PHARMAC
Pharmaceutical Management Agency

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17 March 2014

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF CONTRACEPTIVE IMPLANTS

PHARMAC invites proposals for the supply of contraceptive implants 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 Friday 11 April, 2014**

If you have any questions about this RFP, please contact Bronwyn Hale at PHARMAC by email (bronwyn.hale@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

(a) PHARMAC is interested in considering any proposal from suppliers of hormonal long acting reversible contraceptives in the presentation of an implant (hereinafter referred to as **"contraceptive implants"**) as a progesterone only method of contraception.

2. Background to RFP

The background to this RFP is as follows:

(a) On 1 August 2010 following an RFP for the supply of hormonal long-acting reversible contraceptives, PHARMAC listed the contraceptive implant brand 'Jadelle', awarding Sole Subsidised Supply status in Section B of the Pharmaceutical Schedule and listing in Part II of Section H of the Pharmaceutical Schedule. The Sole Subsidised Supply period for Jadelle ended on the 31 December 2013.

(b) PHARMAC is again interested in considering proposals that would result in a sole supply listing of a contraceptive implant in Section B and Part II of Section H of the Pharmaceutical Schedule.

3. Types of proposals sought

(a) PHARMAC is seeking proposals for the supply of a contraceptive implant to be listed in the Pharmaceutical Schedule for contraception. PHARMAC is willing to consider the following types of proposals:

(i) proposals that include a period of sole subsidised supply in the community for contraception (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 1 January 2018;

(ii) proposals that include a period of subsidy protection and/or protection from delisting; and

(iii) proposals that include expenditure caps, rebates or other risk-sharing arrangements.

(b) Please note:

(i) the proposal does not include the supply of hormonal long-acting reversible contraceptives in the presentation of an intra-uterine system device or contraceptive methods that require administration more frequently than annually.

(ii) PHARMAC would accept proposals for sole supply of implants under this RFP in relation to contraception only. any supplier awarded Sole Subsidised Supply would be expected to implement training clinicians nationwide in the use of its product. An outline of the supplier's proposed training program and timetable for regional coverage and delivery must be supplied with the proposal.

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

(i) proposals that include products other than hormonal contraceptive implants;

(ii) proposals that involve listing hormonal contraceptive implants with a partial subsidy;

(iii) cross-deal or bundling arrangements in respect of more than one chemical entity, therapeutic group or sub-group;

(iv) proposals that involve an end date for a risk-sharing arrangement; and

(v) 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.

(d) 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 no later than **5.00 p.m**. (New Zealand time) on Friday **11 April 2014.** 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 to the attention of **Bronwyn Hale,** Therapeutic Group Manager either by facsimile (+64 4 460 4995) or email (Bronwyn.hale@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) any clinical advice from PTAC or its relevant sub-committee;

      (iii) 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. **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) a sample of the product included in your proposal (and if you intend supplying this in a different form from that sample, information about the form in

which it would be supplied) in which case you must supply that information within 10 business days of PHARMAC requesting it.

(b) If PHARMAC requests further information from or about you it is not obliged to request the same or any other information form or about 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 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 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:

(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 contraceptive implants 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 April/May 2014

(ii) negotiating with submitter(s) of one or more preferred proposals in May 2014

(iii) consulting on a provisional agreement in June 2014

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after July 2014

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 September 2014.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of contraceptive implants in the community**.**

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 contraceptive implants 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.

PHARMAC wish to advise that market dynamics and therefore the data below may be subject to change with the absence or inclusion of other long term contraceptives that may be sole supply on the pharmaceutical schedule.

The estimated number of dispensings of contraceptive implants in the community for the financial years ending 30 June 2011, 30 June 2012 and 30 June 2013.

Pharmaceutical and presentation	**July 2010 to June 2011**	**July 2011 to June 2012**	**July 2012 to June 2013**
Levonorgestrel implants	10,264	13,965	12,914

Schedule 4: Proposal form

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

[*Supplier to insert date*]

Director of Operations
C/- Bronwyn Hale
Therapeutic Group Manager
PHARMAC

By email: bronwyn.hale@pharmac.govt.nz

Dear Bronwyn

Proposal for the supply of contraceptive implants

In response to your request for proposals (**RFP**) dated 14 March, 2014, we put forward the following proposal in respect of contraceptive implants

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. 75 mg)]	
Form [(e.g. rods)]	
Brand name	
Pack size [(e.g. 1 - 2)]	
Packaging type [(e.g. disposable sterile applicator)]	

(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]	

(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) Information about our proposed training programme and implementation timetable

(j) Reasons why PHARMAC should accept our proposal:

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