

21 May 2018

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 via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **5.00 p.m.** on **15 June 2018**.

If you have any questions about this RFP, please post these on GETS, responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely



Lisa Williams

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.

For the purposes of this RFP:

- (a) erythropoietin alfa and erythropoietin beta are considered ‘short-acting’; and
- (b) modified erythropoietin with a longer half-life (including but not limited to darbepoetin or methoxy polyethylene glycol epoetin beta) is considered ‘long-acting’.

2. Background to RFP

The background to this RFP is as follows:

Erythropoietin is a growth factor that stimulates the production of red blood cells.

Funding history of erythropoietin

Short-acting erythropoietin was first listed on the Pharmaceutical Schedule in May 1994 restricted to the treatment of chronic renal failure.

Following an RFP in 2014, erythropoietin beta was delisted following the awarding of sole supply to erythropoietin alfa. At the same time, access was widened for use in the treatment of myelodysplasia and in the hospital setting for use in patients where blood transfusion is not a viable treatment alternative.

Current Funding

The table below outlines the current Pharmaceutical Schedule listing of short-acting erythropoietin.

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
EPOETIN ALFA [ERYTHROPOIETIN ALFA]				
Inj 1,000 iu in 0.5 ml, syringe	48.68	6	✓	Eprex
Inj 2,000 iu in 0.5 ml, syringe	120.18	6	✓	Eprex
Inj 3,000 iu in 0.3 ml, syringe	166.87	6	✓	Eprex
Inj 4,000 iu in 0.4 ml, syringe	193.13	6	✓	Eprex
Inj 5,000 iu in 0.5 ml, syringe	243.26	6	✓	Eprex
Inj 6,000 iu in 0.6 ml, syringe	291.92	6	✓	Eprex
Inj 8,000 iu in 0.8 ml, syringe	352.69	6	✓	Eprex
Inj 10,000 iu in 1 ml, syringe	395.18	6	✓	Eprex
Inj 40,000 iu in 1 ml, syringe	263.45	1	✓	Eprex

►SA1469 Special Authority for Subsidy [Section B] / Restricted [part II of Section H]

Initial application — (chronic renal failure) from any specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1. Patient in chronic renal failure; and
- 2. Haemoglobin is less than or equal to 100g/L; and
- 3. Any of the following:
 - 3.1 Both:

-
- 3.1.1 Patient does not have diabetes mellitus; and
 - 3.1.2 Glomerular filtration rate is less than or equal to 30ml/min; or
 - 3.2 Both:
 - 3.2.1 Patient has diabetes mellitus; and
 - 3.2.2 Glomerular filtration rate is less than or equal to 45ml/min; or
 - 3.3 Patient is on haemodialysis or peritoneal dialysis.

Note: Erythropoietin alfa 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.

Initial application — (myelodysplasia) from any specialist. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

1. The 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, low or intermediate 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/L; and
6. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

Note: Indication marked with * is an Unapproved Indication

Renewal — (chronic renal failure) from any specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Erythropoietin alfa 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.

Renewal — (myelodysplasia) from any specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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.

Note: Indications marked with * are Unapproved Indications

Initiation [part II of Section H only] — **(all other indications)** from a Haematologist. For use in patients where blood transfusion is not a viable treatment alternative (Unapproved Indication)

Clinical Advisory Committee Advice

PHARMAC has previously sought clinical advice on erythropoietin. During the 2014 RFP process, PHARMAC received clinical advice from specialists and the Pharmacology and Therapeutics Advisory Committee (PTAC) that erythropoietin alfa and erythropoietin beta can be considered therapeutically equivalent and dose equivalent. Feedback from the Haematology and Nephrology Subcommittees of PTAC following the brand changed raised no significant clinical concerns.

PHARMAC has recently sought advice from the [Haematology](#) and Nephrology Subcommittees of PTAC (held in October 2017 and March 2018 respectively) regarding long-acting erythropoietin. Based on this advice, PHARMAC considers that long-acting agents are unlikely to provide significant health benefits over short-acting erythropoietin, but may be more convenient for some patients. PHARMAC would consider funding a long-acting erythropoietin for the treatment of chronic renal failure as a result of this RFP if the listing would be cost-neutral compared with the use of funded short-acting erythropoietin.

Reason for running the RFP

PHARMAC is aware of a number of short and long-acting erythropoietin products currently registered with Medsafe or available overseas. As a result of this competition, the purpose of this RFP is:

- (a) to reduce the total expenditure in the erythropoietin market;
- (b) to secure supply of funded short-acting erythropoietin for another three years;
- (c) to determine if funded access to a long-acting erythropoietin would be possible from within the available budget and, if so, to progress funding and secure supply of a long-acting erythropoietin via the RFP process.

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its OPPs with reference to the [Factors for Consideration](#).

3. Types of proposals sought

- (a) Suppliers wishing to submit proposals **MUST** submit proposals for community and hospital supply of short-acting erythropoietin (injections) **AND/OR** long-acting erythropoietin (injections).
- (b) All proposals for short-acting erythropoietin **MUST** include pricing for the current funding scenario (ie only short-acting erythropoietin is listed, with current access and restrictions) **AND** pricing for a scenario where a long-acting presentation is listed (for chronic renal failure) alongside short-acting erythropoietin (with current access and restrictions).
- (c) PHARMAC is willing to consider the following types of proposals:
 - (i) proposals for short-acting erythropoietin subject to the current Special Authority criteria in Section B and the current Hospital Restrictions in Part II of Section H of the Pharmaceutical Schedule.
 - (ii) proposals for long-acting erythropoietin subject to the current Special Authority and Hospital Restrictions **for the treatment of chronic renal failure only**. Note that any long-acting presentation would be listed in addition to one short-acting erythropoietin (which would be listed subject to the current Special Authority criteria and Hospital Restrictions);
 - (iii) proposals that include supply of both short-acting erythropoietin and long-acting erythropoietin, provided a supplier who submits a proposal for supply of both types of erythropoietin **MUST** also submit individual proposals for each type of erythropoietin capable of being accepted on their own;
 - (iv) proposals that involve a period of sole subsidised supply in the community and hospital supply status with a discretionary variance (DV) limit of 1% in DHB hospitals (hereinafter referred to as "Sole Supply") for a period of up to, but no more than 3 years, noting that short-acting and long-acting erythropoietin would be defined as separate pharmaceuticals for the purposes of erythropoietin Sole Supply;

- (v) proposals that involve the listing of a different range of short-acting presentations to those currently subsidised must include, at a minimum, the same or a similar range of strengths as the currently funded strengths;
 - (vi) proposals that include the following:
 - expenditure caps, rebates or other risk-sharing arrangements;
 - proposals that include a 'hard cap', where a 100% rebate exists over a certain level of expenditure, provided that the proposal also includes an alternative bid with a flat rebate structure of one net price per unit regardless of expenditure.
 - proposals that include a 'soft cap', where a rebate of less than 100% exists over a certain level of expenditure, or a tiered pricing structure where the level of rebate is linked to certain levels of expenditure, provided that a supplier also submits an alternative bid with a flat rebate structure of one price per unit regardless of expenditure;
 - (vii) proposals that include pharmaceuticals that have not yet gained all necessary Consents. Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate your ability to obtain those consents within a time frame acceptable to PHARMAC.
- (d) PHARMAC is not willing to consider the following types of proposals:
- (i) proposals that include pharmaceuticals other than erythropoietin;
 - (ii) proposals that include the widening of access to erythropoietin, or removal of restrictions from short-acting erythropoietin, although PHARMAC reserves the right at any time to widen access as a result of proposals received;
 - (iii) proposals that involve the listing of erythropoietin with a partial subsidy;
 - (iv) proposals that involve an end date for expenditure caps;
 - (v) proposals that involve foreign currency exchange rate clauses or prices linked to any index; and
 - (vi) 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.
- (e) Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.
- (f) Suppliers should provide PHARMAC with samples of the erythropoietin presentations included in the proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within 10 business days from the date specified in Schedule 2, clause 1 (b).

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 must provide for supply, at PHARMAC's discretion, under two separate pricing scenarios as stated in Schedule 1, clause 3(b): the current funding scenario or a scenario where a long-acting presentation is listed alongside the currently funded presentations. If a supplier wishes to propose different terms (such as pricing, packaging or lead times) under these two scenarios they must specify this in the proposal.
- (b) Proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **5.00 p.m.** (New Zealand time) on **15 June 2018**. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.
- (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (d) If you have any enquiries about this RFP you should submit them on GETS, responses to all enquires will be published on GETS.

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 Factors for Consideration (Factors) that form part of PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.
- (c) The requirement for PHARMAC to pursue its statutory objective means that emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.
- (d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:
 - (i) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below;
 - (ii) any advice from PTAC, its relevant subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical

advice regarding relative risks and benefits of erythropoietin following the closing of this RFP; and

- (iii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.
- (e) 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.
- (f) 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):
 - (i) detailed information about your company structure, credit status and any other relevant company information; and
 - (ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant subcommittee, any relevant professional organisations or healthcare professionals with regards to your product including evaluation of any product samples.

- (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, provided that in PHARMAC's judgment this would not be unfair to any other party.

4. Negotiation

- (a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals, in the latter case only where the acceptance of either supplier's proposal would not 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 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 PHARMAC's decision-making framework as outlined in its OPPs with reference to the [Factors for Consideration](#).
- (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.

6. Miscellaneous

- (a) PHARMAC reserves the right, having regard to probity principles:
 - (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; and
 - (viii) to readvertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from PTAC or its relevant subcommittee 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, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC 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.

7. Anticipated timetable

- (a) Following receipt of proposals, PHARMAC anticipates:
 - (i) the Evaluation Committee evaluating proposals in June/July 2018;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in July 2018;
 - (iii) consulting on a provisional agreement in July/August 2018;
 - (iv) PHARMAC's Board, or the Board's delegate, making a decision in August/September 2018,

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 November 2018.
- (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.

8. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of erythropoietin. 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.

1. Usage of erythropoietin

Usage for erythropoietin (number of individual injections) for the 2016 and 2017 financial years is shown in the following table:

Strength	2016		2017	
	Community	DHB Hospitals	Community	DHB Hospitals
Inj 1,000 iu in 0.5 ml	1,252	272	1,499	222
Inj 2,000 iu in 0.5 ml	17,799	835	16,261	733
Inj 3,000 iu in 0.3 ml	18,256	642	17,085	668
Inj 4,000 iu in 0.4 ml	90,537	3,786	86,015	3,811
Inj 5,000 iu in 0.5 ml	14,900	606	14,076	400
Inj 6,000 iu in 0.6 ml	50,191	1,997	45,970	1,698
Inj 8,000 iu in 0.8 ml	14,973	563	22,015	858
Inj 10,000 iu in 1 ml	61,989	3,823	62,672	3,337
Inj 40,000 iu in 1 ml	920	32	1,687	74
Total	270,817	12,556	267,280	11,801

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[Supplier to insert date]

Director of Operations
PHARMAC
C/- Tim Nuthall

By electronic transfer using GETS (www.gets.govt.nz)

Dear Sir/Madam

Proposal for the supply of erythropoietin

In response to your request for proposals (**RFP**) dated 21 May 2018, 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(s) (e.g. 1,000 IU)	
Form(s) (e.g. injection)	
Brand name	
Pack size (e.g. 6 injections)	
Packaging type (e.g. prefilled syringe)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	

(c) Details of pharmaceutical manufacture:

Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(d) Key features of our proposal:

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(e) 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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(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 or changed-medicine notification submission (please attach confirmation from Medsafe that this has been	

submitted)	
OR Expected date of dossier or changed-medicine notification submission to Medsafe (please provide details)	

- (g) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required:

- (h) Information about our ability to ensure the continuity of supply of the pharmaceutical, including other countries where the product is provided:

- (i) Information about our previous supply performance, existing supply commitments and relevant expertise:

- (j) 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:

- (k) Reasons why PHARMAC should accept our proposal:

- (l) Additional information that PHARMAC should consider when evaluating our proposal (e.g. if applicable, an estimate of any savings to the patient and/or health system as a result of less-frequent injections) [Please include information you consider relevant under PHARMAC's [Factors for Consideration](#) decision making framework]: