PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
Information line **0800 66 00 50**
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

12 May 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ORAL GABAPENTIN AND/OR PREGABALIN

PHARMAC invites proposals for the supply of oral gabapentin and/or pregabalin 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 via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **5.00 p.m. on 6 July 2017.**

If you have any questions about this RFP, please post these on GETS or alternatively contact Chloë Dimock by email at procurement@pharmac.govt.nz at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

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 oral (capsules or tablets) gabapentin and/or pregabalin.

2. Background to RFP

The background to this RFP is as follows:

Gabapentin and pregabalin are anticonvulsant agents that have a structural resemblance to gamma-aminobutyric acid (GABA), an amino acid which acts to inhibit the transmission of nerve impulses in the central nervous system. Both are indicated for the same or similar therapeutic uses, such as the treatment of neuropathic pain and seizure control in some forms of epilepsy.

Funding history

Gabapentin was first listed on the Pharmaceutical Schedule in April 2001 with a Special Authority restricting funding to its use in epilepsy. In July 2005, the funding restrictions were widened to include gabapentin as a third line treatment of neuropathic pain (the requirement to try an anticonvulsant agent and tricyclic antidepressant were removed in November 2008 and October 2014 respectively). Gabapentin has also been funded for use in chronic kidney disease associated pruritus since October 2014. In Part II of Section H (Hospital Medicines List), gabapentin is available to be used preoperatively and/or postoperatively and for pain management of burns patients since July 2013.

Pregabalin is not listed on the Pharmaceutical Schedule – meaning it is not funded in the community nor able to be used in DHB hospitals.

Current funding

Currently there are three different brands of gabapentin listed on the Pharmaceutical Schedule and 3 different strengths (Cap 100 mg, 300 mg, and 400 mg). The table below outlines the current Pharmaceutical Schedule gabapentin listings and funding restrictions:

		Subsidy/ Price	Per	Fully Subsidised	Brand or Generic Manufacturer
GABAPENTIN	Special Authority see SA1477 below – Retail pharmacy				
Cap 100 mg	……	7.16	100	✓	**Arrow-Gabapentin**
				✓	**Neurontin**
					Nupentin
Cap 300 mg	……	11.00	100	✓	**Arrow-Gabapentin**
				✓	**Neurontin**
				✓	**Nupentin**
Cap 400 mg	……	13.75	100	✓	**Arrow-Gabapentin**
				✓	**Neurontin**
				✓	**Nupentin**

SA1477 Special Authority for Subsidy [Section B]

Initial application—(Epilepsy) 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 — (Neuropathic pain or Chronic Kidney Disease associated pruritus) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1. The patient has been diagnosed with neuropathic pain; or
2. Both:
   2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritus can be identified (e.g. scabies, allergy); and
   2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.

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.

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.

Renewal — (Neuropathic pain or Chronic Kidney Disease associated pruritus) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

Note: Indications marked with * are Unapproved Indications (see Interpretations and Definitions). Dosage adjustment of gabapentin is recommended for patients with renal impairment.

➥Restricted [part II of Section H]

Initiation — preoperative and/or postoperative use

Limited to 8 days treatment

Initiation — pain management of burns patients

Re-assessment required after 1 month

Continuation — pain management of burns patients

Re-assessment required after 1 month

The treatment remains appropriate and the patient is benefiting from treatment.

Initiation — epilepsy

Re-assessment required after 15 months

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.

Continuation — epilepsy

Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life**.**

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

Initiation — Neuropathic pain or Chronic Kidney Disease-associated pruritus

Re-assessment required after 3 months

Either:

1. The patient has been diagnosed with neuropathic pain; or
2. Both:
   2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritus can be identified (e.g. scabies, allergy); and
   2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.

Continuation — Neuropathic pain or Chronic Kidney Disease-associated pruritus

Either:

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

Note: Indications marked with * are Unapproved Indications. Dosage adjustment of gabapentin is recommended for patients with renal impairment.

Pharmacology and Therapeutics Advisory Committee (PTAC) and Subcommittee Advice

PHARMAC has frequently sought clinical advice on both gabapentin and pregabalin, and the current and future funding opportunities for these pharmaceuticals. Listed below is the most recent clinical advice received and web links to the relevant minutes.

- **11-12 August 2011** PTAC considered a funding application for pregabalin. The August 2011 PTAC minutes are on the PHARMAC website.

- **24 April 2012** Analgesic Subcommittee considered a proposal from PHARMAC staff following PTAC's review of a funding application from Pfizer for pregabalin (Lyrica) for the treatment of neuropathic pain. The April 2012 Analgesic Subcommittee minutes are on the PHARMAC website.

- **24 July 2012** The Neurological Subcommittee noted the minutes from PTAC and the Analgesic Subcommittee's review of an application to fund pregabalin for neuropathic pain and provided its own view. The July 2012 Neurological Subcommittee minutes are on the PHARMAC website.

- **20 September 2013** The Neurological Subcommittee reviewed literature relating to gabapentin use for chronic daily headache. The September 2013 Neurological Subcommittee minutes are on the PHARMAC website.

- **8-9 May 2014** PTAC recommended that gabapentin for uraemic pruritus be funded with a high priority. PTAC also recommended removing the Special Authority from gabapentin but noted that open listing was a financial risk. The May 2014 PTAC minutes are on the PHARMAC website.

- **27 August 2014** The Neurological Subcommittee advised PHARMAC on the benefits of pregabalin, compared with gabapentin, as a second-line agent for patients who have not received adequate therapeutic benefit from gabapentin and for patients who have received benefit from gabapentin but were unable to tolerate it at therapeutic doses due to adverse effects. The Subcommittee recommended that pregabalin only be listed for neuropathic pain, if cost-neutral to gabapentin, subject to the same restrictions. The August 2014 Neurological Subcommittee minutes are on the PHARMAC website.

- **11 November 2015** The Neurological Subcommittee provided clinical advice on Antiepileptic Drug Switching. The November 2015 Neurological Subcommittee minutes are on the PHARMAC website.

- **7 November 2016** The Neurological Subcommittee provided clinical advice on running a commercial process that could result in sole supply of both gabapentin and pregabalin PHARMAC website. The November 2016 Neurological Subcommittee minutes are on the PHARMAC website.

Reason for running the RFP

Under current restrictions gabapentin represents significant expenditure to the Combined Pharmaceutical Budget (CPB). Table One below details the approximate expenditure for the last three calendar years.

Table One: Approximate expenditure on funded gabapentin in the Community and gabapentin and pregabalin (gabapentinoids) in DHB Hospitals

	2014	2015	2016
Approximate expenditure on funded gabapentin in the Community market	$2,816,000	$3,315,000	$3,894,000
Approximate expenditure on Gabapentinoids in the DHB Hospital market*	$71,000	$83,000	$87,000
Total	$2,887,000	$3,398,000	$3,982,000
*Pregabalin is not currently listed on the Hospital Medicines List. However, data available indicates very small volumes of pregabalin are used in DHB hospitals (pregabalin use is less than 1% of all gabapentinoid capsules and tablets. Please note: PHARMAC has taken all reasonable care in preparing the information set out in the tablet above, 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 stated above.			

Since PHARMAC's April 2001 decision to fund gabapentin for its use in epilepsy, numerous applications have been received to widen funded access to gabapentin and to fund pregabalin. Advice from PTAC and its relevant Subcommittees' is that pregabalin should only be listed for neuropathic pain if cost-neutral to gabapentin (subject to the same restrictions); and there is potential for significant growth and therefore financial risk should restrictions for gabapentin [but similarly pregabalin] be removed.

PHARMAC is aware that there are a number of gabapentin and pregabalin products currently registered with Medsafe or available overseas. As a result of this significant competition, the purpose of this RFP is:

(a) to reduce the total expenditure of the gabapentinoid market;

(b) to determine if it is possible to achieve pregabalin pricing at a level referred to in PTAC's funding recommendation; i.e. cost-neutral to gabapentin, subject to the same restrictions;

(c) if funding gabapentin or gabapentin and/or pregabalin with widened funding access or without restrictions would be possible from within the available budget. Noting that:

  (i) PTAC has previously advised PHARMAC of the potential for high growth due to indication creep and that open listing gabapentin [at current pricing] was a financial risk.

  (ii) PHARMAC expects that a significant proportion of the existing pregabalin private market would switch to a funded treatment if PHARMAC were to fund pregabalin.

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

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) **AND/OR** pregabalin 25 mg, 75 mg, 150 mg and 300 mg tablets or capsules.

(b) **ALL** proposals must include pricing for the current funding restrictions applying to gabapentin (restricted listing) **AND** pricing for unrestricted funded access (open listing*****).

***Please note:** if both gabapentin and pregabalin are listed on the Pharmaceutical Schedule funding would be restricted to use of one chemical ie a patient could not receive funding for gabapentin AND pregabalin at the same time. This would also apply under an open listing scenario.

For the avoidance of doubt, the open listing of gabapentin and the open listing of pregabalin are not interdependent. Through this process PHARMAC may, depending on proposals received, decide to:

(i) list one of the chemicals with restrictions and the other with no restrictions; or

(ii) list both chemicals with restrictions; or

(iii) list both chemicals without restrictions; or

(iv) only list gabapentin (with or without restrictions).

(v) only progress a proposal for the listing and supply of pregabalin (with or without restrictions).

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

(i) proposals that include additional strengths of pregabalin;

(ii) proposals that include supply of both gabapentin and pregabalin, in the strengths stated in paragraph 3 (a) above, provided a supplier who submits a proposal for supply of both gabapentin and pregablin **MUST** also submit individual proposals for each chemical capable of being accepted on its own;

(iii) proposals that involve a period of sole subsidised supply in the community and hospital supply status with a discretionary variance (DV) limit of 1% in DHB hospitals (hereinafter referred to as “Sole Supply”) for a period of time, provided that the Sole Supply period does not extend beyond 30 June 2021;

Please note advice received is that a managed brand switch would require a transition period of 3 to 6 months.

(iv) proposals which include pharmaceuticals which have not yet gained all necessary **Consents**. Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate your ability to obtain those consents within a time frame acceptable to PHARMAC.

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

(i) proposals that do not include all strengths of gabapentin and/or pregabalin in paragraph 3 (a) above;

(ii) proposals that include Sole Supply for some but not all strengths of gabapentin and pregabalin included in the proposal;

(iii) proposals that include pharmaceuticals other than gabapentin and pregabalin;

(iv) proposals that involve listing gabapentin or pregabalin with a partial subsidy;

(v) proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms (including volume base tiered pricing); 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; and

(vi) parity pricing, whereby PHARMAC may reduce the subsidy payable for a pharmaceutical in a particular therapeutic sub-group to the level of the subsidy payable for a pharmaceutical in any other sub-group

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

(f) Suppliers should provide PHARMAC with samples of the gabapentin/pregabalin capsules and/or tablets included in the proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within 10 business days from the dated specified in Schedule 2, clause 1 (b).

4. **Patents**

(a) PHARMAC is aware that there are current patents in New Zealand which may be relevant to some pregabalin synthetic methods and formulations (potentially including, but not necessarily limited to, NZ519551, NZ549698, NZ552220, NZ711702, NZ507162, NZ508015, NZ567414 and NZ509980).

(b) PHARMAC makes no representation as to the patent status of pregabalin, or any particular synthetic methods or formulations of pregabalin, and it is the responsibility of the supplier to ensure its product does not infringe any third party intellectual property rights. PHARMAC accepts no liability for any patent infringement that might occur as a result of this RFP process or PHARMAC's acceptance of a proposal, including infringement of process patents.

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 to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **5.00 p.m. (New Zealand time) on 6 July 2017.** Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

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

   (d) If you have any enquiries about this RFP you should submit them on GETS or alternatively contact Chloë Dimock, Procurement Manager, by email at procurement@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 Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the Factors for Consideration (Factors) that form part of PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

   (c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.

   (d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

      (i) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below;

      (ii) any advice from PTAC, its relevant Subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of pregabalin following the closing of this RFP;

(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).

(e) 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.

(f) 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):

(i) detailed information about your company structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant subcommittee, any relevant professional organisations or healthcare professionals with regards to your product including evaluation of any product samples.

(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, provided that in PHARMAC's judgment this would not be unfair to 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 by the Board's delegate acting under delegated authority) in accordance with the Factors 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, having regard to probity principles:

(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 the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC 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 or pregabalin 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 **July/August 2017**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **August 2017**;

(iii) consulting on a provisional agreement in **August/September 2017**;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after **September 2017**.

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 **November 2017**.

(c) Please note that if a proposal for sole supply is accepted, the date of implementation may be later to allow for an orderly transition to any sole supply arrangement.

8. **Governing Law**

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

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 (or pregabalin if included) 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.

In its 27 August 2014 Meeting, the Neurological Subcommittee of PTAC recommended that pregabalin only be listed for neuropathic pain, if cost-neutral to gabapentin, subject to the same restrictions. The Neurological Subcommittee of PTAC advised that 150 mg, 300mg, 600 mg, and 900 mg doses of pregabalin would be therapeutically equivalent to approximately 600 mg, 900 mg, 1800 mg, and 2400 mg of gabapentin, respectively.

Table Two below outlines the approximate number of subsidised units (capsules or tablets) for gabapentin in the community and DHB hospitals for the last three calendar years.

Table Two: Usage (number of caps/tabs) of gabapentin in the last three calendar years

Pharmaceutical/form/ strength	2014		2015		2016	
	community	DHB hospitals	community	DHB hospitals	community	DHB hospitals
Gabapentin capsule 100 mg	5,911,000	252,000	7,732,000	309,000	9,657,000	329,000
Gabapentin capsule 300 mg	18,488,000	391,000	21,720,000	440,000	25,786,000	466,000
Gabapentin capsule 400 mg	2,025,000	43,000	2,337,000	43,000	2,664,000	49,000
Gabapentin tablet 600 mg * delisted 1 November 2015	3,000	<1,000	2,000	<1,000	-	-

Table Three below outlines community patient numbers, number of prescriptions (scripts) and usage data for the 2016 calendar year. As shown in table Three, approximately 3% of all patients are taking gabapentin for epilepsy. This accounts for approximately 1-2% of gabapentin use in the community. This split has been consistent for the last three calendar years.

Table Three: 2016 calendar year community patient numbers, number of scripts and usage (number of caps/tabs) by indication

Pharmaceutical/form/ strength	Epilepsy			Neuropathic Pain + CKD-AP		
	Number of patients	Total number of scripts	Usage* (%of total usage)	Number of patients	Total number of scripts	Usage* (%of total usage)
Gabapentin (all presentations)	1,398	1,884	438,000 (1.2%)	46,037	143,305	37,679,000 (98.8%)

Gabapentin capsule 100 mg	368	383	71,900 (0.7%)	48222	20973	9,613,000 (99.3%)
Gabapentin capsule 300 mg	870	1218	304,000 (1.2%)	86773	29839	25,469,000 (98.8%)
Gabapentin capsule 400 mg	144	283	62,000 (2.3%)	8310	2616	2,588,000 (97.7%)
*please note there is a <1% variance in usage data compared with figures stated in Table two due to incomplete indication data.						

Table Four below shows community patient numbers and number of scripts by gabapentin dose range and indication for the time period: 1 October to 31 December 2016, where this information was available. Also shown at the bottom of the table is the average daily dose of gabapentin for use in epilepsy and neuropathic pain and CKD associated pruritus (CKD-AP).

Table Four: Patient numbers and number of scripts by dose range and indication for Oct-Dec 2016

Gabapentin dose (mg per day)*	Epilepsy*		Neuropathic Pain + CKD-AP Other*	
	Number of patients	Number of scripts	Number of patients	Number of scripts
0-300	36	51	6,187	8,626
301-600	34	48	4,693	6,718
601-900	53	85	6,054	8,542
901-1,200	23	34	2,122	3,042
1,201-1,500	4	6	418	593
1,501-1,800	30	47	3,066	4,458
1,801-2,100	6	9	237	324
2,100-2,400	19	32	696	1,059
2,401-2,700	20	29	1,294	1,950
2,701-3,000	1	1	134	194
3,001-3,300	1	1	109	163
3,301-3,600	5	7	731	1,168
3,601+	1	2	41	55
The Average Daily Dose for Gabapentein for Epilepsy is 1980mg The Average Daily dose of gabapentin for Neuropathic Pain and CKD associated pruritus is 1550mg *patient indication and dosage information was available for 23,055 out of 30,591 patients. Please note ~3,000 patients may have had change in dose over this period and will be represented multiple times in the above table. *script indication and dosage information was available for 37,237 out of 51,229 scripts				

Table Five below shows the number of Special Authority initial approvals and renewal approvals for the past five calendar years by indication.

Table Five: Number of Special Authority initial approvals and renewal approvals by indication for years 2012-16 by indication

Year	Epilepsy	Neuropathic Pain and CKD associated pruritus

	Initial approval	Renewal approval	Initial approval	Renewal approval
2012	72	118	10,441	6,547
2013	57	140	11,622	8,509
2014	76	158	14,014	9,244
2015	73	223	18,347	11,599
2016	83	266	23,101	13,817

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
C/- Chloë Dimock

Dear Sir/Madam

Proposal for the supply of gabapentin and/or pregabalin.

In response to your request for proposals (**RFP**) dated **12 May 2017** 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:

	Restricted listing	**Open listing**
Chemical name (eg Gabapentin)		
Strength (eg 100 mg)		
Form (eg capsule)		
Colour (eg orange hard gelatine capsules)		
Shape (eg elliptical film-coated tablets)		
Markings (eg breakline-scored in half or scored in quarters, marked with 'compX' in the cap and 'GBA 100' on the body with black ink)		
Brand name		

Pack size (e.g. 90 capsules)		
Packaging type (e.g. blister pack)		
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)		
Indications		

(c) Details of pharmaceutical manufacture:

	Restricted listing	**Open listing**
Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc.)		
Lead time -Time from notification of award to product available in the New Zealand market		
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)		
Batch size/s		
Approximate manufacture time		
Approximate time for shipping		

(d) Key features of our proposal:

Restricted listing
Open listing

(e) 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.):

Restricted listing
Open listing

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

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]	
Insert any other consents required for pharmaceutical	

(g) Information about our ability to ensure the continuity of supply of the pharmaceutical [please include risk mitigation strategies]:

(h) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required (please refer to the information stated in Schedule 1, clause 4).

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

(j) 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:

Restricted listing
Open listing

(k) Additional information that PHARMAC should consider when evaluating our proposal [Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework]:

Restricted listing
Open listing