

1 April 2010

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF HORMONAL LONG ACTING REVERSIBLE CONTRACEPTIVES**

PHARMAC invites proposals for the supply of **hormonal long acting reversible contraceptives** 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 30 April 2010**.

If you have any questions about this RFP, please contact Christine Chapman at PHARMAC (see Schedule 2 for Christine's contact details).

We look forward to receiving your proposal.

Yours sincerely



Matthew Brougham  
Chief Executive

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

### 1. Pharmaceutical

- (a) PHARMAC is interested in considering proposals from suppliers of hormonal long acting reversible contraceptives (hereinafter collectively referred to as “**hormonal LARCs**”).
- (b) For the purposes of this RFP, hormonal LARCs refer to progesterone-only methods of contraception (e.g. intrauterine systems, injectables and implants) that require administration no less frequently than annually.

### 2. Background to RFP

The background to this RFP is as follows:

- (a) PHARMAC has received three applications to list hormonal LARCs on the Pharmaceutical Schedule:
  - (i) Family Planning Association of New Zealand – to list a hormonal LARC
  - (ii) Bayer New Zealand – 75 mg levonorgestrel (Jadelle)
  - (iii) Bayer New Zealand – levonorgestrel 20 µg per 24 hours (Mirena)
- (b) The Hormone and Contraceptive Subcommittee of PTAC reviewed long acting reversible contraception at its May 2009 meeting and recommended the listing of a hormonal LARC on the Pharmaceutical Schedule with no restrictions; it noted that any of the currently available forms of hormonal LARCs would be acceptable. Copies of the relevant minutes are attached in **Appendix One** (pages 12-13).
- (c) Hormonal LARCs are not currently subsidised by PHARMAC for contraception. One hormonal LARC, levonorgestrel 20 µg per 24 hours (Mirena), is listed on the Pharmaceutical Schedule with access to funding via Special Authority for the treatment of heavy menstrual bleeding.
- (d) PHARMAC notes that any listing of hormonal LARCs would not affect the listing of non-hormonal Intra-Uterine Devices or medroxyprogesterone acetate injections.
- (e) PHARMAC is interested in considering proposals that would result in the listing of one or more hormonal LARC.

### 3. Types of proposals sought

- (a) PHARMAC is seeking proposals for the supply of hormonal LARCs 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 2014;

- (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) If you wish to submit more than one proposal, at least one must be a proposal for sole supply of a hormonal LARC.
  - (ii) PHARMAC would only accept proposals for sole supply for hormonal LARCs under this RFP in relation to contraception only. Accordingly:
    - (A) awarding sole supply to a hormonal LARC as a result of this RFP would not preclude PHARMAC from listing another long-acting progestogen-only product, provided that it was subsidised for purposes other than contraception; and
    - (B) awarding sole supply to a hormonal LARC as a result of this RFP would not affect the current listing for levonorgestrel 20 µg per 24 hours (Mirena) for the treatment of heavy menstrual bleeding.
  - (iii) 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 LARCs;
  - (ii) proposals that involve listing hormonal LARCs with a partial subsidy;
  - (iii) proposals that involve an end date for a risk-sharing arrangement; 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.
- (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 23 April 2010**. 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 **Christine Chapman**, Therapeutic Group Manager, either by facsimile (+64 4 460 4995) or email ([christine.chapman@pharmac.govt.nz](mailto:christine.chapman@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](http://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 from 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 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.

## 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 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 hormonal LARCs 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 May 2010;
  - (ii) negotiating with submitter(s) of one or more preferred proposals in May 2010;
  - (iii) consulting on a provisional agreement in May/June 2010;
  - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after June 2010,

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 August 2010.

### Schedule 3: Current listing and market information

There is currently no subsidised market for hormonal LARCs. The following information relates to the estimated subsidised contraceptive market size of hormonal LARCs. 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 hormonal LARCs. The size of the market is dependent on a number of factors and PHARMAC makes no representation as to what these factors may be or what effect they may have on the market. 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 Hormone and Contraceptive Subcommittee of PTAC reviewed long acting reversible contraception at its May 2009 meeting and recommended the listing of a hormonal LARC on the Community Pharmaceutical Schedule with no restrictions and noted that any of the currently available forms of hormonal LARC would be acceptable.

The Hormone and Contraceptive Subcommittee considered “that if access was widened to include LARC approximately 10% (maximum 20%) of patients using the copper IUD would switch to levonorgestrel IUS”. The members also estimated that 10% of patients on Depo-Provera and 10% of patients on an oral contraceptive would choose to have an implant if one was funded. In total, the Subcommittee considered that approximately a total of 30% of contraceptive users would switch to implants or levonorgestrel IUS if access were widened.

The estimated number of patients on subsidised contraceptives in the community for the years ending 30 June 2007, 30 June 2008 and 30 June 2009 is shown below.

<b>Pharmaceutical</b>	<b>July 2006 to June 2007</b>	<b>July 2007 to June 2008</b>	<b>July 2008 to June 2009</b>
Copper intra-uterine devices	40,000	40,000	45,000
Combined oral contraceptives	235,000	228,000	223,000
Medroxyprogesterone acetate injections	38,000	38,000	38,000

#### Schedule 4: Proposal form

**An electronic version of this form is available on request from [christine.chapman@pharmac.govt.nz](mailto:christine.chapman@pharmac.govt.nz).**

***You should expand the boxes as necessary.***

**[Supplier to insert date]**

Chief Executive  
C/- Christine Chapman  
PHARMAC

Dear Chris

#### **Proposal for the supply of hormonal long acting reversible contraceptives**

In response to your request for proposals (**RFP**) dated 1 April 2010, we put forward the following proposal in respect of hormonal long acting reversible contraceptives.

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:

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- (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.):

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- (e) Evidence of market approval and any other required consents:

Date of market approval (please attach copy of Medsafe Gazette notice)	
Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
Expected date of dossier submission to Medsafe	

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

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

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- (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:

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(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:

## **Appendix One - Minutes of the May 2009 Hormone and Contraceptive Subcommittee of PTAC<sup>1</sup>**

### **Long Acting Reversible Contraception**

The Subcommittee considered that Long Acting Reversible Contraception (LARC) encompassed any form of contraception that required administration less than once a month. Members noted that currently PHARMAC subsidises medroxyprogesterone acetate injection (Depo-Provera) and a copper Intra-Uterine Device (IUD) for this use.

The Subcommittee considered that Depo-Provera was an effective LARC but had a high failure rate due to compliance issues. Members considered that the 3 monthly dosing, and the difficulty in remembering to attend for a dose, was the main cause of non-compliance. The Subcommittee considered that this issue explained the difference in failure rates between typical and perfect use.

The Subcommittee considered that the copper IUD was an effective LARC. Members noted that heavy menstrual bleeding meant that it was not clinically acceptable for some patients, and switching patients to levonorgestrel intra-Uterine System (IUS), Mirena, was the preferred treatment option.

The Subcommittee noted that a new copper 380A IUD was available in other countries which could be inserted for use for up to 10 years. The Subcommittee recommended that PHARMAC should investigate funding the copper 380A IUD as this provided longer protection than the currently funded Multiload Cu 375 IUD.

The Subcommittee considered that the levonorgestrel IUS provided benefits additional to contraception and noted endometrial protection in Polycystic Ovary Syndrome (PCOS), an alternative to oral progestins for women with a uterus using oestrogen replacement, and conservation of iron. Members also noted that the levonorgestrel IUS was an effective LARC and noted it may be slightly more effective than tubal ligation, although there was no direct evidence to support this.

The Subcommittee noted that there was a mild increase in the risk of sexually transmitted infections (STIs) when copper IUDs and levonorgestrel IUS were compared to other LARC.

The Subcommittee noted there were two implants available in New Zealand; currently one implant is registered (Jadelle) and one implant is likely to be registered soon (Implanon). Members noted that one Jadelle insertion is effective for up to 5 years and one Implanon insertion is effective for up to 3 years. Members considered the both implants were effective LARC methods and recommended the funding on the Pharmaceutical Schedule of either implant with a high priority.

The Subcommittee noted that there was less dysmenorrhagia associated with implants than the copper IUD, but that implants did affect bleeding patterns (irregular bleeding and amenorrhoea) with moderate rates of removal for this reason. Members noted that younger women at particularly high risk of unplanned pregnancies for whom other contraceptive methods (including combined oral contraceptives, progestogen only pills and injections and IUDs/IUSs) are unsuitable might be a target population.

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<sup>1</sup> This Minute was considered (and noted by) PTAC at its meeting on August 2009

The Subcommittee noted that both the levonorgestrel IUS and implants had to be inserted within 7 days of menstruation. The Subcommittee considered that the window of opportunity to insert a copper IUD was longer due to its use as an emergency contraceptive. Members noted that implants were potentially easier to insert (30 minute appointment and 5 minute insertion time) than levonorgestrel IUS and copper IUDs on completion of appropriate training and experience.

The Subcommittee discussed the number of visits to a clinician a patient would require for the various LARC and noted the following amounts would be adequate for the majority of patients:

	Oral Contraceptive	medroxyproges terone acetate injection	IUS/IUD	Implant
GP visits	6 monthly	2 years	6 weeks post insertion	Once only for insertion
Nurse	-	12 weekly	-	-

Members noted that there would be an appointment for removal for IUS/IUD and the implant and considered that the appointment for removal of the implant would be longer.

Members noted that approximately 10% of levonorgestrel IUS and copper IUDs move or are expelled and require reinsertion within the 5 year period.

The Subcommittee considered that the copper IUD should be considered the first line agent for LARC unless excessive menstrual bleeding made this clinically inappropriate. Members noted that excessive menstrual bleeding was dependent upon an individual's perception and for this reason difficult to quantify.

The Subcommittee considered that if access was widened to include LARC approximately 10% (maximum 20%) of patients using the copper IUD would switch to levonorgestrel IUS. The members estimated that about 10% of patients on Depo-Provera and 10% of patients on an oral contraceptive would choose to use an implant if one was funded. Approximately a total of 30% of contraceptive users would switch to implants and levonorgestrel IUS if access was widened.

The Subcommittee recommended the listing of a hormonal LARC on the Community Pharmaceutical Schedule with a high priority and no restrictions; and noted that any of the currently available forms of hormonal LARC would be acceptable.

*The Decision Criteria particularly relevant to this recommendation are:*

- (i) The health needs of all eligible people within New Zealand;*
- (ii) The particular health needs of Maori and Pacific peoples;*
- (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;*
- (iv) The clinical benefits and risks of pharmaceuticals;*
- (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;*
- (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule;*
- (vii) The direct cost to health service users;*