

5 May 2011

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF FILGRASTIM

PHARMAC invites proposals for sole supply of filgrastim (recombinant granulocyte colony-stimulating factor) to DHB Hospitals commencing on or after 1 January 2013, and also possibly to the community commencing on or after 1 January 2012.

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 17 June 2011.

If you have any questions about this RFP, please contact Sue Anne Yee at PHARMAC by telephone 04 9167 549 or email sueanne.yee@pharmac.govt.nz.

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

PHARMAC is interested in considering any proposal from suppliers of **filgrastim** (recombinant granulocyte colony-stimulating factor (**GCSF**)).

2. Background to RFP

The background to this RFP is as follows:

- Filgrastim, in presentations of 300 µg per 0.5 ml prefilled syringe, 300 µg per 1 ml vial and 480 µg per 0.5 ml prefilled syringe is currently listed in Part II and III (Discretionary Community Supply Pharmaceuticals list, hereinafter referred to as “**DCS**”) of Section H (hospital supply) of the Pharmaceutical Schedule. Filgrastim is not currently listed in Section B (community supply) of the Pharmaceutical Schedule.
- Roche’s brand of filgrastim (Neupogen) is currently the only brand listed and it has Hospital Supply Status until 31 December 2011 and is also protected from delisting in Section H until 31 December 2012.
- There are currently no rebates associated with Neupogen. Pricing is as follows:

Pharmaceutical	Brand	Presentation	Pack Size	Price
Filgrastim	Neupogen	Inj 300 µg per 0.5 ml prefilled syringe	1	\$135.00
Filgrastim	Neupogen	Inj 300 µg per 1 ml vial	5	\$650.00
Filgrastim	Neupogen	Inj 480 µg per 0.5 ml prefilled syringe	1	\$216.00

- DCS funding of filgrastim is subject to the following criteria:

Indefinite supply for any appropriate indication for the management of patients with cancer.

This listing enables hospitals to supply, from their own budgets, filgrastim to patients in the community setting.

- PHARMAC has received requests to extend DCS funding to include management of neutropenia not related to cancer such as neutropenias associated with congenital disorders, autoimmune diseases and infections.
- Pegfilgrastim (pegylated GCSF) is also currently listed in Part II of Section H of the Pharmaceutical Schedule and on the DCS list subject to the same criteria currently applying to filgrastim.
- Roche’s brand of pegfilgrastim (Neulastim) is currently the only brand listed. Neulastim has protection from delisting until 31 December 2012 and is listed at a

price of \$1,395.00 per injection (6 mg per 0.6ml prefilled syringe). There is a discount on invoice for Neulastim which reduces its net effective price to DHB Hospitals.

- PHARMAC now seeks proposals for sole supply of filgrastim to DHB hospitals, and also possibly via listing in the community Pharmaceutical Schedule.

3. Types of proposals sought

(a) PHARMAC is willing to consider the following types of proposals:

Exclusivity and access

- (i) Proposals for Hospital Supply Status of filgrastim for a period of up to, but not more than 3 years, provided that the Hospital Supply Status period does not commence before 1 January 2013 and does not extend beyond 31 December 2015; and/or
- (ii) Proposals for community Sole Subsidised Supply of filgrastim for a period of up to, but no more than, 4 years, provided that the Sole Subsidised Supply period does not commence before 1 January 2012 and does not extend beyond 31 December 2015; and/or
- (iii) Proposals for DCS funding restricted via the current DCS criteria and proposals that include widening of access to filgrastim; and/or
- (iv) Proposals for community Sole Subsidised Supply to be restricted via Special Authority criteria similar to current DCS criteria, and also proposals that include widening of access to filgrastim via alternative Special Authority criteria, or removal of criteria.

Commercial options

- (v) Proposals that include expenditure caps, rebates or other risk-sharing arrangements; and/or
- (vi) Proposals that include the listing of different presentations or strengths of filgrastim to those currently listed; and/or
- (vii) Proposals that include cross-deal or bundling arrangements with other pharmaceuticals including, for example pegylated granulocyte colony-stimulating factor.

Requirement for status quo proposal

(b) Please note:

- If you submit a combined proposal for both Hospital Supply Status and community Sole Subsidised Supply you must also submit individual proposals for Hospital Supply Status and community Sole Subsidised Supply alone.
- If you submit a proposal for widened access to filgrastim on the DCS list and/or in the community Pharmaceutical Schedule, you must also submit a proposal for access similar to the current DCS criteria.

- If you provide a proposal including pharmaceuticals other than filgrastim you must provide at least one proposal that only includes filgrastim.

Information requirements for clinical evaluation

- (c) Where a change in brand or access is being considered as a result of a proposal(s) it is anticipated that clinical advice would be sought from relevant experts; therefore your proposal must include:
- (i) Details of any educational support and training activity that would be provided to clinicians, pharmacists and patients to support the product(s).
 - (ii) Where applicable, a summary of registration (and other) data supporting the claim of equivalence to Neupogen, and commentary/data on the international use of the filgrastim product. Where such information is not available, an expected timeline for provision of such information should be provided.
 - (iii) Provision of a sample pack for each strength and presentation of filgrastim included in the proposal, and, if supply is intended to be in a different form from that sample pack, information about the form in which they will be supplied. If sample packs contain active filgrastim (i.e rather than placebo) they should be addressed to PHARMAC, care of the Medical Director.

Exclusions

- (d) PHARMAC is **not** willing to consider the following types of proposals:
- (i) Proposals that do not include filgrastim; or
 - (ii) Proposals that involve listing filgrastim with a partial subsidy; or
 - (iii) Two part pricing arrangements, whereby PHARMAC is required to make up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

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 17 June 2011**. 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 **Sue Anne Yee** either by facsimile (+64 4 460 4995) or email (sueanne.yee@pharmac.govt.nz). **Email is preferred.**

2. **Evaluation**

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff (including PHARMAC's General Counsel) 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) the quality of patient and clinician support and education outlined in the proposal, including issues relating to the transition of patients to an alternative brand of filgrastim if required;
 - (iv) the registration status of the pharmaceutical with Medsafe;
 - (v) continuity of supply and supply record;
 - (vi) 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, 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 of 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 filgrastim 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 **June 2011**;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in **July 2011**;
 - (iii) consulting on a provisional agreement in **August 2011**;
 - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after **August 2011**,

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 **January 2012**.

Schedule 3: Current listing and market information

The following information relates to the current market size of filgrastim being sold to DHB hospitals. PHARMAC does not currently subsidise filgrastim 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 future sales of filgrastim 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 filgrastim vials and pre-filled syringes sold to DHB hospitals for the years ending June 2008, June 2009 and June 2010 are shown below:

Pharmaceutical	2008	2009	2010
Inj 300 µg per 0.5 ml prefilled syringe	22,735	22,825	17,846
Inj 300 µg per 1 ml vial	9,570	3,230	1,270
Inj 480 µg per 0.5 ml prefilled syringe	2,201	3,656	5,787

Schedule 4: Proposal form

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

[Supplier to insert date]

Sue Anne Yee
PHARMAC
Level 9
40 Mercer Street
PO Box 10-254
Wellington
New Zealand

Dear Sue Anne

Proposal for the supply of filgrastim

In response to your request for proposals (**RFP**) dated 5 May 2011, we put forward the following proposal in respect of filgrastim.

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. 300 µg per 0.5 ml)	
Form (e.g. prefilled syringe)	
Brand name	
Pack size (e.g. 1)	

(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, 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)	
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:

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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) Reasons why PHARMAC should accept our proposal:

- (j) Summary of registration data supporting the claim of biosimilarity and any international clinical experience, if applicable (may be provided separately):

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