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Pharmaceutical Management Agency

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8 March 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF GONADOTROPIN-RELEASING HORMONE ANALOGUES

PHARMAC invites proposals for the supply of gonadotropin-releasing hormone analogues 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 approximate market size of the pharmaceutical in the community and 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) no later than **5.00 p.m. on 7 April 2016**

If you have any questions about this RFP, please post these on the Government Electronic Tenders Service (www.gets.govt.nz) or alternatively contact Chloë Dimock at PHARMAC by email procurement@pharmac.govt.nz.

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 proposals from suppliers **of gonadotropin-releasing hormone analogues** (hereinafter referred to as **"GnRH analogues"**). For the purposes of this RFP **"GnRH analogues"** refers to the chemicals goserelin (goserelin acetate) and leuprorelin (leuprorelin acetate).

2. **Background to RFP**

The background to this RFP is as follows:

(a) Two GnRH analogues (goserelin and leuprorelin) are currently listed and fully subsidised by PHARMAC without any restrictions. There are two presentations of goserelin and seven presentations of leuprorelin currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule as follows:

		Subsidy/Price	Per	Fully Subsidised	Brand or Generic Manufacturer
GOSERELIN					
Inj 3.6 mg, depot implant	……	166.20	1	✓	**Zoladex**
Inj 10.8 mg, depot implant	……	443.76	1	✓	**Zoladex**
LEUPRORELIN					
Inj 3.75 mg prefilled syringe	……	221.60*	1	✓	**Lucrin Depot PDS**
Inj 7.5 mg	……	166.20	1	✓	**Eligard**
Inj 11.25 mg prefilled syringe	……	591.68*	1	✓	**Lucrin Depot PDS**
Inj 22.5 mg	……	443.76	1	✓	**Eligard**
Inj 30 mg	……	591.68	1	✓	**Eligard**
Inj 30 mg prefilled syringe	……	1,109.40*	1	✓	**Lucrin Depot PDS**
Inj 45 mg	……	832.05	1	✓	**Eligard**

*A rebate exists

(b) The currently funded GnRH analogues represent significant expenditure to the Combined Pharmaceutical Budget (CPB). For the 2015 calendar year, the approximate expenditure on leuprorelin and goserelin was as follows:

Chemical	**Approximate net expenditure for community market**	**Approximate net expenditure for DHB hospital market***
Leuprorelin	$5.3 million*	$90,000*
Goserelin	$4.2 million	$150,000
Total	$9.5 million*	$230,000*

*a rebate exists for three presentations of leuprorelin

(c) PHARMAC previously received advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) that goserelin and leuprorelin were in the same therapeutic sub-group, and had the same or similar therapeutic effect. As such reference pricing has been applied to this subgroup. The currently listed GnRH analogue presentations have the same net price for all listed brands with the same

dose formulations, i.e. monthly, 3 monthly and 6 monthly (previous notifications relating to goserelin and leuprorelin pricing can be found on our website).

(d) In September 2015, PHARMAC received advice from the Cancer Treatments Subcommittee (CatSoP) of PTAC. The Subcommittee considered that it would be clinically reasonable to reference price goserelin to leuprorelin (or vice versa), or to run a competitive process that would result in only one of goserelin or leuprorelin being funded. The relevant minutes can be found on the PHARMAC website: CaTSoP minute.

(e) PHARMAC recently received advice from the Endocrinology Subcommittee of PTAC that on the basis that leuprorelin and goserelin can be expected to provide the same or similar therapeutic effect in the endocrinology indications, it would be clinically reasonable to apply reference pricing of leuprorelin to goserelin (or vice versa), or to run a competitive process that would result in only one of leuprorelin or goserelin being funded. The relevant minutes can be found on the PHARMAC website: Endocrinology Subcommittee minute.

(f) PHARMAC is now seeking proposals for the funding of a single GnRH analogue with an opportunity to reduce the expenditure on GnRH analogues and improve health outcomes for New Zealanders. PHARMAC may also consider the possibility of the continued funding of two GnRH analogues (both goserelin and leuprorelin), depending on pricing and types of proposals received.

(g) PHARMAC would follow its usual processes, including consulting with interested parties where appropriate, prior to a decision to make any change in this market as a result of this RFP.

3. Types of proposals sought

(a) *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 with a discretionary variance (DV) limit of 1% in DHB hospitals (hereinafter referred to as “Sole Supply”) for a period of up to, but no more than, 3 years provided that the Sole Supply period does not extend beyond 30 June 2019;

Note: Suppliers who are not familiar with hospital supply status arrangements (including DV limits) should consult Part I of Section H of the Pharmaceutical Schedule.

Specifically, PHARMAC will consider:

(ii) proposals for Sole Supply at the chemical level where both goserelin and leuprorelin would remain listed in the Pharmaceutical Schedule. Proposals could include a range of dose formulations (monthly and 3-monthly and could include 6 monthly administered presentations, but not 4 monthly or 12 monthly administered presentations) of goserelin or leuprorelin. For example:

		Subsidy/Price	Per	Fully Subsidised	Brand or Generic Manufacturer
GOSERELIN					
Inj XX mg, monthly implant	……	$XX.XX	1	✓	**BrandX**
Inj XX mg, 3 monthly implant	……	$XX.XX	1	✓	**BrandX**
LEUPRORELIN					
Inj XX mg, monthly injection	……	$XX.XX	1	✓	**BrandY**
Inj XX mg, 3 monthly injection	……	$XX.XX	1	✓	**BrandY**
Inj XX mg, 6 monthly injection	……	$XX.XX	1	✓	**BrandY**

(iii) proposals for Sole Supply at the therapeutic sub-group level (i.e. sole supply of a GnRH analogue) where either goserelin or leuprorelin would be listed (but not both). Proposals could include a range of dose formulations (monthly and 3-monthly and could include 6 monthly administered presentations, but not 4 monthly or 12 monthly administered presentations) of goserelin or leuprorelin. For the avoidance of doubt if a proposal for goserelin monthly and 3 monthly was selected the 6 monthly leuprorelin presentation could not be listed under this scenario. For example:

		Subsidy/Price	Per	Fully Subsidised	Brand or Generic Manufacturer
GOSERELIN					
Inj XX mg, monthly implant	……	$XX.XX	1	✓	**BrandX**
Inj XX mg, 3 monthly implant	……	$XX.XX	1	✓	**BrandX**

Note: under this scenario the alternative chemical would be listed in Part II of Section H of the Pharmaceutical Schedule as a DV Pharmaceutical. Using the above example, leuprorelin presentations would remain listed in Part II of Section H as DV Pharmaceuticals.

(iv) Suppliers that wish to submit proposals for Sole Supply at the chemical level and/or at the GnRH therapeutic sub-group level as outlined in clause 3 (a)(iii) or 3 (a)(iv) above must also submit separate proposals for the individual dose formulations that are able to be accepted individually. For example if a proposal is submitted for both a monthly and 3 monthly formulation of a chemical, a supplier needs to also submit individual proposals for both formulations able to be accepted independently of one another.

(v) proposals that include a period of subsidy protection in the community and price protection in DHB hospitals and/or protection from delisting for a period of up to, but no more than, 3 years provided that the protection period does not extend beyond 30 June 2019;

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

(vii) for the avoidance of doubt, PHARMAC is willing to consider all different presentation types of goserelin and leuprorelin, for example, prefilled

syringes, depot injections and depot implants. However, there may be a preference for some patient populations (specifically children) for non-implant presentations. Suppliers with implant presentations may wish to consider an allowance for a non-implantable presentation to be accessed for children.

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

(i) proposals that include products other than goserelin or leuprorelin.**;**

(ii) proposals that involve listing goserelin or leuprorelin with a partial subsidy;

(iii) proposals that involve an end date for expenditure caps, rebates or other risk-sharing arrangements; and

(iv) 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.

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

4. **Consents not yet held**

(a) 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);

(b) PHARMAC would consider proposals where your product/s are yet to obtain all necessary Consents. 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.

5. **Training, education and support**

(a) Any supplier awarded Sole Supply would be expected to provide initial and ongoing health professional education, training and product support services throughout the term of the contract. Suppliers would be expected to provide support to aid any transition from another brand or chemical that would occur as a result of acceptance of its proposal.

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 **7 April 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 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 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. The information to be taken into account in applying the decision mechanism by the Evaluation Committee will include, in particular:

(i) the information included in your proposal in the form set out in Schedule 4, including outlined training and education plan or provided under clause 3 below; and

(ii) any advice from PTAC, its relevant sub-committee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of GnRH analogues following the closing of this RFP; and

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

(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. **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 GnRH analogues 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) no later than 10 business days of PHARMAC's request;

(ii) additional information on any patient and clinician support, training and educational resources that may be available to health professionals during any major switchover to your brand of GnRH analogue and throughout the term of any contract;

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

(iv) any other additional information about your Pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant sub-committee, 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 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;

(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 GnRH analogue/s 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 April 2016;

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

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

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after July 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 sole supply is accepted, the date of implementation may be later to allow for an orderly transition to any sole supply arrangement.

Schedule 3: Current listing and market information

The following information relates to the approximate subsidised market size of goserelin and leuprorelin in both the community and 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 goserelin and leuprorelin 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.

In addition, PHARMAC notes that market dynamics, and therefore the volumes reflected below, may be subject to change with the absence or inclusion of other GnRH analogue presentations that may be listed in the Pharmaceutical Schedule.

Community usage

Table One below indicates the approximate numbers of units (injections or implants) of the GnRH analogue presentations subsidised by PHARMAC, and claimed for by community pharmacies for the calendar years 2013, 2014 and 2015.

Table One: community usage of GnRH analogue presentation

Dose formulation	Chemical	Brand	Presentation	List Price	Units		
					2013	2014	2015
1 monthly	Goserelin	Zoladex	Inj 3.6 mg, syringe, depot implant	$166.20	3,100	3,200	4,000
	Leuprorelin	Eligard	Inj 7.5 mg, prefilled syringes	$166.20	40	30	50
	Leuprorelin	Lucrin Depot 1- Month Injection	Inj 3.75 mg, dual chamber syringe	221.60*	1,400	1,700	1,400
	Leuprorelin	Lucrin Depot 1- Month Suspension	Inj 3.75 mg, vial	Not currently listed	100	10	0
3 monthly	Goserelin	Zoladex	Inj 10.8 mg, syringe, depot implant	$443.76	7,900	7,700	7,900
	Leuprorelin	Eligard	Inj 22.5 mg , prefilled syringes	$443.76	250	300	400
	Leuprorelin	Lucrin Depot 3- Month Injection	Inj 11.25 mg, dual chamber syringe	$591.68*	4,100	5,100	5,600
	Leuprorelin	Lucrin Depot 3- Month Suspension	Inj 11.25 mg, vial	Not currently listed	560	370	0
4 monthly	Leuprorelin	Eligard	Inj 30 mg, prefilled syringes	$591.68	<5	<5	<5
6 monthly	Leuprorelin	Eligard	Inj 45 mg, prefilled syringes	$832.05	1,100	1,100	1,200
	Leuprorelin	Lucrin Depot 6- Month Injection	Inj 30 mg, dual chamber syringe	$1,109.40*	1,400	1,500	1,700

*A rebate exists

Hospital Usage

Table Two below indicates the approximate use GnRH analogues in DHB hospital as a percentage of the community dose formulation market for goserelin and leuprorelin:

Table Two Hospital Usage Data as a percentage of Community Usage (in number of injections)

Dose formulations	Chemical	Community market			Hospital Market Usage (% of community market use)		
		2013	2014	2015	2013	2014	2015
1 month	Goserelin	3,100	3,200	4,000	4%	4%	4%
	Leuprorelin	1,500	1,700	1,400	11%	14%	7%
3 month	Goserelin	7,900	7,700	7,900	4%	4%	3%
	Leuprorelin	4,900	5,500	6,000	1%	2%	2%
6 month	Leuprorelin	2,500	2,600	2,900	1%	1%	1%

Patient Demographic Usage

Table Three below indicates the approximate numbers of units (injections or implants) of goserelin and leuprorelin dose formulations subsidised by PHARMAC, and claimed for by community pharmacies for the years 2013, 2014 and 2015 for patients under 20 years old.

Table Three: approximate number of injections used by patients under 20 years old

Dose formulation	Chemical	Number of injections used in patients 12 and under and patients between 12 -19 by calendar year					
		2013		2014		2015	
		00 to 12	13 to 19	00 to 12	13 to 19	00 to 12	13 to 19
1 month	Goserelin	10	130	15	70	<5	70
	Leuprorelin	510	115	600	165	410	115
3 month	Goserelin	<5	10	10	15	<5	15
	Leuprorelin	310	165	395	240	550	400
6 month	Leuprorelin	-	-	<5	<5	<5	<5

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz) or on PHARMAC's website at (www.pharmac.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Chloë Dimock
Procurement Manager

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

Proposal for the supply of a gonadotropin-releasing hormone (GnRH) analogue/s presentation/s

In response to your request for proposals (**RFP**) dated **8 March 2016** we put forward the following proposal in respect of GnRH analogues.

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 Sole Supply, reference price protection, risk sharing mechanisms, etc.):

(e) Information of 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: