PHARMAC
Pharmaceutical Management Agency

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31 October 2012

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PREPARATIONS FOR TEAR DEFICIENCY AND EYE LUBRICATION

PHARMAC invites proposals for the supply of preparations for Tear Deficiency and Eye Lubrication 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 no later than 5.00 p.m. on **30 November 2012**

If you have any questions about this RFP, please contact Greg Williams at PHARMAC on 04 916 7524 or greg.williams@pharmac.govt.nz

We look forward to receiving your proposal.

Yours sincerely

Steffan Crausaz
Chief Executive

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

1. **Pharmaceutical**

PHARMAC is interested in considering any proposal from suppliers of the following products (referred to collectively within this RFP as 'preparations for Tear Deficiency and Eye Lubrication):

- **thin (low viscosity) eye drops**;
- **thick (medium viscosity) eye drops**;
- **ophthalmic gel;**
- **eye ointment**;
- **preservative-free thin (low viscosity) eye drops**;
- **preservative-free thick (medium viscosity) eye drops**; and/or
- **preservative-free ophthalmic gel**.

2. **Background to RFP**

Currently PHARMAC subsidises the following products in the Pharmaceutical Schedule for tear deficiency and eye lubrication:

Preparation	Pack Size	Subsidy (manufacturer's price)	Brand
Hypromellose Eye drops 0.3%	15 ml	$2.62	Poly-Tears
Hypromellose Eye drops 0.5%	15 ml	$2.00 ($3.92)	Methopt
Polyvinyl alcohol Eye drops 1.4%	15 ml	$2.68	Vistil
Polyvinyl alcohol Eye drops Eye drops 3%	15ml	$3.75	Vistil Forte
Paraffin liquid with wool fat liquid Eye oint 3% with wool fat liq 3%	3.5 g	$3.63	Poly-Visc
Paraffin liquid with soft white paraffin Eye oint with soft white paraffin	3.5 g	$3.63	Lacrilube

At its 9 March 2012 meeting the Ophthalmology Subcommittee recommended that PHARMAC list preservative-free lubricating eye preparations in addition to preserved eye formulations with

a medium priority. The full minute from the meeting can be found at the following link (http://pharmac.govt.nz/2012/06/20?Q=ophthalmology). The relevant excerpt is as follows:

> The Subcommittee considered that there were certain patient groups who would benefit from preservative free eye drops. Members noted that patients with Sjögren's syndrome (with diagnosed dry eye), neurotrophic keratopathy, atopic blepharitis, severe epitheliopathy and chemical injuries and those with proven allergic reaction to preservatives may benefit. Members considered that the allergic reaction would usually present with itch, swelling, papillae and mucous and would be confirmed by improvement on cessation of treatment which worsened on restarting The Subcommittee considered that 1-5% of the population would benefit from preservative free eye drops as detailed above and that treatment should be targeted.
>
> The Subcommittee considered that dry eyes should be diagnosed with a slit lamp prior to the prescribing of preservative free eye drops to ensure appropriate diagnosis of secretory tear deficiency.
>
> The Subcommittee considered that a minimum of a one thin, one thick , one gel and one ointment preparation for dry eyes was required to ensure appropriate therapy could be provided for patients.
>
> One member noted that there were ongoing trials using serum for patients with severe dry eye and these trials looked promising.
>
> The Subcommittee recommended listing preservative free lubricating eye drops under the following Special Authority with a medium priority:
>
> > Initial application from any relevant practitioner
> >
> > Approvals valid for 12 months for patients meeting the following criteria:
> > Both:
> > 1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
> > 2 Either:
> > 2.1 Patient is using eye drops more than four times daily on a regular basis; or
> > 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop;
> >
> > Renewal from any relevant practitioner
> > Approvals valid for 24 months for patients meeting the following criteria:
> > Both:
> > 1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
> > 2 Either:
> > 2.1 Patient is using eye drops more than four times daily on a regular basis; or
> > 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop;
>
> The Subcommittee noted that prescriber education was needed regarding secretory dry eyes and considered a BPAC campaign may be beneficial.

3. Types of proposals sought

3.1 PHARMAC is seeking proposals for the following preparations:

(a) Preserved preparations for tear deficiency and eye lubrication in the following presentations (without Special Authority):

- thin (low viscosity) eye drops;
- thick (medium viscosity) eye drops;

- ophthalmic gel; and/or
- eye ointment.

(please note: any proposals for hypromellose 0.3% eye drops must be dextran containing).

(b) Preservative free presentations of preparations for tear deficiency and eye lubrication in the following presentations (with Special Authority)

- thin (low viscosity) eye drops;
- thick (medium viscosity) eye drops; and/or
- ophthalmic gel

3.2 PHARMAC is willing to consider proposals involving the following:

- sole subsidised supply and hospital supply status (hereinafter referred to as "sole supply") of up to, but no more than, 3 years, provided that the start of the sole supply period does not occur before 1 July 2013 and does not extend beyond 30 June 2016;
- subsidy and delisting protection of up to, but no more than, 3 years, provided that this does not extend beyond 30 June 2016;
- unrestricted access to preserved preparations for tear deficiency and eye lubrication;
- restricted access to preservative free presentations of preparations for tear deficiency and eye lubrication (i.e. Special Authority);
- unrestricted access to preservative free presentations of preparations for tear deficiency and eye lubrication(for example no Special Authority);
- expenditure caps, rebates, or other expenditure risk sharing mechanisms; and/or
- cross-deal or bundling arrangements in respect of more than one chemical entity defined in this RFP.

3.3 PHARMAC is not willing to consider the following types of proposals:

- Numerical limits for patients to whom subsidy would be available;
- Proposals for part-funding of preparations for tear deficiency and eye lubrication;
- Proposals which involve cross-deal or bundling arrangements which involve any chemical entity other than preparations for tear deficiency and eye lubrication as defined in this RFP.

- 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 or preparations for tear deficiency and eye lubrication on specific terms.

3.4 Please note**;** if you submit a bundle proposal for preparations for tear deficiency and eye lubrication products, you must submit individual proposals for each of the preparations for tear deficiency and eye lubrication included in the bundle proposal.

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

3.6 Please note samples of the pharmaceuticals should be delivered to PHARMAC when any submission is made.

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 no later than 4.00 p.m. (New Zealand time) on 30 November 2012. Late proposals will only be considered at PHARMAC's discretion.

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

   (d) All proposals must be submitted to PHARMAC for the attention of **Greg Williams** either by facsimile (+64 4 460 4995) or email (greg.williams@pharmac.govt.nz). Email is preferred.

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 basis on which the Evaluation Committee will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are to be determined by the Evaluation Committee at its sole discretion. The matters to be taken into account by the Evaluation Committee will, however, include:

      (i) the decision criteria 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;

      (ii) Product acceptability;

      (iii) any clinical advice from PTAC or its relevant sub-committee;

      (iv) 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).

   (c) 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.

   (d) 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 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).

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 Board approval (or approval by PHARMAC's Chief Executive 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 PHARMAC's Chief Executive under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.

(d) If the Board or the Chief Executive 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 Chief Executive's decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

5. **Miscellaneous**

(a) PHARMAC reserves the right:

(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 Chief Executive.

(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 Preparations for Tear Deficiency and Eye Lubrication 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.

6. **Anticipated timetable**

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in December 2012;

(ii) negotiating with submitter(s) of one or more preferred proposals between December 2012 and January 2013;

(iii) consulting on a provisional agreement in January or February 2013;

(iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after February 2013,

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 March 2013.

(c) Please note that if a proposal for sole supply for the supply of eye ointment is accepted, the date of implementation would not be prior to 1 July 2013 due to current contractual arrangements.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of Preparations for Tear Deficiency and Eye Lubrication. 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 Preparations for Tear Deficiency and Eye Lubrication 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.

The number of packs claimed for preparations for tear deficiency and eye lubrication in the previous three financial years ending 30 June are shown in the table below;

Packs	2010	2011	2012
Hypromellose 0.3%	97,309	109,266	126,037
Hypromellose 0.5%	8,388	9,891	9,684
Polyvinyl 1.4%	24,501	24,002	23,466
Polyvinyl 3%	7,437	7,868	9,457
Tyloxapol	419	384	373
Paraffin liquid with soft white paraffin	32,792	36,241	41,038
Paraffin liquid with wool fat liquid	8,783	9,054	9,687

Schedule 4: Proposal form

An electronic version of this form is available on request from greg.williams@pharmac.govt.nz. You should expand the boxes as necessary.

[*Supplier to insert date*]

Chief Executive
C/- [***insert contact person at PHARMAC***]
PHARMAC
PO Box 10-254
(or for courier delivery:
Level 9
40 Mercer Street)
Wellington 6011
New Zealand

Dear Sir/Madam

Proposal for the supply of [*insert pharmaceutical*]

In response to your request for proposals (**RFP**) dated [***insert date***], 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:

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

(c) Key features of our proposal:

(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 sole supply, reference price protection, risk sharing mechanisms, etc.):

(e) 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	

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

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

(h) 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:

(i) Reasons why PHARMAC should accept our proposal:

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