

13 August 2009

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF DONEPEZIL HYDROCHLORIDE

PHARMAC invites proposals for the supply of **donepezil hydrochloride** tablets in New Zealand.

Please note that the funding of donepezil hydrochloride would only be progressed subject to an acceptable price being achieved and budget availability.

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 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 Friday 25 September 2009**. 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



Matthew Brougham
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 tablet or capsule preparations of **donepezil hydrochloride**. Suppliers may submit more than one proposal.

2. Background to RFP

Donepezil hydrochloride is an acetylcholinesterase inhibitor registered for use in the treatment of mild, moderate and severe Alzheimer's disease and the treatment of vascular dementia (dementia associated with cerebrovascular disease). Other acetylcholinesterase inhibitors include galantamine hydrobromide and rivastigmine tartrate. There are currently no funded acetylcholinesterase inhibitors in New Zealand.

In 2003 PHARMAC completed an economic analysis on acetylcholinesterase inhibitors, which indicated that these medicines were not good value for money compared with other pharmaceuticals that could be funded. These medicines were not, therefore, considered to be a high priority for investment compared to other pharmaceuticals awaiting funding and in 2004 PHARMAC's Board resolved not to fund acetylcholinesterase inhibitors.

In 2008 the Pharmacology and Therapeutics Advisory Committee (PTAC) provided updated advice around acetylcholinesterase inhibitors. A full copy of the relevant minutes from the February 2008 and July 2008 meetings at which these treatments were discussed can be found on PHARMAC's website at www.pharmac.govt.nz/PTACminutes

In summary, PTAC recommended listing acetylcholinesterase inhibitors in the Pharmaceutical Schedule with a low priority under the following Special Authority criteria:

SAXXX Special Authority for Subsidy

Initial application from any relevant practitioner. Applications valid for six months for applications meeting the following criteria:

All of:

- 1 Applicant works in a DHB specialist health service for older people;
- 2 Patient has mild-to-moderate Dementia of the Alzheimer's type or Lewy Body Dementia; and
- 3 Patient is living in the community (not in institutional care) and has adequate social support.

Renewal from any relevant practitioner. Applications valid for six months for applications meeting the following criteria:

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment (applicants are encouraged to consider stopping therapy where the patient has been institutionalised, as this could indicate disease progression to the extent that the treatment could no longer be considered effective).

The Committee considered that the acetylcholinesterase inhibitors were similar to the extent that it would be reasonable to choose to fund one over the others based on price.

We note that the cost effectiveness of acetylcholinesterase inhibitors is heavily dependent on price. Having become aware of significant competition in the donepezil hydrochloride market, the purpose of this RFP is to attempt to obtain the best possible pricing to determine (a) if the cost effectiveness of funding donepezil hydrochloride would be favourable compared to other funding proposals currently being considered by

PHARMAC and (b) if funding of donepezil hydrochloride would be possible from within the available budget.

Please note that if a proposal for donepezil hydrochloride was progressed as a result of this RFP, it would not preclude the listing of other acetylcholinesterase inhibitors in the future.

Note also that an application for another treatment for Alzheimer's disease, memantine, was recommended for decline by PTAC in February 2008 and is not currently actively under consideration for funding by PHARMAC.

3. Types of proposals sought

- (a) Suppliers wishing to submit proposals must submit proposals for community and hospital supply of donepezil hydrochloride tablets or capsules. Please note that a listing of donepezil hydrochloride in Section B of the Pharmaceutical Schedule would be subject to Special Authority restrictions substantially similar to those proposed by PTAC (set out on page 2 of this RFP).

PHARMAC is willing to consider the following types of proposals:

- proposals that include a period of subsidy protection and protection from delisting; and/or
- proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms; and/or
- proposals that include a period of sole subsidised supply and hospital supply status (hereinafter referred to as "**sole supply**") from the date of listing until 30 June 2012. For the avoidance of doubt, if proposals include a period of sole supply, the proposed sole supply must be sole subsidised supply and hospital supply status for all strengths of donepezil hydrochloride tablets included in the proposal; and/or
- proposals that are subject to registration approval by Medsafe.

Suppliers should provide PHARMAC with a sample pack of the various strengths of donepezil hydrochloride included in the proposal (and if you intend supplying these 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.

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

- proposals that contain presentations of donepezil hydrochloride other than tablets or capsules (including, but not limited to, oral solutions, patches and orodispersible formulations); or
- proposals that include pharmaceuticals other than donepezil hydrochloride; 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.

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 Friday 25 September 2009**. 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**, either by facsimile (+64 4 460 4995) or email (geraldine.macgibbon@pharmac.govt.nz). **Email is preferred.**

2. Evaluation

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff (including PHARMAC's Legal Counsel) 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;
 - (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 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.

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 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 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 donepezil hydrochloride 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 **October 2009**;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in **October or November 2009**;
 - (iii) consulting on a provisional agreement in or after **November 2009**;
 - (iv) PHARMAC's Board or Chief Executive considering a provisional agreement in or after **December 2009**,

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 **February 2010** (although, as noted on page 1 of this RFP, this RFP may be terminated, or implementation may be delayed, or any proposal to fund may be declined, if insufficient funding is available in the Pharmaceutical Budget).

Schedule 3: Market information

There are currently no funded acetylcholinesterase inhibitors. The following information relates to the estimated subsidised market size for donepezil hydrochloride if it was funded subject to the Special Authority restrictions proposed by PTAC. The information provided 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 donepezil hydrochloride 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 estimates that approximately 5,000–7,200 patients in year 1, 8,500–10,800 patients in year 2 and 12,000–14,300 patients in year 3 would be treated in the community if donepezil hydrochloride was funded under the Special Authority criteria proposed by PTAC.

The number of units (tablets) of donepezil hydrochloride purchased by DHB Hospitals for the past three years for which we have full data are shown below.

Pharmaceutical/form/ strength	1 April 2006 to 31 March 2007	1 April 2007 to 31 March 2008	1 April 2008 to 31 March 2009
Donepezil hydrochloride tab 5 mg	4,228	4,403	5,446
Donepezil hydrochloride tab 10 mg	7,504	7,476	6,272

Schedule 4: Proposal form

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

[Supplier to insert date]

Chief Executive
C/- Geraldine MacGibbon
PHARMAC
Level 9, Cigna House
40 Mercer Street, PO Box 10-254
Wellington 6143
NEW ZEALAND

By email geraldine.macgibbon@pharmac.govt.nz or facsimile (+64) 04 460 4995.

Dear Geraldine

Proposal for the supply of donepezil hydrochloride

In response to your request for proposals (**RFP**) dated 13 August 2009 we put forward the following proposal in respect of **donepezil hydrochloride**.

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	Donepezil hydrochloride
Strength (eg 10 mg)	
Form (eg tablet)	
Brand name	
Pack size (eg 100's)	
Packaging type (eg blister)	

(c) Key features of our proposal:

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(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.):

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(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	
<i>Insert any other consents required for pharmaceutical</i>	

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

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

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(h) Reasons why PHARMAC should accept our proposal:

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