide services to the parties specified in sub-clauses (i) and (ii) above under a smoking cessation programme (such as Quitline),

with a view to influencing the outcome of this RFP process. For the avoidance of doubt, your failure to comply with this restriction on communication will entitle PHARMAC, in its absolute discretion, to disqualify you from this RFP process.

- (e) PHARMAC is not liable for any direct or indirect costs incurred in submitting a proposal.
- (f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

- (g) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated. Further, PHARMAC is no way contractually bound to follow the process outlined in this RFP, which is simply indicative.

6. Anticipated timetable

- (a) Following receipt of proposals, PHARMAC anticipates:
 - (i) evaluating proposals in September 2004;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in September 2004;
 - (iii) consulting on a provisional agreement by 1 October 2004;
 - (iv) PHARMAC's Board or Chief Executive considering the provisional agreement in October 2004.
- (b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 January 2005.

Schedule 3: Current listing and market information

The estimated approximate annual volume for the smoking cessation programme is likely to be around 90,000 four-week courses of treatment with NRT patches or gum. This figure is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this figure or as to the level of sales or likely sales of NRT patches and gum for the smoking cessation programme. PHARMAC accepts no liability in respect of this figure and is not obliged to notify you in the event of any change to it.

Schedule 4: Proposal form

An electronic version of this form is available from PHARMAC's website at <www.pharmac.govt.nz>. You should expand the boxes as necessary.

[Supplier to insert date]

Chief Executive
C/- Hew Norris
PHARMAC
PO Box 10-254
(or for courier delivery:
Level 14 Cigna House
40 Mercer Street)
Wellington
New Zealand

Dear Sir

Proposal for the supply of [insert pharmaceutical]

In response to your request for proposals (**RFP**) dated 28 July 2004, we put forward the following proposal in respect of [insert pharmaceutical].

Set out below is further information in support of our proposal.

- (a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

- (b) Details of pharmaceutical presentation (please include a sample of pharmaceutical presentation and packaging with the proposal):

Chemical/product name	
Strength (e.g. 5mg)	
Form (e.g. patch or gum)	
Brand name	
Pack size (e.g. 30's)	
Packaging type	

(c) Key features of our proposal:

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(d) Information relating to pricing (ex-manufacturer, \$NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC:

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(e) Evidence of market approval and any other required consents (please note that, given the timing of the sole supply period, preference is likely to be given to products that already have market approval):

Date of market approval (please attach copy of Medsafe Gazette notice)	
[OR Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)]	
[OR Expected date of dossier submission to Medsafe]	
[Evidence of any other approval required or otherwise obtained in relation to the supply of the pharmaceutical]	
[If not registered, please indicate the countries in which your product is registered and supplied]	

(f) Information about our ability to ensure the reliability and continuity of supply of the pharmaceutical over the sole supply period, including to those providers specified by the Ministry of Health to be members of the Au Kati Kaupapa Program nationwide (either directly or through an agent):

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(g) Information about our previous supply performance and relevant expertise:

[Empty rectangular box]

(h) Proposals/suggestions regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

[Empty rectangular box]

(i) Reasons why PHARMAC should accept our proposal:

[Empty rectangular box]

(j) Additional information that PHARMAC should consider when evaluating our proposal:

[Empty rectangular box]