

16 July 2019

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RITUXIMAB

PHARMAC invites proposals for the supply of rituximab 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 12 August 2019.

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



Andrew Davies

Acting Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers of rituximab.

2. Background to RFP

The background to this RFP is as follows:

Rituximab is a monoclonal antibody, given by intravenous (IV) infusion, that destroys B cells by acting against CD20 proteins on their surface. It is funded for numerous haematological, rheumatologic and autoimmune conditions, which include both approved and unapproved (off-label) indications¹. Rituximab is given by an extended infusion (approx. 3 hours, longer for first infusion) usually in a DHB Hospital outpatient clinic setting.

In addition to funding at a national level, there is a number of individual patients that use rituximab for various indications through the Named Patient Pharmaceutical Assessment (NPPA) funding pathway. In 2018, there were 52 initial applications (30 approvals) through NPPA for rituximab.

Current funding

Rituximab has been listed on the Pharmaceutical Schedule since 2005 subject to Special Authority restrictions (see: [SA1783 – Rituximab](#)).

The table below outlines the current listing of rituximab in the Hospital Medicines List (Part II of Section H of the Pharmaceutical Schedule) for use in DHB Hospitals.

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
RITUXIMAB – Restricted see RS1599				
Inj 10 mg per ml, 10 ml vial	1,075.50	2	✓	Mabthera
Inj 10 mg per ml, 50 ml vial	2,688.30	1	✓	Mabthera

The table below outlines the current listing of rituximab in Section B of the Pharmaceutical Schedule for the purposes of DHB claiming.

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
RITUXIMAB Special Authority see SA1783 – Retail pharmacy				
Inj 100 mg per 10 ml vial	1,075.50	2	✓	Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	✓	Mabthera
Inj 1 mg for ECP	5.64	1 mg	✓	Baxter

¹ Section 25 of the Medicines Act 1981 permits an authorised prescriber to use any medicine (approved or unapproved) for the treatment of a particular patient.

[From 1 April 2019](#), all patients treated with rituximab (for any indication) are required to have valid Special Authority approvals, and DHBs are now required to submit subsidy claims for all rituximab patients. This situation previously only applied to rituximab for its use in blood cancers.

DHBs are able to procure rituximab from a third-party compounder (a Contract Manufacturer) provided that the DHB ensures that the all of the component pharmaceuticals used in its manufacture are listed on the Pharmaceutical Schedule and comply with any national contracting obligations. The “Inj 1mg for ECP” formulation of rituximab listed in Section B of the Schedule allows DHBs to claim a subsidy for the correct number of mg provided by the compounder.

If, as a result of this process, two brands of rituximab were listed in the Schedule for use in different indications, PHARMAC would take steps to ensure that indication specificity/exclusivity also applied to rituximab procured via Contract Manufacturers.

The currently listed brand of rituximab (Mabthera, supplied by Roche) is subject to a listing agreement with PHARMAC, which included subsidy and delisting protection until 30 June 2019. Note that a confidential rebate applies to all sales of Mabthera to DHB Hospitals (including via Contract Manufacturers), which reduces the net expenditure on this product.

PHARMAC is aware of the following New Zealand patents owned by Roche relating to rituximab:

Patent Number	Expiry	Brief description
NZ528199	11 August 2019	Use of an anti-CD20 antibody to reduce the risk of relapse of B-cell lymphoma.
NZ573838	11 August 2019	Use of rituximab for maintenance therapy of low grade B-cell non-Hodgkin's lymphoma if the lymphoma has previously been treated with other therapy.
NZ585860	11 August 2019	Co-therapy of B-cell non-Hodgkin's lymphoma with an anti-CD20 antibody and chemotherapy.
NZ514914	4 May 2020	Use of an anti-CD20 antibody to treat non-malignant autoimmune diseases; rituximab is listed in a dependant claim.
NZ580116	6 April 2024	Use of rituximab for treating rheumatoid arthritis using a specific dosage and treatment regime.
NZ587776	6 April 2024	Use of rituximab to treat rheumatoid arthritis in a patient who has an inadequate response to a TNF alpha inhibitor, using a specific dosage and treatment regime and giving a specific clinical response.
NZ567709	14 November 2026	Use of rituximab to treat rheumatoid arthritis joint damage with a specific dosage and dosing regime, where patient has had an inadequate response to TNF inhibitors and has been treated with rituximab before.

PHARMAC makes no representation as to the patent status and descriptions outlined above and accepts no liability for any patent infringement that might occur as a result of this RFP process or PHARMAC's acceptance of any proposals.

Clinical Advisory Committee Advice

In February 2019, the Pharmacology and Therapeutics Advisory Committee (**PTAC**) reviewed a funding application from Celltrion for a biosimilar rituximab (CT-P10) and recommended that PHARMAC list it on the Pharmaceutical Schedule only if cost saving compared with the currently listed rituximab reference product.

The Committee considered that the evidence available to date supports the bioequivalence and therapeutic equivalence of CT-P10 compared with reference rituximab. The full minutes of the meeting are available on our [website](#).

Reason for running the RFP

PHARMAC is aware of multiple brands of rituximab currently registered with Medsafe or available overseas. In light of this competition, the purpose of this RFP is:

- (a) to reduce the total expenditure in the rituximab market;
- (b) to determine if widened access to rituximab 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**

PHARMAC is willing to consider the following types of proposals:

- (a) Suppliers wishing to submit proposals **MUST** submit proposals for intravenous rituximab for both currently funded strengths and all funded indications in the current Special Authority criteria (excluding rheumatoid arthritis), noting that many of these indications are unapproved.
- (b) Proposals **MUST** include a period of indication exclusivity (i.e. your brand of rituximab would be the only rituximab product funded in New Zealand for all indications other than rheumatoid arthritis), following a transition period, until 30 June 2023, with PHARMAC retaining the sole right, upon 6 months prior notice, to extend the access arrangements for one additional one-year period (until 30 June 2024).
- (c) Suppliers **MAY** also submit proposals for rituximab with widened access. Widening access options may require ranking² following analysis of the proposals received. Note that:
 - (i) At the time of release of the RFP, the only new indication that has been considered by PHARMAC and has a positive PTAC recommendation for funding (including high, medium or low priority or cost-neutral

² Ranking would involve the proposal being ranked relative to other potential investment options that PHARMAC is currently considering.

recommendations) is for rituximab maintenance in CD20+ low grade or follicular B-cell Non-Hodgkin's Lymphoma (NHL). See PHARMAC's application tracker below;

<https://www.pharmac.govt.nz/wwwtrs/ApplicationTracker.php?SearchTerm=rituximab>.

- (ii) PHARMAC reserves the right, at any time, to widen access to rituximab, regardless of whether or not the proposals received include a component of widening access.
- (d) All proposals that would require a brand switch for the indications other than rheumatoid arthritis **MUST** include:
- (i) an option that permits Mabthera 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 rituximab and commencement of indication exclusivity.
- (e) Proposals **MAY** include any of the following arrangements:
- (i) confidential rebates; and/or
 - (ii) 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). PHARMAC may require suppliers to demonstrate their ability to obtain the necessary Consents. RFP award would be subject to gaining all necessary consents within a timeframe acceptable to PHARMAC.
- (g) PHARMAC is **NOT** willing to consider the following types of proposals:
- (a) proposals involving any exclusivity for the rheumatoid arthritis indication;
 - (b) proposals involving pharmaceuticals or related products other than rituximab;
 - (c) proposals involving subcutaneous rituximab;
 - (d) proposals that include the widening of access to rituximab for new indications not previously considered by PHARMAC or new indications without a positive PTAC, or a relevant subcommittee, recommendation for funding;
 - (e) proposals that include a 'hard cap', where a 100% rebate exists over a certain level of expenditure;

- (f) proposals that involve foreign currency exchange rate clauses or prices linked to any index; and
- (g) 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.

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 labelling and images of the products with their proposal. Samples of the rituximab presentations included should be able to be provided upon request by PHARMAC (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 a reasonable timeframe of such a request.

Schedule 2: RFP process

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

1. Submission

- (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.
- (b) Proposals must be submitted no later than 5.00 p.m. (New Zealand time) on 12 August 2019. Late proposals will only be considered at PHARMAC's discretion, considering 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 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 particular 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 rituximab 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 March 2020. 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 PHARMAC's 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 regard 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;

- (viii) to re-advertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.
 - (c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.
 - (d) You must not at any time initiate any communication with PHARMAC, 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 rituximab 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 (or its delegate) 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 August/September 2019;
 - (ii) seeking clinical advice (if necessary) in August/September 2019;
 - (iii) negotiating with submitter(s) of one or more preferred proposals in September 2019;
 - (iv) consulting on a provisional agreement in October 2019;
 - (v) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after November/December 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, PHARMAC expects the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 March 2020.

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 rituximab under the current eligibility criteria and restrictions. 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 rituximab 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 Rituximab

Oncology usage of rituximab (comprised of either individual vials or mg from Extemporaneously Compounded Preparations (ECP) from a third-party compounder) claimed by DHB Hospitals in the 2017 and 2018 calendar years is shown in the following table.

Presentation	2017 calendar year	2018 calendar year
Inj 100 mg per 10 ml vial	1,262 vials	1,143 vials
Inj 500 mg per 50 ml vial	1,327 vials	1,260 vials
Inj 1 mg for ECP	2,267,594 mg	2,652,875 mg
Total mg	3,057,454 mg	3,397,017 mg

In the year ending 30 June 2018, there were 742 Special Authority initial approvals for non-Hodgkin's lymphoma (NHL) in its various forms and 69 Special Authority initial approvals for Chronic Lymphocytic Leukaemia (CLL).

Non-oncology usage of rituximab (number of individual vials and mg from a third-party compounder (ECP)) purchased by DHB Hospitals in the 2017 calendar year is shown in the following table.

Presentation	2017 calendar year
Inj 100 mg per 10 ml vial	243 vials
Inj 500 mg per 50 ml vial	1135 vials
Inj 1 mg for ECP	1,125,179 mg
Total mg	1,716,979 mg

Note that there is no Special Authority data prior to 1 April 2019 for non-oncology use. From 1 April 2019 PHARMAC required all patients being treated with rituximab (for any indication) to have valid Special Authority approvals.

Note that a confidential rebate applies to all oncology and DHB usage of the Mabthera brand of rituximab, which reduces the net expenditure on this product.

Widened access to NHL maintenance treatment, if progressed, would likely result in approximately 100 additional incident patients per year on 2 years maintenance. The standard dose is 375 mg/m² body surface area once every 2 months until disease progression or for a maximum period of two years (12 infusions). By year 2, this could result in approximately 800,000 additional funded mg of rituximab. A proposal for this indication has a positive PTAC recommendation and is ranked on PHARMAC's options for investment list.

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/- Katie Brownless

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

Dear Sir/Madam

Proposal for the supply of rituximab

In response to your request for proposals (**RFP**) dated 16 July 2019, we put forward the following proposal in respect of rituximab.

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. 500 mg)	
Form(s) (e.g. injection)	
Brand name	
Pack size (e.g. 1 vial)	
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:

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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 it has been submitted)	

OR Expected date of dossier or changed-medicine notification submission to Medsafe (please provide details)	
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- (g) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product for the proposed indications in New Zealand, with additional information if required:

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

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

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- (j) Proposals/suggestions (e.g. pricing, rebate 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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- (k) Reasons why PHARMAC should accept our proposal:

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- (I) Please include any additional information you consider relevant under PHARMAC's [Factors for Consideration](#) decision making framework: