PHARMAC
Pharmaceutical Management Agency

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28 February 2014

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ERYTHROPOIETIN

PHARMAC invites proposals for the supply of erythropoietin 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 1 April 2014.

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

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of erythropoietin. Proposals should be in relation to the supply of erythropoietin only and should not include any other pharmaceuticals.

2. Background to RFP

The background to this RFP is as follows:

2.1 *Current listing in the Pharmaceutical Schedule*

(a) The following erythropoietin products are currently fully subsidised subject to Special Authority restrictions in Section B of the Pharmaceutical Schedule (community listings) and are listed on the Hospital Medicines List (HML; Part II of Section H of the Pharmaceutical Schedule) with restrictions (see the following page for details of restrictions):

Erythropoietin alpha presentation	Current list price* (ex-manufacturer, excluding GST)	Brand (Supplier)
Inj 1,000 iu, prefilled syringe, 6 inj pack	$48.68	Eprex (Janssen-Cilag)
Inj 2,000 iu, prefilled syringe, 6 inj pack	$120.18	
Inj 3,000 iu, prefilled syringe, 6 inj pack	$166.87	
Inj 4,000 iu, prefilled syringe, 6 inj pack	$193.13	
Inj 5,000 iu, prefilled syringe, 6 inj pack	$243.26	
Inj 6,000 iu, prefilled syringe, 6 inj pack	$291.92	
Inj 10,000 iu, prefilled syringe, 6 inj pack	$395.18	

**Prices subject to confidential rebate*

Erythropoietin beta presentation	Current list price* (ex-manufacturer, excluding GST)	Brand (Supplier)
Inj 2,000 iu, prefilled syringe, 6 inj pack	$120.18	NeoRecormon (Roche)
Inj 3,000 iu, prefilled syringe, 6 inj pack	$166.87	
Inj 4,000 iu, prefilled syringe, 6 inj pack	$193.13	
Inj 5,000 iu, prefilled syringe, 6 inj pack	$243.26	
Inj 6,000 iu, prefilled syringe, 6 inj pack	$291.29	
Inj 10,000 iu, prefilled syringe, 6 inj pack	$395.18	

**Prices subject to confidential rebate*

2.2 *Current Special Authority criteria in Section B of the Pharmaceutical Schedule*

(a) The listing of erythropoietin in Section B of the Pharmaceutical Schedule is subject to the following Special Authority criteria:

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:
Both:
1. Both:
   1.1 patient in chronic renal failure; and
   1.2 Haemoglobin ≤ 100g/L; and
2. Any of the following:
   2.1. Both:
      2.1.1 patient is not diabetic; and
      2.1.2 glomerular filtration rate ≤ 30ml/min; or
   2.2 Both:
      2.2.1 patient is diabetic; and
      2.2.2 glomerular filtration rate ≤ 45ml/min; or
   2.3 patient is on haemodialysis or peritoneal dialysis.

Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Notes: Erythropoietin beta is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.
The Cockroft-Gault Formula may be used to estimate glomerular filtration rate (GFR) in persons 18 years and over:
GFR (ml/min) (male) = (140 - age) x Ideal Body Weight (kg) / 814 x serum creatinine (mmol/l)
GFR (ml/min) (female) = Estimated GFR (male) x 0.85

2.3 *Current HML restrictions in Part II of Section H of the Pharmaceutical Schedule*

(a) The listing of erythropoietin in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions:

Both:
1. Both:
   1.1 patient in chronic renal failure; and
   1.2 Haemoglobin ≤ 100g/L; and
2. Any of the following:
   2.1. Both:
      2.1.1 patient is not diabetic; and
      2.1.2 glomerular filtration rate ≤ 30ml/min; or
   2.2 Both:
      2.2.1 patient is diabetic; and
      2.2.2 glomerular filtration rate ≤ 45ml/min; or
   2.3 patient is on haemodialysis or peritoneal dialysis.

2.4 *PTAC recommendation to fund an erythropoietin for the treatment of anaemia associated with myelodysplasia.*

(a) Following review of a funding application for erythropoietin in myelodysplasia at its meetings in August 2012, November 2012 and February 2013, PTAC recommended that erythropoietin be funded for anaemia associated with

myelodysplasia with a low priority. PTAC recommended that it be funded subject to the following Special Authority criteria:

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 months for applications meeting the following criteria:

1. Patient has a confirmed diagnosis of myelodysplasia (MDS); and
2. Has had symptomatic anaemia with haemoglobin <100g/L and is red cell transfusion-dependent*; and
3. Patient has very low or low risk MDS based on the WHO classification based prognostic scoring system for myelodysplastic syndrome (WPSS) ; and
4. Other causes of anaemia such as B12 and folate deficiency have been excluded; and
5. Patient has a serum erythropoietin level of <500 IU/mL; and
6. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

Renewal application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

1. The patient's transfusion requirement continues to be reduced with erythropoietin treatment; and
2. Transformation to acute myeloid leukaemia has not occurred; and
3. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

*Transfusion dependence is defined as a transfusion requirement of at least 4 units of red cells per month over a period of 4 months.

Further details of PTAC's recommendations can be found at:

http://www.pharmac.health.nz/about/committees/ptac/ptac-minutes

We note that myelodysplasia is not a registered indication for the currently listed erythropoietin products.

2.5 PHARMAC now seeks proposals for the supply of erythropoietin in DHB hospitals and in the community.

3. Types of proposals sought

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

(a) Proposals for sole subsidised supply of a brand of erythropoietin in the community and DHB hospitals for a period up to, but no more than 3 years with the following conditions:

(i) If sole subsidised supply is awarded, there would be a transition period (with the length to be determined at PHARMAC's discretion) where the successful supplier's brand of erythropoietin would be available for sale or supply and subsidised or purchased but would not be the sole subsidised brand of erythropoietin, or brand of erythropoietin with hospital supply status; and

(ii) If sole subsidised supply is awarded, PHARMAC expects to reserve the right to list an alternative brand of erythropoietin on the Pharmaceutical Schedule for up to 5% of the erythropoietin market, for patients that require treatment with a specific type of erythropoietin.

(b) Proposals involving, expenditure caps, rebates, or other expenditure risk sharing mechanisms (PHARMAC notes a DHB preference for effective prices being the list prices; however risk-sharing mechanisms will be considered);

(c) Proposals for current access and restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule, respectively;

(d) Proposals that include widening of access to erythropoietin in Section B and Part II of Section H of the Pharmaceutical Schedule, for example widening access to patients with anaemia associated with myelodysplasia;

(e) Proposals that involve the listing of a different range of presentations to those currently subsidised must include, at a minimum, the same or a similar range of strengths as the currently funded strengths.

Please note: If you wish to submit a proposal for widened access as described in 3.1 (d) above, you must also submit a separate proposal for current access and restrictions as described in 3.1 (c) above.

3.2 *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 on-going subsidy) in return for the listing of erythropoietin on specific terms; and

(b) proposals that include any pharmaceuticals other than erythropoietin.

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 1 April 2014. Late proposals will only be considered at PHARMAC's discretion.

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

(d) All proposals must be submitted to PHARMAC to the attention of **Sue Anne Yee, Senior Therapeutic Group Manager** by email to sueanne.yee@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) 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.health.nz), to the extent applicable;

(ii) any clinical advice from PTAC or its relevant sub-committee;

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

(iv) the registered indications and administration routes for the pharmaceutical;

(v) continuity of supply and supply record; and

(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.

(e) Suppliers should provide PHARMAC with samples of the various presentations 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) within 10 business days from the close of the RFP.

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 erythropoietin 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 April 2014;

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

(iii) consulting on a provisional agreement in June 2014;

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

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 September 2014.

(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 erythropoietin in the community and DHB hospitals.

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 erythropoietin 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.

Erythropoietin alpha usage in the community and DHB hospitals (number of injections)						
Form and strength	**Year ending 30 June 2011**		**Year ending 30 June 2012**		**Year ending 30 June 2013**	
	Community	DHB hospital	Community	DHB hospital	Community	DHB hospital
Inj 1,000 iu, prefilled syringe	10	6	107	None	239	None
Inj 2,000 iu, prefilled syringe	60	36	26	None	1,254	None
Inj 3,000 iu, prefilled syringe	0	None	70	None	606	None
Inj 4,000 iu, prefilled syringe	224	None	666	None	3,632	34
Inj 5,000 iu, prefilled syringe	112	None	246	None	634	None
Inj 6,000 iu, prefilled syringe	16	None	29	None	1,061	None
Inj 10,000 iu, prefilled syringe	64	22	74	None	1,123	48

Erythropoietin beta usage in the community and DHB hospitals (number of injections)						
Form and strength	**Year ending 30 June 2011**		**Year ending 30 June 2012**		**Year ending 30 June 2013**	
	Community	DHB hospital	Community	DHB hospital	Community	DHB hospital
Inj 2,000 iu, prefilled syringe	18,177	720	17,615	548	16,257	628
Inj 3,000 iu, prefilled syringe	17,679	445	18,243	676	16,885	689
Inj 4,000 iu, prefilled syringe	83,554	2,023	83,988	239	80,736	743
Inj 5,000 iu, prefilled syringe	16,597	418	15,220	352	12,752	334
Inj 6,000 iu, prefilled syringe	47,470	1,553	47,835	1,285	47,277	927
Inj 10,000 iu, prefilled syringe	43,098	1,449	47,256	841	44,415	1,666

Schedule 4: Proposal form

An electronic version of this form is available from PHARMAC. You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Sue Anne Yee
Senior Therapeutic Group Manager

Email: **sueanne.yee@pharmac.govt.nz**

Dear Sir/Madam

Proposal for the supply of erythropoietin

In response to your request for proposals (**RFP**) dated 28 February 2014, we put forward the following proposal in respect of erythropoietin.

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. 1,000 IU)	
Form (e.g. injection)	
Brand name	
Pack size (e.g. 6 injections)	
Packaging type (e.g. prefilled syringe)	

(c) Key features of our proposal:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

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

Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
OR Expected date of dossier submission to Medsafe	
Insert any other consents required for pharmaceutical	

(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) 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:
