PHARMAC
Pharmaceutical Management Agency

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8 October 2013

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF SOMATROPIN

PHARMAC invites proposals for the supply of somatropin 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 11 November 2013.

If you have any questions about this RFP, please contact **Christine Chapman** at PHARMAC by telephone (04) 916 7569 or email christine.chapman@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers of **somatropin** for the treatment of patient groups who are eligible for subsidised treatment in the community.

2. Background to RFP

The background to this RFP is as follows:

2.1 *Current listing in the Pharmaceutical Schedule*

(a) The following products are currently fully subsidised with a Special Authority restriction in Section B of the Pharmaceutical Schedule.

Chemical and presentation	Brand (Supplier)	Current price (excl. GST)
Somatropin inj cartridge 16 iu (5.3 mg)	Genotropin (Pfizer)	$160.00 per injection
Somatropin inj cartridge 36 iu (12 mg)	Genotropin (Pfizer)	$360.00 per injection

(b) *Special Authority criteria*

(i) The listing of somatropin in the Pharmaceutical Schedule is subject to Special Authority criteria. These criteria are available on the PHARMAC website (http://www.pharmac.govt.nz/2012/11/28/SA1279.pdf).

(ii) The following patient groups are currently eligible for funding, subject to meeting the Special Authority criteria:

1. Growth hormone deficient children;
2. Growth hormone deficient adults and adolescents;
3. Patients diagnosed with Turner syndrome;
4. Patients of short stature without growth hormone deficiency;
5. Patients of short stature due to chronic renal insufficiency including dialysis; and
6. Patients diagnosed with Prader-Willi syndrome.

3. Types of proposals sought

3.1 PHARMAC is willing to consider the following types of proposals:

(a) Proposals for the Sole Subsidised Supply of somatropin in the community and Hospital Supply Status in DHB hospitals for a period of up to, but no more than, 42

months, provided that the Sole Subsidised Supply period does not commence before 1 July 2014 and does not extend beyond 31 December 2017;

(b) Proposals for Dual Subsidised Supply of somatropin in the community for a period of up to, but no more than, 42 months, provided that the Dual Subsidised Supply period does not commence before 1 July 2014 and does not extend beyond 31 December 2017;

(c) Proposals that involve rebates; and

(d) Proposals that involve the listing of a different range of presentations to those currently subsidised.

3.2 Please note:

(a) If Sole Subsidised Supply or Dual Subsidised Supply is awarded, and a new brand is chosen, there would be a transition period of up to 6 months to allow for training of any patients and clinicians in the use of that brand of somatropin. The earliest that this transition period would commence is 1 January 2014.

(b) Any supplier that is awarded Sole Subsidised Supply or Dual Subsidised Supply shall be responsible for all costs incurred in transitioning patients and clinicians to its subsidised brand of somatropin.

(c) In the event that Dual Subsidised Supply is awarded, PHARMAC reserves the right to contract with one supplier from 1 January 2014 and contract with an alternative supplier at a later date.

(d) If you submit a proposal for Sole Subsidised Supply, you must also submit a proposal for Dual Subsidised Supply.

(e) If PHARMAC awards Sole Subsidised Supply or Dual Subsidised Supply for somatropin, this may result in the currently subsidised brand of somatropin being delisted from the Pharmaceutical Schedule.

(f) The current supplier of somatropin is currently responsible for the provision of the following goods and services, including any associated costs and service contracting, and any supplier awarded Sole Subsidised Supply or Dual Subsidised Supply of somatropin would also be responsible for:

(i) educational support and training to patients and clinicians;

(ii) needles, sharps containers and injection devices to patients;

(iii) containers and any other materials required for the delivery of somatropin to eligible patients (see Schedule Three); and

(iv) delivery of somatropin, by courier, direct to eligible patients.

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

(a) 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; or

(b) proposals that involve products other than somatropin.

Subject to sub-paragraphs (a) and (b) above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

3.4 Proposals must include information on the proposed educational support and training that would be provided by you as well as the proposed distributor and distribution process.

3.5 PHARMAC may request samples of the auto-injector device, cartridges/vials and any related consumables, and such samples must be provided within 10 working days of such a request.

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted no later than 4.00 p.m. (New Zealand time) on 11 November 2013. Late proposals will only be considered at PHARMACs 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 **Christine Chapman**, **Therapeutic Group Manager** by email to christine.chapman@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) PHARMAC may also seek external advice on proposals, including but not limited to, the New Zealand Growth Hormone Committee (NZGHC) or Adult Growth Hormone Panel as part of the evaluation process. It is anticipated that any such evaluation may include the assessment of devices, proposed education and support, potential dosing issues and any other issues that PHARMAC may deem appropriate. PHARMAC may approach submitters of proposals to provide further information on their products as part of this evaluation process.

(c) 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.helath.nz), to the extent applicable;

(ii) any clinical advice from the NZGHC or Adult Growth Hormone Panel;

(iii) the quality of patient and clinician support and education outlined in the proposal, including discussion on the proposed transition of patients to an alternative brand of somatropin where required;

(iv) the temperature stability of the pharmaceutical (specifically during the distribution process);

(v) the registration status of the pharmaceutical with Medsafe;

(vi) continuity of supply and supply record; and

(vii) 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).

(d) 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.

(e) 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 re-advertise 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 somatropin by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

(j) PHARMAC will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) in the course of consultation on a provisional agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that agreement; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

6. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in November 2013;

(ii) negotiating with submitter(s) of one or more preferred proposals in November/December 2013;

(iii) consulting on one or more provisional agreement(s) in December 2013 / January 2014;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after January / February 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 March 2014.

(c) As noted above, please be aware that if a proposal for Sole or Dual Subsidised Supply is accepted, the date of implementation of Sole or Dual Subsidised Supply will be up to 6 months from the notification date to allow for an orderly transition to any such arrangement.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of somatropin 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 somatropin and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

The number of subsidised vials of somatropin dispensed in the community for the years ending June 2010, June 2011 and June 2012 is shown below:

Pharmaceutical	Year ending 30 June 2010	Year ending 30 June 2011	Year ending 30 June 2012
Inj cartridge 16 iu (5.3 mg)	2,502	6,360	16,308
Inj cartridge 36 iu (12 mg)	57,036	72,792	91,140
Total mg dispensed (approx)	59,538	79,152	107,448

For the 2012/13 financial year, total somatropin expenditure is estimated to be approximately $3 million.

Background to somatropin management in New Zealand

- Paediatric applications for somatropin are assessed by the New Zealand Growth Hormone Committee (NZGHC), a group of three Paediatric Endocrinologists contracted by PHARMAC to determine which paediatric patients are eligible for subsidised somatropin treatment under the Special Authority criteria, and, for approved patients, the appropriate dose of somatropin. Applications are managed within PHARMAC by a Coordinator.

- Applications for adults and adolescents are assessed by the Adult Growth Hormone Panel (the Panel), a group of four Endocrinologists, contracted to PHARMAC to determine which adult and adolescent patients are eligible for subsidised somatropin treatment under the Special Authority criteria. Applications are managed within PHARMAC by a Coordinator.

- Once a patient has been approved for treatment, PHARMAC contacts the relevant supplier of somatropin notifying it of a patient's approval and provides details of the patient's NHI and clinician details. The supplier then makes contact with the treating clinician to instigate training with the patient.

- The somatropin supplier supplies injection pens, needles, sharps containers and other relevant educational material free of charge to approved patients. The supplier operates an 0800 number to answer any queries from patients and their families and through which patients can order new supplies, for example needles, sharps containers and replacement injection devices.

- Subsidised somatropin is not dispensed by retail pharmacies, PHARMAC contracts with a single pharmacy (currently based in Auckland) to dispense and package the product in

plastic containers (provided by the supplier) and distribute somatropin directly to eligible patients throughout New Zealand (it is delivered overnight, via the supplier's courier, to each patient's nominated delivery address). This pharmacy contract is in place until 30 June 2014 unless terminated earlier.

- Each month, the Coordinator generates prescriptions and an order for all patients approved for treatment. NZGHC members sign somatropin prescriptions for all paediatric patients approved for treatment. Adult and adolescent patients approved for treatment have prescriptions signed and their dose adjusted by their individual clinicians.

- The current distribution process is not "cold chain", but PHARMAC is interested in the use of better insulated containers for the distribution of somatropin particularly in the warmer months (October – March) where there is a risk of somatropin being exposed to higher temperatures.

- Currently the somatropin supplier is responsible for supplying product to the dispensing pharmacy each month and for the cost of couriering somatropin to individual patients throughout New Zealand. The supplier provides an account through which the dispensing pharmacy can order courier bags and book deliveries.

- Please note the distribution processes outlined above are currently being reviewed by PHARMAC. The way that the subsidy is claimed and that somatropin is dispensed/distributed could therefore change during the Sole Subsidised Supply period or Dual Subsidised Supply period resulting from the RFP. Any proposals for changes to the current process would be consulted on prior to a decision being made.

Schedule 4: Proposal Form

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

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Christine Chapman
Therapeutic Group Manager

By email: christine.chapman@pharmac.govt.nz

Dear Sir/Madam

Proposal for the supply of somatropin

In response to your request for proposals (**RFP**) dated 8 October 2013, we put forward the following proposal in respect of somatropin.

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. 10 mg)	
Form (e.g. solution for injection)	
Brand name	
Pack size	
Packaging type (e.g. vial)	

(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, 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 on 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:
