PHARMAC
Pharmaceutical Management Agency

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11 September 2015

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PROGESTOGEN-ONLY LONG-ACTING INTRAUTERINE SYSTEMS

PHARMAC invites proposals for the supply of progestogen-only long-acting intrauterine systems 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 4.00 p.m. on 9 October 2015.

Any questions can be sent to Bronwyn Hale, Therapeutic Group Manager, at bronwyn.hale@pharmac.govt.nz or post your questions on the Government Electronic Tenders Service (www.gets.govt.nz).

We look forward to receiving your proposal.

Yours sincerely

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 progestogen-only intrauterine systems (hereinafter referred to as **"IUS"**). This would include a levonorgestrel intrauterine system (hereinafter referred to as **"LIUS"**), as levonorgestrel is a synthetic progestogen.

For the avoidance of doubt, PHARMAC is not seeking proposals from suppliers of non-hormonal intrauterine devices (hereinafter referred to as **"IUDs"**) or of hormonal long acting reversible contraceptives in the form of an implant.

2. Background to RFP

The background to this RFP is as follows:

(a) PHARMAC currently lists the 20 mcg/24 hr LIUS (Mirena) in Section B of the Pharmaceutical Schedule (for Community use) subject to the following Special Authority criteria:

> **Initial application (no previous use)** only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
> Both:
> 1. Both of the following:
> 1.1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
> 1.2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
> 2. Any of the following:
> 2.1 serum ferritin level < 16 mcg/l (within the last 12 months); or
> 2.2 haemoglobin level < 120 g/l.
>
> **Note:** Applications are not to be made for use in patients as contraception except where they meet the above criteria.
>
> **Initial application (previous use before 1 October 2002)** only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
> 1. All of the following:
> 1.1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
> 1.2 The patient demonstrated clinical improvement of heavy menstrual bleeding; and
> 1.3 Applicant to state date of the previous insertion.
>
> **Note:** Applications are not to be made for use in patients as contraception except where they meet the above criteria.
>
> **Renewal** only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
> Both:
> 1. Any of the following:
> 1.1 The patient demonstrated clinical improvement of heavy menstrual bleeding; or
> 1.2 Previous insertion was removed or expelled within 3 months of insertion; and
> 2. And the following:
> 2.1 Applicant to state date of the previous insertion.

(b) PHARMAC currently lists a 20 mcg per day LIUS in Part II of Section H of the Pharmaceutical Schedule (for Hospital use) subject to the following restrictions:

Initiation (heavy menstrual bleeding) only from an obstetrician or gynaecologist for patients meeting the following criteria:
Both:
1. Both of the following:
   1.1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
   1.2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
2. Any of the following:
   2.1 serum ferritin level < 16 mcg/l (within the last 12 months); or
   2.2 haemoglobin level < 120 g/l; or
   2.3 the patient has had a uterine ultrasound and either a hysteroscopy or endometrial biopsy.

Continuation (heavy menstrual bleeding) only from an obstetrician or gynaecologist for patients meeting the following criteria:
Either:
   1.1 The patient demonstrated clinical improvement of heavy menstrual bleeding; or
   1.2 Previous insertion was removed or expelled within 3 months of insertion.

Initiation (endometriosis) only from an obstetrician or gynaecologist for patients meeting the following criterion:
   1.1 The patient has a clinical diagnosis of endometriosis confirmed by laparoscopy.

Continuation (endometriosis) only from an obstetrician or gynaecologist for patients meeting the following criteria:
Either:
   1.1 Patient demonstrated satisfactory management of endometriosis; or
   1.2 Previous insertion was removed or expelled within 3 months of insertion.

Note: Endometriosis is an unregistered indication.

(c) A progestogen-only LIUS was first reviewed by the Pharmacology and Therapeutics Advisory Committee (PTAC) in February 1999 for the indications of contraception and menorrhagia without associated pathology. The relevant minute is in Appendix One.

(d) On 1 October 2002, a progestogen-only LIUS (Mirena) was listed subject to a Special Authority in Section B of the Pharmaceutical Schedule for the indication of Heavy Menstrual Bleeding (HMB).

(e) The Hormone and Contraceptive Subcommittee of PTAC considered Long Acting Reversible Contraception (LARC) in August 2009 for the indication of contraception. The relevant minute can be found here.

(f) The Reproductive and Sexual Health Subcommittee of PTAC considered hormonal contraceptives in July 2014 for the indications of contraception. The relevant minute can be found here.

(g) On 1 July 2013 a progestogen-only LIUS was listed subject to restrictions in Part II of Section H of the Pharmaceutical Schedule, for the treatment of HMB. On 1 December 2013, PHARMAC widened the restrictions in Part II of Section H to include the treatment of the unregistered indication of endometriosis.

3. Types of proposals sought

(a) PHARMAC is seeking proposals for the supply of a progestogen-only LIUS:

(i) for the currently funded restrictions in Section B of the Pharmaceutical Schedule and Part II of Section H of the Pharmaceutical Schedule; and

(ii) for widening of funded access to include the indication of contraception listed in Section B and Part II of Section H of the Pharmaceutical Schedule. This may be subject to further clinical advice and analysis.

Note: widened access for contraception will be assessed on cost comparison to other currently funded contraceptives.

If you wish to submit more than one proposal, at least one must be a proposal for supply for the currently funded indications. PHARMAC is willing to consider the following types of proposals:

(i) proposals that include a period of sole subsidised supply in the community and hospital supply status 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;

(ii) proposals that include a period of subsidy protection in the community and price protection in DHB hospitals and/or protection from delisting; and

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

Any supplier awarded Sole Supply would be expected to implement training of clinicians nationwide in the use (including insertion and removal) 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.

(b) Please note proposals are not sought for the supply of:

(i) hormonal long-acting reversible contraceptives in the presentation of a contraceptive implant. Sole supply for an implant was awarded to Bayer (Jadelle) from 1 October 2014 until 31 December 2017.

(ii) a non-hormonal intrauterine device (IUD).

(iii) any progestogen-only IUS that requires administration more frequently than every three years.

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

(i) proposals that include products other than a progestogen-only IUS**;**

(ii) proposals that involve listing a progestogen-only IUS 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 to PHARMAC no later than **4.00 p.m.** (New Zealand time) on **9 October 2015, via the Government Electronic Tenders Service (GETS)**. Late proposals will only be considered at PHARMAC's discretion.

(c) If you have any inquiries about this RFP you should submit them on GETS or alternatively contact Bronwyn Hale, Therapeutic Group Manager by email at bronwyn.hale@pharmac.govt.nz.

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

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 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. The information to be taken into account in applying the decision criteria by the Evaluation Committee will be at its discretion, however it will include:

(i) the information you include in your proposal; and

(ii) any advice from PTAC, its relevant sub-committee or any relevant professional organisation; and

(iii) any relevant costs associated with the insertion and removal of the pharmaceutical.

(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 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).

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 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.

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 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 progestogen-only IUS 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 otherwise (including the Government Rules of Sourcing) and the terms of this RFP are subject to those obligations.

6. **Anticipated timetable**

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in October 2015;

(ii) negotiating with submitter(s) of one or more preferred proposals in October/November 2015;

(iii) consulting on a provisional agreement in November 2015;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after November 2015;

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 February 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 estimated subsidised market size of progestogen-only IUS (currently LIUS) in both the community and hospital.

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 progestogen-only IUS 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 wishes 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 listed in the Pharmaceutical Schedule.

The table below indicates the estimated number of dispensing's of LIUS for the currently funded indications in the community and DHB hospitals for the calendar years of 2012, 2013 and 2014.

LIUS dispensings	**2012**	**2013**	**2014**
Community	4600	4900	5300
Hospital	4000	4000	4000

The table below indicates the current list price and the number of units dispensed in the community for the following financial years, for the currently funded forms of contraception.

Pharmaceutical	**List price**	**Units dispensed**		
		2012	**2013**	**2014**
Ethinyloestrodial with levonorgestrel (30 mcg with levonorgestrel 150 mcg and 7 inert tablets) – 84 tablets	$2.30	3,741,556	5,530,718	6,547,400
Medroxyprogesterone acetate injection (150 mg per ml)	$7.00	14,4390	14,1985	14,4938
Intra-uterine device (IUD)	$31.60	6,896	7,143	10,409
Levonorgestrel subdermal implant (2 x 75 mg rods)	$133.65*	14,317	13,340	12,038

*confidential rebate exists

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*]

Bronwyn Hale
Therapeutic Group Manager
PHARMAC

Email: bronwyn.hale@pharmac.govt.nz

Proposal for the supply of a progestogen-only long-acting intrauterine system (IUS)

In response to your request for proposals (**RFP**) dated 9 October 2015, we put forward the following proposal in respect of progestogen-only IUS.

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. 52 mg)	
Initial Release Rate (e.g. 20 µg/24 h)	
Brand name	
Pack size (e.g. 1 dose unit)	
Packaging type (e.g. foil wrap)	
Duration of effectiveness	

(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) An outline of our proposed training program and timetable for regional coverage and delivery:

(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:

(j) Reasons why PHARMAC should accept our proposal:

(k) Additional information that PHARMAC should consider when evaluating our proposal including any relevant certification eg TGA, FA, CE and ISO standards:

Appendix One: Minutes of the Pharmacology and Therapeutics Advisory Committee Meeting of 25 February 1999

Levonorgestrel 20μg/24h intrauterine system (Mirena)

The committee considered an application from Schering for the listing on the Pharmaceutical Schedule of levonorgestrel 20μg/24h intrauterine system (Mirena) for use as a contraceptive device and the treatment of menorrhagia.

The committee agreed that the evidence provided by the supplier on the safety and effectiveness of Mirena was of good quality.

The committee noted that, although responsible for initial increased spotting, the device appeared to be very effective when used as a contraceptive, giving results close to sterilisation. It also noted the high incidence of amenorrhoea after 12 months of use and the high percentage of women expected to discontinue treatment after 3 years. The safety of the device during breast-feeding was also noted.

In addition, the committee acknowledged the effectiveness of the device when used for the treatment of menorrhagia. Specifically, it noted that there was good evidence on the potential of this device to avoid or delay hysterectomies in patients affected by menorrhagia.

The committee agreed that the group of patients most likely to benefit from Mirena who would be expected to switch from other contraceptive methods are multiparous women who had completed families and peri-menopausal women with menorrhagia.

Although recognising the clinical value of Mirena, especially in women affected by menorrhagia, the committee however agreed that the economics of listing required further analysis of the data provided by the supplier, particularly considering the high cost of the device and the high drop out rate at 3 years for patients using the device for contraception.

The committee therefore decided to reserve its final recommendation on the listing of Mirena until the next PTAC meeting.