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12 December 2008

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF GABAPENTIN**

PHARMAC invites proposals for the supply of **gabapentin** 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 **5.00 pm on Friday 13 February 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](mailto: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 **gabapentin**.

### 2. Background to RFP

The background to this RFP is as follows:

- Gabapentin 100 mg, 300 mg and 400 mg capsules and 600 mg tablets are currently listed fully subsidised in Section B and in Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies:

Pharmaceutical	Brand Name	Form	Strength	Pack size	Price and subsidy
Gabapentin	Nupentin	Capsule	100 mg	100	\$13.26
Gabapentin	Neurontin	Capsule	100 mg	100	\$15.67
Gabapentin	Nupentin	Capsule	300 mg	100	\$39.76
Gabapentin	Neurontin	Capsule	300 mg	100	\$47.00
Gabapentin	Nupentin	Capsule	400 mg	100	\$53.01
Gabapentin	Neurontin	Capsule	400 mg	100	\$62.66
Gabapentin	Neurontin	Tablet	600 mg	100	\$79.79

- Neurontin dispensed in the community is subject to a confidential rebate, which brings the effective cost of Neurontin to be in line with the price of Nupentin.
- Gabapentin is currently listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority restrictions:

#### **SA0873 Special Authority for Subsidy**

**Initial application - (Epilepsy - new patients)** from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Either:

- 1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents.

Note: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

**Initial application - (Epilepsy - patient has had an approval for gabapentin, lamotrigine, topiramate or vigabatrin for epilepsy prior to 1 August 2007)** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life from gabapentin, topiramate, vigabatrin and /or lamotrigine.

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

**Initial application - (Neuropathic pain - new patients)** from any relevant practitioner.

Approvals valid for 3 months where the patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant.

**Initial application - (Neuropathic pain - patient has had an approval for gabapentin for neuropathic pain prior to 1 August 2007)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either

- 1 Patient has demonstrated a marked improvement in their control of pain (prescriber determined); or
- 2 Patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

**Renewal - (Epilepsy)** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

If the patient had an approval for gabapentin, lamotrigine, topiramate or vigabatrin for epilepsy prior to 1 August 2007 the applicant is required to submit a fresh initial application in the first instance, not a renewal application.

**Renewal - (Neuropathic pain)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either

- 1 Patient has demonstrated a marked improvement in their control of pain (prescriber determined); or
- 2 Patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

Note: If the patient had an approval for gabapentin for neuropathic pain prior to 1 August 2007 the applicant is required to submit a fresh initial application in the first instance, not a renewal application.

- Neurontin has protection from subsidy reduction and delisting until 1 August 2009.

### 3. Types of proposals sought

- (a) Suppliers wishing to submit proposals must submit proposals for community and hospital supply of gabapentin 100 mg, 300 mg and 400 mg tablets or capsules. PHARMAC is willing to consider the following types of proposals:

- proposals that include additional strengths of gabapentin;
- proposals that include a period of subsidy protection and protection from delisting;
- proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms; and
- proposals that include a period of sole subsidised supply and hospital supply status (hereinafter referred to as "**sole supply**") of up to, but no more than, 3 years, provided that the start of the sole supply period does not occur before 1 August 2009 and does not extend beyond 31 July 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 any and all strengths of gabapentin included in the proposal.

Please note if a proposal for sole supply of gabapentin is accepted and the successful supplier's brand of gabapentin is not currently listed in Section B of the Pharmaceutical Schedule, there may be a minimum 6 months' transition period where the successful supplier's brand is to be available for sale or supply and subsidised or purchased but would not be the sole subsidised brand of gabapentin, or brand of gabapentin with hospital supply status.

- (b) PHARMAC is also willing to consider proposals for widening of access to gabapentin via removal of the Special Authority; however, all suppliers must provide at least one proposal for supply of gabapentin under the current restrictions. Please note that in order for PHARMAC to consider a proposal to remove the gabapentin Special Authority the pricing of gabapentin would need to be cost-neutral or better versus equivalent doses of alternative treatments for neuropathic pain (ie, the funded tricyclic antidepressants, in particular nortriptyline).
- (c) PHARMAC is not willing to consider the following types of proposals:
- proposals that do not include all of the 100 mg, 300 mg and 400 mg strengths;
  - proposals that include sole supply for some but not all strengths of gabapentin included in the proposal;
  - proposals that include pharmaceuticals other than gabapentin;
  - proposals requesting PHARMAC's support for priority assessment of Medsafe New Medicine Applications; 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 13 February 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](mailto: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](http://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, including (but not limited to) a sample pack of gabapentin (and if you intend supplying it in a different form from that sample pack, information about the form in which it will be supplied), 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;
  - (viii) 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 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 gabapentin 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 **February/March 2009**;
  - (ii) negotiating with submitter(s) of one or more preferred proposals in **March 2009**;
  - (iii) consulting on a provisional agreement in **March/April 2009**;
  - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after **April 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 **June 2009**.

### Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of gabapentin. 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 gabapentin 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.

The number of subsidised units (capsules or tablets) for gabapentin in the community for the years ending 30 June 2006, 30 June 2007 and 30 June 2008 is shown below (note that access to gabapentin was widened to include use in neuropathic pain in July 2005).

<b>Pharmaceutical/form/ strength</b>	<b>July 2005 to June 2006</b>	<b>July 2006 to June 2007</b>	<b>July 2007 to June 2008</b>
Gabapentin capsule 100 mg	454,115	800,197	1,011,721
Gabapentin capsule 300 mg	2,860,697	5,088,557	6,297,607
Gabapentin capsule 400 mg	333,116	600,005	728,036
Gabapentin tablet 600 mg	(not subsidised)	7,910 (subsidised from December 2006)	57,842

Currently, approximately 5%-7% of gabapentin use in the community is for epilepsy. The average daily dose of gabapentin (all indications) is approximately 1,300 mg.

The number of units (capsules or tablets) of gabapentin purchased by DHB Hospitals for the years ending 30 June 2006, 30 June 2007 and 30 June 2008 is shown below:

<b>Pharmaceutical/form/ strength</b>	<b>July 2005 to June 2006</b>	<b>July 2006 to June 2007</b>	<b>July 2007 to June 2008</b>
Gabapentin capsule 100 mg	25,189	42,028	48,211
Gabapentin capsule 300 mg	158,402	156,590	168,700
Gabapentin capsule 400 mg	17,176	15,702	20,776
Gabapentin tablet 600 mg	0	0	200

#### Schedule 4: Proposal form

***An electronic version of this form is available on PHARMAC's website, [www.pharmac.govt.nz](http://www.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](mailto:geraldine.macgibbon@pharmac.govt.nz) or facsimile (+64) 04 460 4995

Dear Geraldine

#### **Proposal for the supply of gabapentin**

In response to your request for proposals (**RFP**) dated 12 December 2008 we put forward the following proposal in respect of gabapentin.

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 100 mg)	
Form (eg capsule)	
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 market approval (please attach copy of Medsafe Gazette notice)	
<b>[OR</b> Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)]	
<b>[OR</b> Expected date of dossier submission to Medsafe]	
<b><i>Insert any other consents required for pharmaceutical</i></b>	

(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) Proposals/suggestions (e.g. pricing, risk sharing arrangements, etc) regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

- (i) Reasons why PHARMAC should accept our proposal:

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