PHARMAC
Pharmaceutical Management Agency

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16 October 2013

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF NICOTINE REPLACEMENT THERAPY

PHARMAC invites proposals for the supply of **nicotine replacement therapy (including, but not limited to, nicotine gum, lozenges and patches)** in New Zealand.

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

- Schedule 1 specifies the pharmaceutical(s) 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(s); 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 **5.00 pm on 7 November 2013.**

If you have any questions about this RFP, please contact Geraldine MacGibbon at PHARMAC on (04) 916 7514 or geraldine.macgibbon@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt
Director of Operations

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

1. **Pharmaceutical**

PHARMAC is interested in considering any proposal from suppliers of nicotine (nicotine replacement therapy), in the form of:

- The nicotine formulations currently funded in the community: nicotine gum, nicotine lozenges and nicotine patches; and/or

- The additional nicotine formulation listed on the Hospital Medicines List (HML): nicotine solution for inhalation.

2. **Background to RFP**

The background to this RFP is as follows:

- Nicotine gum, lozenges and patches are currently listed, fully funded on prescription or Quitline exchange cards, in Section B of the Pharmaceutical Schedule. They are also listed on the HML and are also provided, fully funded, directly to certain 'Authorised Providers' (explained in more detail below and on the following page).

- The current prices and subsidies (as applicable) for these nicotine presentations are as follows:

Formulation and presentation	Pack size	Price and subsidy
Gum 2 mg (Classic, Fruit and Mint)	384	$36.47
Gum 4 mg (Classic, Fruit and Mint)	384	$42.04
Lozenge 1 mg	216	$19.94
Lozenge 2 mg	216	$24.27
Patch 7 mg	28	$18.13
Patch 14 mg	28	$18.81
Patch 21 mg	28	$19.14

- Nicotine gum, lozenges and patches are currently supplied under the brand name Habitrol and are subject to a sole supply agreement with Novartis Consumer Health Australasia Pty Ltd. Sole supply ends on 1 July 2014.

- Nicotine gum, lozenges and patches are also provided, fully funded by PHARMAC, directly to Authorised Providers. Authorised Providers are the New Zealand Prison Services and any health service provider authorised by PHARMAC to supply subsidised nicotine replacement therapy to a person as part of a smoking cessation initiative co-ordinated by the Ministry of Health, District Health Boards. Orders are managed via PHARMAC Online (www.pharmaconline.co.nz) and distribution is arranged by the supplier. Orders are distributed quarterly and can be placed at any time during the quarter up until the order deadline for each quarter. The distribution costs are met by the supplier, and delivery of the entire order to the Authorised

Provider is expected to occur within 4 weeks of the quarterly order deadline. The supplier invoices PHARMAC directly for the pharmaceutical cost.

- There are currently 70 Authorised Providers, including 17 NZ Prison Services. It is anticipated that at least a further 13 health service providers will become Authorised Providers in the coming year. In the 12 months to 30 June 2013 there were, on average, 27 individual orders per quarter delivered to Authorised Providers.

- Nicotine solution for inhalation 15 mg cartridge is currently listed on the HML subject to the restrictions outlined below. The brand currently used by DHB hospitals is Nicorette Inhalator (supplied by Johnson & Johnson); however, this is not subject to a listing agreement with PHARMAC and there is no set price for this brand on the HML. This presentation is not listed in Section B of the Pharmaceutical Schedule.

  Nicotine soln for inhalation 15 mg cartridge
  Restricted
  Any of the following:
  1 For perioperative use in patients who have a 'nil by mouth' instruction; or
  2 For use within mental health inpatient units; or
  3 For acute use in agitated patients who are unable to leave the hospital facilities.

- PHARMAC now seeks proposals for community supply (including to Authorised Providers) and hospital supply of nicotine gum, lozenges and patches, as well as hospital supply of nicotine solution for inhalation, from 1 July 2014.

3. Types of proposals sought

(a) Proposals for the supply of different nicotine formulations (eg gum, patch, lozenge, inhaler etc) **must be capable of being accepted independently and may not be bundled**. In other words, individual proposals must not contain more than one nicotine formulation and must not be tied or linked to any other proposal.

- Proposals may bundle different strengths, flavours and/or pack sizes within each formulation; however, PHARMAC reserves the right to negotiate with preferred suppliers around the range of strengths, flavours and/or pack sizes for each formulation that is ultimately progressed for funding.

- Proposals for the currently funded formulations in the community (lozenges, gum, patches) must include, at a minimum, the same or a similar range of strengths as the currently funded strengths for each formulation.

- For the purposes of this RFP, including consideration of sole supply proposals, sublingual tablets may be considered interchangeable with lozenges (ie sublingual tablets and lozenges are considered to constitute a single nicotine formulation).

(b) PHARMAC is willing to consider the following types of proposals:

- proposals that include a period of subsidy protection and/or protection from delisting; and/or

- proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms. Note that PHARMAC expects that the existence of any risk sharing mechanism would not be confidential and it would prefer that the net effect of such a mechanism (eg the net price) was able to be included in

any public consultation document(s) issued by PHARMAC. Note that preference may be given to proposals with transparent net pricing, even if the net price was higher than a competing proposal with confidential net pricing; and/or

- proposals that include a period of sole subsidised supply and hospital supply status (hereafter referred to as "**sole supply**"), which is not to extend beyond 30 June 2017. Note that if a proposal for sole supply of a nicotine formulation is accepted and the successful supplier's brand of that nicotine formulation is not currently listed in the Pharmaceutical Schedule, there would be a transition period (with the length to be determined at PHARMAC's discretion) where the successful supplier's brand would be available for sale or supply and subsidised or purchased but would not be the sole subsidised brand of that nicotine formulation, or brand of that nicotine formulation with hospital supply status; and/or

- proposals with a flexible start date to allow for any stock availability issues to be resolved; and/or

- proposals that are subject to registration approval by Medsafe.

(c) PHARMAC is not willing to consider the following types of proposals:

- proposals that include pharmaceuticals other than nicotine; or

- proposals that contain more than one formulation of nicotine (but note that a supplier can submit multiple separate proposals); or

- two-part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

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

(e) Suppliers should provide PHARMAC with a sample pack of the various strengths and/or flavours of nicotine formulations included in the proposal (and, if supply is intended to be in a different form from that sample pack, information about the form in which they will be supplied) within 10 business days from the close of the RFP.

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. **Submission**

   (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

   (b) Proposals must be submitted no later than **5.00 p.m. (New Zealand time) on Thursday 7 November 2013**. Late proposals will only be considered at PHARMAC's discretion.

   (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

   (d) All proposals must be submitted to PHARMAC to the attention of **Geraldine MacGibbon** by email at geraldine.macgibbon@pharmac.govt.nz.

2. **Evaluation**

   (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).

   (b) The basis on which the Evaluation Committee will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are to be determined by the Evaluation Committee at its sole discretion. The matters to be taken into account by the Evaluation Committee will, however, 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 PTAC or its relevant Subcommittee or any other relevant clinical expert sought by PHARMAC;

      (iii) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

   (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. **PHARMAC may request further information**

   (a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, in which case you must supply that information within 10 business days of PHARMAC requesting it.

(b) If PHARMAC requests further information from or about you it is not obliged to request the same or any other information from or about any other party.

4. **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 either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, 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 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).

5. **Consultation and approval**

(a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting 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 its delegate) in accordance with the decision criteria in PHARMAC's then current OPPs.

(d) If the Board or its delegate 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 delegate's decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

6. **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;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) 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; and

(viii) to readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant Subcommittee or any other relevant clinical expert 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 its delegate.

(d) You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, the Minister of Health or District Health Boards, with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your 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) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of nicotine by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

(j) PHARMAC will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) in the course of consultation on a provisional agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that agreement; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in **November 2013**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **November or December 2013**;

(iii) consulting on a provisional agreement in or after **December 2013**;

(iv) PHARMAC's Board or its delegate considering a provisional agreement in or after **January or February 2014**,

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is **1 July 2014**.

Schedule 3: Market information

The following information relates to the estimated subsidised market size of nicotine replacement therapy, including nicotine provided directly to Authorised Providers (see next page). The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of nicotine replacement therapy and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

The approximate number of subsidised units (pieces of gum and individual lozenges and patches) for nicotine in the community for the years ending 30 June 2011, 30 June 2012 and 30 June 2013 is shown below:

Pharmaceutical/form/strength	YE 30 June 2011	YE 30 June 2012	YE 30 June 2013
Nicotine gum 2 mg	13,100,000	14,000,000	13,600,000
Nicotine gum 4 mg	7,600,000	7,600,000	8,100,000
Nicotine lozenge 1 mg	6,100,000	7,100,000	6,500,000
Nicotine lozenge 2 mg	5,800,000	6,700,000	6,700,000
Nicotine patch 7 mg	290,000	350,000	300,000
Nicotine patch 14 mg	940,000	1,100,000	940,000
Nicotine patch 21 mg	2,600,000	2,500,000	2,100,000

The approximate number of units (pieces of gum and individual lozenges and patches) of nicotine purchased by DHB hospitals for the years ending 30 June 2011, 30 June 2012 and 30 June 2013 is shown below:

Pharmaceutical/form/strength	YE 30 June 2011	YE 30 June 2012	YE 30 June 2013
Nicotine gum 2 mg	130,000	200,000	220,000
Nicotine gum 4 mg	130,000	200,000	170,000
Nicotine lozenge 1 mg	60,000	80,000	100,000
Nicotine lozenge 2 mg	140,000	160,000	180,000
Nicotine patch 7 mg	12,000	12,000	9,000
Nicotine patch 14 mg	48,000	37,000	34,000
Nicotine patch 21 mg	92,000	95,000	97,000

The approximate number of units (pieces of gum and individual lozenges and patches) of nicotine supplied to Authorised Providers for the year ending 30 June 2013 is shown below:

Pharmaceutical/form/strength	YE 30 June 2013
Nicotine gum 2 mg	4,400
Nicotine gum 4 mg	3,400
Nicotine lozenge 1 mg	16,500
Nicotine lozenge 2 mg	10,300
Nicotine patch 7 mg	8,300
Nicotine patch 14 mg	15,800
Nicotine patch 21 mg	16,400

Schedule 4: Proposal form

An electronic version of this form is available on request from catherine.kingsbury@pharmac.govt.nz. You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
C/- Geraldine MacGibbon
PHARMAC
Level 9, 40 Mercer Street
PO Box 10-254
Wellington 6143
NEW ZEALAND

By email geraldine.macgibbon@pharmac.govt.nz

Dear Geraldine

Proposal for the supply of nicotine

In response to your request for proposals (**RFP**) dated 16 October 2013 we put forward the following proposal in respect of **nicotine**.

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:

Chemical name	
Strength (eg 2 mg)	
Form (eg gum)	
Brand name	
Pack size (eg 10's)	
Packaging type (eg blister)	

(c) Key features of our proposal:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

(e) Evidence of market approval and any other required consents:

Date of Medsafe market approval	
OR Date of submission of dossier	
OR Expected date of dossier submission to Medsafe	
Insert any other consents required for pharmaceutical	

(f) Information about our ability to ensure the continuity of supply of the pharmaceutical:

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

(h) Reasons why PHARMAC should accept our proposal:

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