

19 June 2020

**INVITATION FOR REGISTRATION OF INTEREST FOR LISTING AGREEMENTS FOR VARIOUS PHARMACEUTICALS (“INVITATION”)**

PHARMAC invites Registration of Interests (“ROIs”) for the supply of various pharmaceuticals (“Pharmaceuticals”) to the New Zealand subsidised market, from parties who are able to supply or procure the supply of the Pharmaceuticals (“Submitter(s)”).

This Invitation is stage one of a two stage procurement process. A Submitter who is notified by PHARMAC that its ROI has been accepted is eligible to submit a proposal in response to any further procurement process which is issued by PHARMAC for the Pharmaceutical (s).

This Invitation for ROIs incorporates the following schedules:

- Schedule 1 sets out the background to the Invitation and a description of ROIs sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the Invitation;
- Schedule 3 contains the ROI response form in which you are to provide details of your submission; and
- Schedule 4 specifies the Pharmaceuticals which are in scope for the purposes of this Invitation.

If you wish to submit a ROI in response to the Invitation, please submit it via the Government Electronic Tenders Service (“GETS”) ([www.gets.govt.nz](http://www.gets.govt.nz)) no later than 5:00 p.m. on Tuesday 7 July 2020.

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

PHARMAC looks forward to receiving your ROI.

Yours sincerely



Lisa Williams  
Director of Operations

## **Schedule 1: Background to Invitation and Description of Registrations of Interest Sought**

### **1. Background to Invitation**

A supplier of a range of subsidised pharmaceuticals is exiting the New Zealand market. This supplier is currently the only supplier for a number of pharmaceuticals in New Zealand and PHARMAC is looking to secure ongoing supply of these pharmaceuticals for the New Zealand market.

We understand that the supply markets and level of competition for these pharmaceuticals may differ, and consequently different procurement approaches to secure supply may be appropriate. This Invitation is being used to identify interested suppliers who have the ability and interest to supply any of the identified pharmaceuticals to the New Zealand subsidised market and to identify the appropriate procurement process for securing supply of the pharmaceuticals.

PHARMAC intends to enter into listing agreements for the Pharmaceuticals in the New Zealand subsidised market following a two-stage procurement process. The second stage of the process would likely differ across the Pharmaceuticals and will be informed by responses to this ROI.

### **2. Description of Registration of Interest Sought**

The purpose of this Invitation is to seek submissions for the supply of any of the Pharmaceuticals by a ROI.

Further detail on each of the Pharmaceuticals which are in scope of this Invitation is provided in Schedule 4 including the presentation and estimated annual usage in the community.

PHARMAC wants to secure supply of Medsafe approved Pharmaceuticals but would consider ROIs for pharmaceuticals that are yet to obtain regulatory approval if this is the only option available for supply to the New Zealand market.

Anticipated timeframes for supply of each of the Pharmaceuticals have been provided in Schedule 4. Please note these are only tentative and indicative. We would still like to hear from you if you are able to supply any of the Pharmaceuticals outside the anticipated timeframes.

It is PHARMAC's preference that supply of the Pharmaceuticals would be contracted under PHARMAC's standard terms and conditions for listing on the Pharmaceutical Schedule. Please include any comments regarding these terms and conditions in the ROI.

Schedule 3 contains the ROI response form in which you are to provide details of your submission.

The ROI will be assessed by PHARMAC and as a result of that assessment each Submitter will be notified whether its ROI has been accepted or not (see Schedule 2, para 3). PHARMAC reserves the right to issue a further procurement process at a later date, to those Submitters whose ROI is accepted.

Pricing proposals are not to be included with the ROI.

## Schedule 2: Invitation Process

PHARMAC expects to follow the process set out below in the sequence indicated.

### 1. Submission

- (a) ROIs must be submitted no later than **5:00 pm on Tuesday 7 July 2020**. ROIs submitted after this time will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the Invitation process.
- (b) All ROIs and any questions arising out of this Invitation must be submitted to PHARMAC via GETS. Responses to all enquiries will be published on GETS.
- (c) Joint ROIs submitted to PHARMAC by one or more Submitters will be considered, provided the ROI provides full details of each Submitter and only one Submitter is identified as the point of contact with PHARMAC in relation to the ROI.

### 2. ROI Assessment

- (a) Following the deadline for submission in accordance with clause 1 above, any ROIs will be assessed by PHARMAC and PHARMAC will determine whether to accept an ROI from a Submitter in relation to any of the Pharmaceuticals.
- (b) PHARMAC will assess ROIs in light 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 PHARMAC will be guided by the Factors for Consideration ("Factors") that form part of PHARMAC's then current OPPs, as published on PHARMAC's website ([www.pharmac.govt.nz](http://www.pharmac.govt.nz)), to the extent applicable. More information on the Factors can be found at [www.pharmac.health.nz/factors-for-consideration](http://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 ROIs 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 PHARMAC, but all Factors are important.
- (d) The information to be taken into account in applying the Factors by PHARMAC will be at its discretion, however it will include:
  - (i) ability to supply any or all of the Pharmaceuticals as set out in Schedule 4 and that are appropriate for use;
  - (ii) quality of Pharmaceuticals, as specified in Schedule 3;
  - (iii) ability to ensure continuity of supply for the Pharmaceuticals included in your ROI response;
  - (iv) experience supplying the pharmaceuticals included in your ROI response

- (v) information provided by you in accordance with Schedule 3 of this ROI, including information in the spreadsheet titled (“Various pharmaceuticals for 19-06-2020 ROI”)

As noted in Schedule 1 clause 2 above, price and/or cost effectiveness will not be evaluated as part of the ROI, but would be considered as part of any future procurement process which is issued for the Pharmaceuticals.

- (e) PHARMAC may accept any number of ROIs for the Pharmaceuticals.
- (f) PHARMAC may consult with interested parties to the extent PHARMAC considers consultation to be necessary or appropriate at any stage.

### 3. **Stage two of the Procurement Process**

In the event a ROI is assessed and accepted, the Submitter is eligible to submit a proposal in response to any future procurement process which is issued by PHARMAC for the Pharmaceuticals. For the avoidance of doubt, it is at PHARMAC’s discretion as to whether a future procurement process is issued and it makes no representation in this respect.

### 4. **ROI Process Completion**

The ROI process will be complete once PHARMAC has notified:

- (a) Submitters whose ROI has:
  - (A) been accepted that they are eligible to submit a proposal in response to any future procurement process, including direct negotiations, which is issued by PHARMAC for the Pharmaceuticals; and
  - (B) not been accepted that they are not eligible to submit a proposal in response to any future procurement process which is issued by PHARMAC for the Pharmaceuticals; or
- (b) the termination of the Invitation process.

### 5. **Miscellaneous**

- (a) PHARMAC reserves the right, having regard to probity principles:
  - (i) to make such adjustments to the above Invitation process as it considers appropriate, at any time during the process, provided that it notifies Submitters affected by those changes;
  - (ii) to meet with any Submitter in relation to its proposal;
  - (iii) not to accept any ROI;
  - (iv) to seek clarification of any ROI;
  - (v) to seek clinical advice if required;
  - (vi) to suspend or cancel this Invitation process. For example, if during the Invitation process it becomes apparent to PHARMAC that further consultation

is appropriate or required PHARMAC may suspend the process in order to consult. In this situation we may ask Submitters to adapt and resubmit its ROI in light of consultation, or alternatively PHARMAC may request that new ROIs be submitted;

- (vii) to terminate this Invitation process at any time, by notifying Submitters who submitted ROIs, and
- (viii) to re-advertise for ROIs.
- (b) The Submitter must not initiate or engage in any communication with other Submitters in relation to the Invitation whether before or after submitting its ROI.
- (c) The Submitter must not at any time initiate any communication with PHARMAC's Board members or staff, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, with a view to influencing the outcome of this Invitation process.
- (d) The Submitter must pay its own costs for preparing and submitting the ROI.
- (e) The Submitter must limit the information provided to that which is requested in Schedule 3 and provide it succinctly and clearly.
- (f) ROIs are submitted in reliance on the Submitter's own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (g) The submission of an ROI as part of the Invitation process will be taken as acceptance of the terms contained in this Invitation. PHARMAC may exclude the Submitter's ROI if it does not comply with any of the terms contained in this Invitation.
- (h) This is an Invitation for ROIs and not a tender. The Invitation is not an offer capable of being converted into a listing agreement by PHARMAC's apparent acceptance.
- (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 the Submitter or any other person in relation to this Invitation.
- (j) PHARMAC will consider the Invitation process and information exchanged between the parties in any negotiations relating to the ROI, excluding information already in the public domain, to be confidential to it and its employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, the Submitter acknowledges that it may be necessary or appropriate for PHARMAC to release Confidential Information:
  - (i) pursuant to the Official Information Act 1982; or
  - (ii) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with the Submitter before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) or (ii) above. The Submitter acknowledges, 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 ROIs, PHARMAC anticipates:

- (i) Invitation closes for ROI on Tuesday 7 July 2020;
- (ii) the Invitation assessment process to be completed July 2020; and
- (iii) Submitters notified of Invitation assessment outcome July 2020

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the Invitation process take longer than anticipated.

**7. Governing Law**

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

### Schedule 3: ROI Response form

The following information should be provided in response to the ROI:

**[Supplier to insert date]**

Dear Sir/Madam

#### Proposal for the supply of Various Pharmaceuticals

In response to your registration of interest (ROI) dated **[insert date]**, we put forward the following response.

Set out below is further information in support of our submission.

#### Our contact details:

Name of organisation	
Department if relevant	
Contact person	
Physical Address	
Phone	
Email address	

#### Conflict of interest declaration:

Please declare any conflicts of interest that you or an associated person or organisation may have that could affect or compromise you or PHARMAC in relation to your participation in this Invitation process or performance under any listing agreement if successful:

- (a) Are you willing to be contacted for any follow up questions relating to your response?  
Yes / No      *(delete as appropriate)*
- (b) Please confirm you have completed columns H-L in the attached spreadsheet (Various pharmaceuticals for 19-06-2020 ROI)?  
Yes / No      *(delete as appropriate)*
- (c) For each of the pharmaceuticals included in your submission please provide details of pharmaceutical presentation (Please duplicate this table as necessary):

Chemical name	
Strength [(e.g. 500mg)]	
Form [(e.g. capsule)]	
Brand name	
Pack size [(e.g. 30's)]	
Packaging type [(e.g. blister)]	

- (d) For the pharmaceuticals included in your submission provide Information about your ability to ensure the continuity of supply:

- (e) For the pharmaceuticals included in your submission please provide details of the markets you currently supply these pharmaceuticals to:

- (f) What are your annual volumes of the pharmaceuticals sold in New Zealand or elsewhere?

- (g) For each of the pharmaceuticals in your submission please provide detail of your supply chain, including:

- Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)
- Details on pharmaceutical manufacturing sites.
- Details of New Zealand distribution

- (h) Please attach a link to your sustainability policy if applicable. Please also include any relevant information around waste reduction and recycling for the products in New Zealand

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

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

#### **Schedule 4: In Scope Pharmaceuticals**

PHARMAC invites ROIs from Submitters for any of the Pharmaceuticals stated in the attached spreadsheet titled "Various pharmaceuticals for 19- 06-2020 ROI".