PHARMAC
Pharmaceutical Management Agency

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14 June 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF LAMOTRIGINE CHEWABLE/DISPERSIBLE TABLETS

PHARMAC invites proposals for the supply of lamotrigine 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 5:00pm on **10 July 2018.**

If you have any questions about this RFP, please post these on GETS, responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers of lamotrigine chewable/dispersible tablets (hereafter referred to as dispersible) 2 mg, 5 mg, 25 mg, 50 mg and 100 mg.

2. Definitions

Paediatric presentations – For the purpose of this RFP, Paediatric presentations refers to the dispersible tablet 2 mg and 5 mg presentations.

Adult presentations – For the purpose of this RFP, Adult presentations refers to the dispersible tablet 25 mg, 50 mg and 100 mg presentations.

3. Background to RFP

The background to this RFP is as follows:

Lamotrigine is an anticonvulsant that has been approved for use in epilepsy in New Zealand since December 1992 and for use in bipolar disorder since April 2003.

History of funding

Lamotrigine (Lamictal brand) was first listed on the Pharmaceutical Schedule in 1994 with access managed through Regional Health Authorities. In July 2000, following a review of funding arrangements, lamotrigine was funded via Special Authority restriction from 1 September 2000 for managing epilepsy.

On 1 February 2007 two generic brands of lamotrigine, Arrow-Lamotrigine and Mogine, were listed on the Pharmaceutical Schedule without restrictions. Restrictions were removed from Lamictal on 1 July 2007 following approval of a provisional agreement that included a rebate that brought the net price of Lamictal in line with the other two brands. Removal of restrictions enabled funded lamotrigine to be prescribed for epilepsy and bipolar disorder as well as off-label uses.

A fourth brand, Logem, was listed on 1 June 2008 without restrictions. Mogine was delisted on 1 April 2016 after it was discontinued by the supplier. A fifth brand, Motrig, was listed on 1 July 2016 and was delisted on 1 April 2018.

Current funding arrangements

Currently there are five strengths and three different brands of lamotrigine listed, without restriction, in Section B and Part II of Section H of the Pharmaceutical Schedule. These are shown in the table below.

LAMOTRIGINE	Subsidy/Price	Per	Fully Subsidised	Brand or Generic Manufacturer
Tab dispersible 2 mg	$6.74	30	✓	**Lamictal**
Tab dispersible 5 mg	$15.00	56	✓	**Arrow-Lamotrigine**
	$9.64	30	✓	**Lamictal**
Tab dispersible 25 mg	$20.40	56	✓	**Arrow-Lamotrigine**
	$29.09*		✓	**Lamictal**
	$19.38		✓	**Logem**
Tab dispersible 50 mg	$34.70	56	✓	**Arrow-Lamotrigine**
	$47.89*		✓	**Lamictal**
	$32.97		✓	**Logem**
Tab dispersible 100 mg	$59.90	56	✓	**Arrow-Lamotrigine**
	$79.16*		✓	**Lamictal**
	$56.91		✓	**Logem**

*rebate applies

Pharmacology and Therapeutics Advisory Committee (PTAC) and Subcommittee Advice

Since the introduction of generic lamotrigine, PHARMAC has continued to monitor the market and seek clinical advice on lamotrigine and other anti-epileptic drugs. PTAC and relevant subcommittees have provided clinical advice at various stages. Both the Neurological Subcommittee of PTAC and Mental Health Subcommittee of PTAC have advised that it would be clinically acceptable to progress with a competitive process for lamotrigine that could involve a brand switch for some or all patients.

Listed below is the most recent clinical advice received and web links to the relevant minutes.

2 August 2013 PTAC meeting minutes, review of proposal for generic sole supply for sodium valproate including a discussion on anti-epileptic drug switching. Full minutes are available on the PHARMAC website.

11 November 2015 The Neurological Subcommittee provided clinical advice on anti-epileptic drug switching. Full minutes are available 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 lamotrigine. Of note, the Subcommittee advised that there would be no problem with having different suppliers for the adult strength [25, 50 and 100 mg] and the paediatric strength [2 and 5 mg] preparations of lamotrigine tablets. Full minutes are available on the PHARMAC website.

23 November 2016 The Mental Health Subcommittee advised that it would not be clinically problematic from a mental health standpoint to switch patients from one brand of lamotrigine to another if necessary (that is, no more or less problematic than any other mood stabiliser brand change). The Subcommittee considered that a 3-6 month transition would be suitable for a funded brand change/sole supply from a mental health perspective. Full minutes are available on the PHARMAC website.

Reason for running the RFP

Lamotrigine represents a significant expenditure to the Combined Pharmaceutical Budget (CPB). For the 2017 financial year (1 July 2016–30 June 2017), the approximate expenditure on lamotrigine formulations was as follows:

Presentation	Approximate gross expenditure in community market	Approximate gross expenditure in DHB hospital market*
Tab dispersible 2 mg	$6,000	$40
Tab dispersible 5 mg	$55,000	$600
Tab dispersible 25 mg	$1,019,000*	$9,800
Tab dispersible 50 mg	$1,771,000*	$16,100
Tab dispersible 100 mg	$7,346,000*	$76,000
Total	**$10,196,000**	**$102,000**
*Rebate applies to Lamictal, which represents approximately 55%-68% of the market by volume for the Adult Presentations - see table two at the end of this document.		

There are currently three brands of lamotrigine funded and there are multiple other brands that are registered with Medsafe or available overseas. As a result of this significant competition, the purpose of this RFP is to obtain the best possible pricing to:

(a) reduce the total expenditure of the lamotrigine market; and

(b) secure supply of lamotrigine Adult and Paediatric presentations through one or two suppliers (see below).

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

4. Types of proposals sought

(a) Suppliers wishing to submit proposals **MUST** submit proposals for community and hospital supply of all Adult presentations (Tab 25 mg, 50 mg and 100 mg) **AND/OR** all Paediatric presentations (Tab 2 mg and 5 mg).

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

(i) proposals that include supply of both Adult and Paediatric presentations, provided that a supplier that submits a proposal for supply of both Adult and Paediatric presentations **MUST** also submit individual proposals for:

- all the Adult presentations; and
- all the Paediatric presentations

each such individual proposal capable of being accepted individually;

(ii) proposals **may** include a period of sole subsidised supply in the community and hospital supply status for the Adult presentations, and separately for the Paediatric presentations, with a discretionary variance (DV) limit of 5% in DHB hospitals (hereinafter referred to as "**Sole Supply**"), provided that the Sole Supply period does not extend beyond 30 June 2022;

(iii) proposals that include pharmaceuticals that 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 include pharmaceuticals other than lamotrigine dispersible tablets;

(ii) proposals that involve different suppliers supplying different presentations (excluding a situation where one supplier supplies all the Paediatric presentations and another supplies all the Adult presentations);

(iii) proposals that include expenditure caps, rebates or other risk-sharing arrangements;

(iv) proposals that involve listing lamotrigine with a partial subsidy;

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

(vi) proposals that involve restricting access.

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

Suppliers should provide PHARMAC with samples of the lamotrigine products included in the proposal (and, if supply is intended to be of a product that differs from the samples, information about differences must be supplied) within 10 business days from the date specified in Schedule 2, clause 1 (b).

Please address samples to the following address;

Tim Nuthall
PHARMAC
Level 9, 40 Mercer Street
Wellington, 6012

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 **10 July 2018**. 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.

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 lamotrigine dispersible tablets following the closing of this RFP;

      (iii) any other matters that the Evaluation Committee considers to be relevant having regard to probity principles (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. **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).

4. **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 PHARMAC 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 PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(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.

5. **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.

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.

(b) 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.

(c) 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.

(d) You must pay your own costs for preparing and submitting your proposal.

(e) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(f) 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.

(g) 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 lamotrigine dispersible tablets by

PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(h) 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.

(i) 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.

6. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in July/August 2018

(ii) negotiating with submitter(s) of one or more preferred proposals in August 2018

(iii) consulting on a provisional agreement in August/September 2018

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement and making a decision in or after September 2018

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 any changes to the Pharmaceutical Schedule could be implemented is October/November 2018.

(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 of at least 6 months to any sole supply arrangement.

7. 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 lamotrigine dispersible tablets. 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 lamotrigine dispersible tablets, 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.

Table One: Usage (units) of lamotrigine dispersible tablets in the last three FYRs

Strength	2015		2016		2017	
	Community	DHB hospitals	Community	DHB hospitals	Community	DHB hospitals
2 mg	19,000	60	19,000	0	25,000	180
5 mg	200,000	1,300	185,000	1,200	179,000	1,600
25 mg	2,160,000	30,900	2,255,000	29,000	2,266,000	83,100
50 mg	2,086,000	30,400	2,273,000	30,300	2,326,000	48,500
100 mg	5,077,000	63,200	5,442,000	105,700	5,700,000	126,200

Table Two: Split between brands of lamotrigine dispersable tablets in the 2017 Financial Year

	Market size – number of tablets	Percentage of the lamotrigine market by number of tablets			
		Lamictal	Arrow-Lamotrigine	Logem	Motrig*
2 mg	25,800	100%	-	-	-
5 mg	181,900	75.2%	24.8%	-	-
25 mg	2,322,300	56.3%	32.2%	11.4%	0.01%
50 mg	2,383,300	61.8%	27.3%	10.5%	0.04%
100 mg	5,830,600	65.1%	26.3%	8.4%	0.02%

* Rex Medical's brand Motrig, was listed from 1 July 2016 until 1 April 2018.

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*]

Lisa Williams, Director of Operations
C/- Tim Nuthall
PHARMAC

Dear Sir/Madam

Proposal for the supply of lamotrigine dispersible tablets

In response to your request for proposals (**RFP**) dated 14 June 2018, we put forward the following proposal in respect of lamotrigine.

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(s):

Chemical name	
Strength (eg 100 mg)	
Form (eg chewable/dispersible tablets)	
Colour, Shape and Markings (eg white to off-white, round tablets with 'LTG' over '2' on one side and scored on the other)	
Indications	
Brand name	
Pack size (eg 30)	
Packaging type (eg blister)	

(c) Details of pharmaceutical manufacture:

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

(d) Any relevant data including disintegration, dispersion, dissolution and chewability;

(e) Key features of our proposal:

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

(g) 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]	

(h) Information about our ability to ensure the continuity of supply of the pharmaceutical (if not currently supplying in New Zealand please detail any other markets which you supply your product), please note that this product will be classed as an Additional Stock Pharmaceutical which will require suppliers to hold additional stock.

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

(j) Information about educational tools and training we could offer health care providers to support any brand switch that may occur;

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

(l) Reasons why PHARMAC should accept our proposal:

(m) Additional information that PHARMAC should consider when evaluating our proposal including resourcing for patient and clinical education [Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework]: