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

3 April 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ARIPIPRAZOLE

PHARMAC invites proposals for the supply of aripiprazole 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 **3 May 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 aripiprazole.

2. Background to RFP

The background to this RFP is as follows:

Aripiprazole is a second-generation (atypical) antipsychotic medicine approved in New Zealand for use in treating schizophrenia and bipolar I disorder.

Funding history of aripiprazole

Aripiprazole (10 mg, 15 mg, 20 mg and 30 mg tablets) was first listed on the Pharmaceutical Schedule in August 2008 restricted to patients with schizophrenia and related psychoses who have tried an effective dose of risperidone or quetiapine and either had an inadequate clinical response or had unacceptable side effects.

Access was widened in August 2015 for use in the treatment of severe irritability associated with autism spectrum disorder. Following this a lower 5 mg tablet strength was listed in October 2015 and use of this strength was restricted to no more than 1 tablet per day.

Current Funding

The table below outlines the current Pharmaceutical Schedule listing of aripiprazole.

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
ARIPIPRAZOLE					
Tab 5 mg	No more than1 tab per day	123.54	30	✓	**Abilify**
Tab 10 mg	……..	123.54	30	✓	**Abilify**
Tab 15 mg	……..	175.28	30	✓	**Abilify**
Tab 20 mg	……..	213.42	30	✓	**Abilify**
Tab 30 mg	……..	260.07	30	✓	**Abilify**

➽**SA1539 Special Authority for Subsidy** [Section B] **/ Restricted** [part II of Section H]

Initial application — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Both:

1. Patient is suffering from schizophrenia or related psychoses; and
2. Either:
   - 2.1 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of unacceptable side effects; or
   - 2.2 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of inadequate clinical response.

Initial application — (Autism spectrum disorder*) only from a paediatrician or psychiatrist. Approvals valid for 12 months for
applications meeting the following criteria:
All of the following:

1. The patient has been diagnosed with an autism spectrum disorder* and has symptoms of severe irritability; and
2. An effective dose of risperidone has been trialled and has been discontinued because of unacceptable side effects or inadequate response; and
3. The patient is aged less than 18 years.

Renewal — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years where the treatment
remains appropriate and the patient is benefiting from treatment.

Renewal — (Autism spectrum disorder*) only from a paediatrician, psychiatrist or medical practitioner on the recommendation
of a paediatrician or psychiatrist (in writing). Approvals valid for 2 years where the treatment remains appropriate and the patient is
benefiting from treatment.
Note: Indications marked with * are Unapproved Indications

Clinical Advisory Committee Advice

PHARMAC has previously sought clinical advice on the appropriateness of including aripiprazole in a competitive process. The Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) has advised that there is no clinical reason not to include aripiprazole in a competitive process.

Reason for running the RFP

Annual expenditure on funded aripiprazole tablets is approaching $5 million per year, and usage is increasing. PHARMAC is aware that there is a growing number of aripiprazole products currently 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:

(a) to reduce the total expenditure of the aripiprazole market; and

(b) to determine if widening funded access to aripiprazole by removing the Special Authority and hospital restrictions would be possible from within the available budget.

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 aripiprazole 10 mg, 15 mg, 20 mg and 30 mg tablets. A 5 mg tablet can be included. If a 5 mg tablet is not included, the 10 mg tablet MUST be scored so the tablet can be easily halved.

(b) All proposals must provide for supply under two separate pricing scenarios:

(i) **current access** with the current Special Authority/hospital restrictions; AND

(ii) **widened access** (open-listing) with the removal of the current Special Authority/hospital restrictions.

If a supplier wishes to propose different terms (such as pricing, packaging or lead times) for each scenario within its proposal, it must clearly specify any differences in its proposal.

Please note that PHARMAC has a preference to widen funded access to aripiprazole, but this would be dependent on the pricing received and remains at PHARMAC's discretion.

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

(i) proposals that involve a period of sole subsidised supply in the community and hospital supply status[1] (hereinafter referred to as "Sole Supply"), provided that the Sole Supply period does not extend beyond 30 June 2021;

(ii) proposals that include "per unit"-based rebates or other expenditure risk-sharing mechanisms.

(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 Tender Item in New Zealand (including Ministry of Health market approval). In these circumstances, you may be required to demonstrate your ability to obtain those consents within a time frame acceptable to PHARMAC. Please note that these consents are required prior to a Pharmaceutical Schedule listing.

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

(i) proposals for dual supply of aripiprazole tablets.

(ii) proposals for formulations other than tablets (for example orodispersible tablets or injection) at the aforementioned doses.

(iii) proposals that include pharmaceuticals other than aripiprazole tablets.

(iv) proposals which involve listing aripiprazole with a partial subsidy.

(v) proposals that involve an end date for risk-sharing arrangements.

(vi) 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.

(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 aripiprazole 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).

4. Patents

(a) PHARMAC is aware that there are current patents in New Zealand which may be relevant to some aripiprazole formulations (potentially including, but not necessarily

[1] with a discretionary variance (DV) limit of 1% in DHB hospitals.

limited to, NZ523313, NZ542985, NZ582415, NZ586648, NZ618111 and NZ630330).

(b) PHARMAC makes no representation as to the patent status of aripiprazole, or any particular formulation of aripiprazole, and it 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 must provide for supply, at PHARMAC's discretion, under two separate pricing scenarios: current or widened (open) access. If a supplier wishes to propose different terms (such as pricing, packaging or lead times) under these two scenarios they must specify this in the 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 **3 May 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 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 aripiprazole following the closing of this RFP; and

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

(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 only where the acceptance of either supplier's proposal would not 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 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.

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; 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 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 aripiprazole 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.

(k) PHARMAC is bound by obligations under law and the terms of this RFP are subject to those obligations.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in May 2017;

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

(iii) consulting on a provisional agreement in June 2017;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after June/July 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 1 September 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 atypical antipsychotics. 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 aripiprazole 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.

1. Usage and expenditure on aripiprazole

Annual community expenditure on aripiprazole is currently approximately $4.92 million. Usage and expenditure for aripiprazole for the 2014, 2015 and 2016 calendar years is shown in the following table:

Table One: Expenditure ($NZ) and Usage (number of tablets) of Abilify for the last 3 Calendar Years Ending 31 December:

	2014		2015		2016	
Strength	**Usage**	**Expenditure**	**Usage**	**Expenditure**	**Usage**	**Expenditure**
Tab 10 mg	482,000	$1,985,000	516,000	$2,125,000	510,000	$2,102,000
Tab 15 mg	158,000	$923,000	173,000	$1,008,000	184,000	$1,076,000
Tab 20 mg	103,000	$730,000	108,000	$768,000	116,000	$826,000
Tab 30 mg	70,000	$605,000	77,000	$671,000	85,000	$741,000
Tab 5 mg	-	-	1,000	$6,000	44,000	$179,000
Grand Total	**813,000**	**$4,243,000**	**875,000**	**$4,578,000**	**939,000**	**$4,924,000**

*Note that tab 5 mg aripiprazole has only been listed since October 2015.

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Chloë Dimock

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of aripiprazole

In response to your request for proposals (**RFP**) dated 3 April 2017, we put forward the following proposal in respect of aripiprazole.

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:

	Current access	**Widened access**
Chemical name		
Strength (e.g. 10 mg)		
Form (e.g. tablet)		
Colour, Shape and Markings (e.g. white modified rectangular tablet embossed with APR 10 on one side and a bisect score line on the other)		

Brand name		
Pack size (e.g. 30's)		
Packaging type (e.g. blister)		
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)		

(c) Details of pharmaceutical manufacture:

	Current access	**Widened access**
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 being available to supply 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:

Current access
Widened access

(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.):

Current access
Widened access

(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	

(g) 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:

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

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

Current access
Widened access

(k) Reasons why PHARMAC should accept our proposal:

Current access
Widened access

(l) 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]:

Current access
Widened access