PHARMAC
Pharmaceutical Management Agency

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5 November 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ETANERCEPT

PHARMAC invites proposals for the supply of etanercept 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 **4.00 p.m.** on **3 December 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 etanercept.

2. Background to RFP

The background to this RFP is as follows:

Etanercept is a recombinant human tumour necrosis factor (TNF) inhibitor that reduces chronic inflammation and immune response activation. It is registered for a range of dermatology and rheumatology indications and is delivered by weekly or twice weekly subcutaneous injection.

Funding history of etanercept

Etanercept has been listed on the Pharmaceutical Schedule since 2003.

Currently, etanercept (Enbrel, supplied by Pfizer) is funded in New Zealand for eligible patients via Special Authority criteria.

Current Funding

The table below outlines the current listing of etanercept in Section B of the Pharmaceutical Schedule for use in the community.

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
ETANERCEPT Special Authority see SA1620 below – Retail pharmacy					
Inj 25 mg	.....	799.96	4	✓	**Enbrel**
Inj 50 mg autoinjector	.....	1,599.96	4	✓	**Enbrel**
Inj 50 mg prefilled syringe	.....	1,599.96	4	✓	**Enbrel**

Etanercept is funded subject to clinical restrictions via Special Authority for community subsidy: SA1620 – Etanercept.

Etanercept is also listed in the Hospital Medicines List (Part II of Section H of the Pharmaceutical Schedule) for use in DHB hospitals, subject to the same clinical restrictions (Hospital Restrictions) as apply to community use.

Etanercept (Enbrel) is supplied and funded through an agreement with Pfizer. Under this agreement, Enbrel has protection from subsidy reduction and delisting until 30 June 2019. Note that a confidential rebate applies to all subsidised sales of Enbrel in the community and in DHB hospitals, which reduces the net expenditure on this product.

Note that etanercept is one of two funded community TNF inhibitors (the other being adalimumab) and three hospital TNF inhibitors (the others being adalimumab and infliximab). All three products are funded subject to separate restrictions. Please refer to the Pharmaceutical Schedule for the restrictions for adalimumab and infliximab.

Clinical Advisory Committee Advice

In August 2018, the Pharmacology and Therapeutics Advisory Committee (**PTAC**) reviewed a funding application from MSD for a biosimilar etanercept and recommended that PHARMAC run a competitive process for the supply of etanercept for currently funded indications. The full minutes of the meeting are available on our website.

Reason for running the RFP

PHARMAC is aware of multiple brands of etanercept 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 etanercept market;

(b) to secure supply of funded etanercept for five years; and

(c) to determine if widened access to etanercept would be possible from within the available budget.

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 etanercept under the current Special Authority criteria in Section B and the current Hospital Restrictions in Part II of Section H of the Pharmaceutical Schedule. Please note that proposals would need to address all currently funded patients and formulations.

(b) Suppliers **may** also submit proposals for etanercept with widened access. Widening access options may require ranking[1] following analysis of the proposals received. Note that:

(i) any widening access proposals should only include indications previously considered by PHARMAC that have a positive PTAC recommendation for funding (including high, medium or low priority or cost-neutral recommendations) prior to the release of this RFP, and/or widening of access to currently funded indications. See PHARMAC's application tracker below;

https://pharmac.govt.nz/wwwtrs/ApplicationTracker.php?SearchTerm=etanercept.

(ii) PHARMAC reserves the right, at any time, to widen access to etanercept; regardless of whether or not the proposals received include a component of widening access;

(c) Proposals **may** include a period of sole subsidised supply in the community and hospital supply status in DHB hospitals (subject to a 5% DV limit) (hereinafter referred to as "**Sole Supply**"), provided that the Sole Supply period does not extend beyond 30 June 2024.

[1] Ranking would involve the proposal being ranked relative to other potential investment options that PHARMAC is currently considering.

(d) All proposals that would require a brand switch **must** include:

(i) an option that permits Enbrel to continue to be used for patients who have a clinical reason that would prevent them switching (e.g. allergic reaction to the new product); and

(ii) a six-month transition period between listing the new brand of etanercept and commencement of any Sole Supply arrangement.

(e) Proposals **may** include any of the following arrangements:

(i) expenditure caps, rebates or other risk-sharing arrangements;

(ii) proposals that include a 'hard cap', where a 100% rebate exists over a certain level of expenditure, provided that the hard cap would be for up to 5 years and then revert back to an average cost per vial (with or without rebate) thereafter. The proposal must also include an alternative bid with a flat rebate structure of one net price per unit regardless of expenditure; and

(iii) 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.

(f) PHARMAC **would** consider 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 the ability to obtain those consents within a time frame acceptable to PHARMAC.

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

(i) proposals that include pharmaceuticals other than etanercept;

(ii) proposals that include the widening of access to etanercept for indications not previously considered by PHARMAC or without a positive PTAC recommendation for funding;

(iii) proposals that include the requirement to place restrictions on other funded products, for example a proposal for etanercept to become the only funded first-line TNF inhibitor for new rheumatology and dermatology patients (which would require funding restrictions to be placed on adalimumab);

(iv) proposals that involve the listing of etanercept with a partial subsidy;

(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.

(h) Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

Samples

Suppliers should provide PHARMAC with samples of the etanercept presentations included in their 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 dated 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 will be considered as a separate proposal.

(b) Proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **4.00 p.m.** (New Zealand time) on **3 December 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 etanercept 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) For the purpose of fiscal evaluation for this RFP, PHARMAC would assess any pricing offered as commencing from 1 July 2019. Suppliers may offer proposals that include a listing or price change prior to this date; however, any fiscal impact from this earlier listing/price change would not be included in PHARMACs primary fiscal evaluation of proposals. If two or more proposals were determined by PHARMAC to be similar, having considered all the Factors for Consideration, PHARMAC may undertake a secondary fiscal evaluation where we may consider the impact of earlier list date/price changes.

(g) 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, 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 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 etanercept 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 November/December 2018;

(ii) seeking clinical advice (if necessary) in January/February 2019;

(iii) negotiating with submitter(s) of one or more preferred proposals in January/February 2019;

(iv) consulting on a provisional agreement in February/March 2019; and

(v) PHARMAC's Board, or the Board's delegate, making a decision in April/May 2019,

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 June 2019.

(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 etanercept. 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 etanercept 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 etanercept

Usage for etanercept (number of individual units and gross cost) in the community for the 2017 and 2018 financial years is shown in the following table. Note that a confidential rebate applies to all subsidised sales of etanercept in the community and in DHB hospitals, which reduces the net expenditure on this product.

Presentation	FYE 30 June 2017	FYE 30 June 2018
Inj 25 mg	2,244 Units	2,307 units
	$449,000	$461,400
Inj 50 mg autoinjector	56,724 units	62,342 units
	$22,689,000	$24,936,600
Inj 50 mg prefilled syringe	8,352 Units	8,662 Units
	$3,340,700	$3,464,700

Hospital usage for etanercept is around $20,000 per annum (gross expenditure).

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 etanercept

In response to your request for proposals (**RFP**) dated 5 November 2018, we put forward the following proposal in respect of etanercept.

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. 50 mg)	
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:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC:

(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: