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Pharmaceutical Management Agency

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05 May 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ANTI VASCULAR ENDOTHELIAL GROWTH FACTOR AGENTS

PHARMAC invites proposals for the supply of anti-vascular endothelial growth factor agents 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 market for the pharmaceutical in DHB hospitals; 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 Tender Service (GETS) (www.gets.govt.nz) no later than 4.00 p.m. on Thursday 9 June 2016. If you have any questions about this RFP, please post these on GETS or alternatively contact Jeremy Price at PHARMAC by email procurement@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Acting 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 anti-vascular endothelial growth factor agents** (hereinafter referred to as **"anti-VEGF agents"**) primarily for the treatment of wet-age related macular degeneration (wAMD).

Background to RFP

The background to this RFP is as follows:

(a) PHARMAC currently lists two anti-VEGF agents for intravitreal use, bevacizumab and ranibizumab in Part II of Section H of the Pharmaceutical Schedule under the following restriction criteria:

Bevacizumab:
Either:
1. Ocular neovascularisation; or
2. Exudative ocular angiopathy.

Ranibizumab:

Initiation: Re-assessment required after 3 doses
1. Either:
   1.1. Age-related macular degeneration; or
   1.2. Chorodial neovascular membrane; and
2. Any of the following:
   2.1. The patient has had a severe ophthalmic inflammatory response following bevacizumab; or
   2.2. The patient has had a myocardial infarction or stroke within the last three months; or
   2.3. The patient has failed to respond to bevacizumab following three intraocular injections; or
   2.4. The patient is of child-bearing potential and has not completed a family.

Continuation
Both:
Documented benefit after three doses must be demonstrated to continue; and
In the case of but previous non-response to bevacizumab, a retrial of bevacizumab is required to confirm non-response before continuing with ranibizumab.

(b) Bevacizumab and ranibizumab were listed in section II of Section H of the Pharmaceutical Schedule from 1 July 2013 as a result of the formation HML (Hospital Medicines List). It should be noted that no anti-VEGF agents are listed in Section B (community use) of the Pharmaceutical Schedule.

(c) The Ophthalmology Subcommittee of PTAC reviewed aflibercept at its October 2014 meeting. The relevant minutes can be found here. The Subcommittee also considered that ranibizumab was the preferred treatment for patients of child bearing potential and those who had recently had a stroke.

(d) PTAC subsequently reviewed aflibercept in February 2015 for the indication of wAMD and recommended PHARMAC run a competitive process for a second line agent in wAMD. The relevant minute can be found here.

2 Types of proposals sought

(a) Suppliers **must** submit a proposal for anti-VEGF agents used in first line treatment.

(b) Suppliers **must** submit proposals anti-VEGF agents for use in second treatment.

(c) Suppliers **must** submit proposals anti-VEGF agents for use in third line treatment.

(d) PHARMAC is willing to consider the following types of proposals for anti-VEGF agents:

i. Proposals that include a period of sole supply in DHB hospitals – known as Hospital Supply Status (HSS) - provided that the sole supply period does not extend beyond 3 years, and may include:

A. Proposals for HSS as a first line treatment, under the current restrictions listed in Part II of Section H of the Pharmaceutical Schedule. We note the current restrictions include both wAMD and diabetic macular oedema (DMO) indications.

B. Proposals for HSS as a second line treatment. The proposed restrictions that would apply to such a listing would be as follows:

Initiation:
Re-assessment required after 3 doses
Both
1. Either:
   1.1. Wet age-related macular degeneration (wAMD); or
   1.2. Polypoidal choroidal vasculopathy; or
   1.3. Choroidal neovascular membrane from causes other than wet AMD; and
2. Any of the following:
   2.1. The patient has had a severe ophthalmic inflammatory response following treatment with [first-line agent]; or
   2.2. Treatment with [first-line agent] has proven ineffective following at least three intraocular injections.

Continuation
Re-assessment required at 6 months, 12 months and 24 months from initiation of treatment, then 2 yearly thereafter.
Both:
1. Documented benefit must be demonstrated to continue; and
2. In the case of previous non-response to [first line agent], a retrial of at least one dose of [first-line agent] is required at 6 months, 12 months and 24 months to confirm non-response before continuing with [second line agent].

For the avoidance of doubt, the proposed restriction criteria for a second line agent do not include DMO.

C. Proposals for HSS as a third line treatment. We note that third line treatment option is currently not listed in the HML. Acceptance of a proposal and development of appropriate restrictions would be dependent on both proposals received and clinical advice. For the avoidance of doubt, the proposed restriction for a third line treatment would not include DMO.

ii. Proposals that include expenditure caps, rebates or other risk-sharing arrangements.

iii. Proposals that include a hard cap provided that the hard cap would be for 3 years and then revert back to an average cost per vial (with rebate) thereafter.

iv. Proposals that include a soft cap/tiered cap, provided that a supplier also submits an alternative bid with a flat rebate structure.

(e) Note suppliers who are not familiar with HSS arrangements should consult Part I of Section H of the Pharmaceutical schedule which can be found here.

(f) For the avoidance of doubt, PHARMAC is willing to consider all different presentation types of anti-VEGF agents, for example, prefilled syringes, vials with filter needles, etc.

(g) Proposals which would require a brand switch must include an option that permits the incumbent second line agent, ranibizumab, to continue to be used for patients who have had a myocardial infarction or stroke within the last three months or if the patient is of child-bearing potential and has not completed a family.

(h) Proposals in respect of product/s where Consents not yet held. PHARMAC would consider proposals where your product/s are yet to obtain all necessary Consents (where 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 those circumstances, you may be required to demonstrate your ability to obtain those Consents within a time frame acceptable to PHARMAC. For example, you may be required to demonstrate that you have the dossier for your product/s ready to submit to Medsafe within one month of such a request being made by PHARMAC.

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

i. Proposals involving pharmaceuticals or related products not specified in clause 1, Schedule 1.

ii. Proposals that involve an end date for expenditure caps (other than described for a hard cap in sub-clause (d) iii. above), rebates or other risk-sharing arrangements.

iii. 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.

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

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 **4.00 p.m.** (New Zealand time) on **Thursday 9 June 2016**. 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 Jeremy Price, 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 decision mechanism set out in PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable.

(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 decision criteria which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all decision criteria are important.

(d) The information to be taken into account in applying the decision mechanism by the Evaluation Committee will include:

(i) any clinical advice from PTAC, its relevant sub-committee, any relevant professional organisation or healthcare professionals; and

(ii) 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) product samples of the various presentations, forms and strengths of anti-VEGF agents 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 no later than 10 business days of PHARMAC's request;

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

(iii) any other additional information about your Pharmaceutical.

(b) Please note that PHARMAC may seek advice from PTAC, the Ophthalmology sub-committee of PTAC, any relevant professional organisations or healthcare professionals with regards to your product including evaluation of any product samples.

(c) 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 will be made available on GETS and on our website, 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 decision criteria 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; and

(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's directors or officers, the Ministry of Health, the Minister of Health or District Health Boards, with a view to influencing the outcome of this RFP process.

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

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

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of anti-VEGF agents 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 June 2016;

(ii) negotiating with submitter(s) of one or more preferred proposals in June 2016;

(iii) consulting on a provisional agreement in July 2016;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after August 2016,

provided that the above timeframes 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 September 2016;

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

Schedule 3: Current listing and market information

The following information relates to the estimated market size of bevacizumab and ranibizumab in DHB hospitals.

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 bevacizumab and ranibizumab 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.

Hospital Usage

The table below indicates the approximate use of anti-VEGF agents in DHB hospitals (in mg)

	Units Purchased (mg)	
Year (FYR)	Bevacizumab (includes all indications)	Ranibizumab
2013	72,064	230
2014	94,884	427
2015	105,956	1,629
2016	125,747	3,257

*2016 financial year figures are best estimates from current usage data.

It should be noted that due to inconsistencies in the reporting of hospital data, the figures above may not accurately represent DHB usage. We are unable to separate the purchasing data by indication, however bevacizumab is almost exclusively for ocular indications and some limited use in oncology through NPPA.

Third Line patient numbers

There is some uncertainty around the number of units or patient numbers requiring a third line agent. Specialist advice received by PHARMAC noted that there could be up to 400 patients per year requiring a third line agent for wAMD.

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/- Jeremy Price
Procurement Manager

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

Proposal for the supply of Anti-Vascular Endothelial Growth Factor Agents (Anti-VEGF agents)

In response to your request for proposals (**RFP**) **dated 5 May 2016** we put forward the following proposal in respect of Anti-VEGF agents.

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

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Email address	

(b) Details of pharmaceutical presentation:

Chemical name	
Strength (e.g. 3.6 mg)	
Duration of action (e.g. monthly)	
Presentation (e.g depot implant)	
Needle length	
Route of administration	
Storage conditions/stability and expiry	
Reconstitution- solution or suspension, storage conditions/stability, and expiry	
Indications	
Pack size	
Pharmacokinetic data	

(c) Key features of our proposal not detailed elsewhere in the response:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for HSS, reference price protection, risk sharing mechanisms, etc.):

(e) Information about our proposed customer support, training and education provided to health professionals:

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

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

(i) 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:
