PHARMAC
Pharmaceutical Management Agency

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1 August 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF SELECTIVE CYCLOOXYGENASE-2 (COX-2) INHIBITORS

PHARMAC invites proposals for the supply of selective cyclooxygenase-2 (COX-2) inhibitors in New Zealand; specifically, celecoxib and etoricoxib.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the pharmaceuticals 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 **26 August 2016**

If you have any questions about this RFP, please post these on GETS or alternatively contact Chloë Dimock by email at procurement@pharmac.govt.nz at PHARMAC.

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 oral selective cyclooxygenase-2 (COX-2) inhibitors in the 'coxib' class; specifically, celecoxib and etoricoxib.

2. Background to RFP

The background to this RFP is as follows:

Selective COX-2 inhibitors are a type of non-steroidal anti-inflammatory drug (NSAID) that directly targets COX-2, an enzyme responsible for inflammation and pain.

Funding history of selective COX-2 inhibitors

In September 2003, PHARMAC made a decision to decline the funding of the oral COX-2 inhibitors meloxicam (Mobic), celecoxib (Celebrex) and rofecoxib (Vioxx). At the time of this decision, the financial impact associated with funding COX-2 inhibitors was estimated to be substantially higher than would have been possible from within the available pharmaceutical budget. In addition, there was emerging evidence of serious cardiovascular safety concerns.[1] Subsequent to PHARMAC's decision to decline the funding of COX-2 inhibitors, rofecoxib and valdecoxib (Bextra) were withdrawn from the market, in September 2004 and April 2005, respectively, due to the cardiovascular safety concerns.

As with any treatment that is declined for funding, PHARMAC has continued to review the funding of COX-2 inhibitors as new evidence becomes available.

Current Funding

Since September 2010, meloxicam has been funded in the community with Special Authority restrictions as a second line treatment for patients with haemophilic arthropathy. PHARMAC approved the funding on the basis that it was for a very small, well-defined patient group in whom the risk:benefit profile of selective COX-2 inhibitors was considered to be favourable compared with other second-line treatment options for this patient group. Celecoxib, etoricoxib and meloxicam are also listed on the Hospital Medicines List (HML) for perioperative use for a total of up to 8 days' use.

Pharmacology and Therapeutics Advisory Committee Advice

PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) has considered COX-2 inhibitors on a number of occasions since the first funding application was received in 1999.

Most recently, in August 2014, PTAC advised that there may be some benefit of COX-2 inhibitors in patients with low cardiovascular risk who have gastrointestinal side effects from nonselective NSAIDs; patients with high-risk colonic polyps who need to be on NSAIDs; and patients on NSAIDs who have adverse effects from proton pump inhibitors.

PTAC considered that the strength and quality of evidence to support selective COX-2 inhibitors providing similar efficacy to funded NSAIDs is high. PTAC considered that, if funded, the main use of selective COX-2 inhibitors would be for chronic inflammatory pain, acute postoperative pain and acute soft tissue injury.

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[1] Grocott R, Metcalfe S. Going against the flow: the impact of PHARMAC not funding COX-2 inhibitors for chronic arthritis. N Z Med J. 2005;118(1223):U1690. http://www.pharmac.govt.nz/assets/nzmj-2005-10-07-going-against-the-flow.pdf

PTAC considered data from large long-term controlled clinical trials that have included a comparison of COX-2 selective and non-selective NSAIDs do not clearly demonstrate that the COX-2 selective agents confer a greater risk of serious adverse cardiovascular events than non-selective NSAIDs. However, the Committee considered that all selective COX-2 inhibitors are associated with increased cardiovascular risks.

PTAC recommended that selective COX-2 inhibitors be funded without restrictions only if they were no more expensive than the weighted combined average daily cost of the currently funded NSAIDs, with a low priority.

PTAC considered it may be preferable to limit it to the "coxib" class (i.e. excluding meloxicam), noting that meloxicam is not considered a 'true' COX-2 inhibitor as it inhibits COX-1 at a 15 mg dose. PTAC considered that if pricing of the "coxibs" was similar, celecoxib would be the preferred agent as it has the best evidence base for risks and benefits.

For the full August 2014 PTAC minute please refer to our website.

As a result of PTAC's advice this RFP is limited to celecoxib and etoricoxib (the two registered 'coxib' treatments in New Zealand) and excludes meloxicam.

Reason for running the RFP

Since the initial funding applications were received in 1999 and 2000, the body of evidence comparing COX-2 selective and non-selective NSAIDS has increased. PTAC has advised (August 2014) that data from large long-term controlled clinical trials to date do not demonstrate that the COX-2 selective agents confer a greater risk of serious adverse cardiovascular events than non-selective NSAIDs.

That updated advice from PTAC on COX-2 inhibitors suggests that there may be some patient groups (with low cardiovascular risks) who would derive benefit from these treatments.

PHARMAC is aware that there are a number of selective COX-2 inhibitors in the "coxib" class currently registered with Medsafe or available overseas. As a result of this significant competition, the purpose of this RFP is to obtain the best possible pricing to determine:

(a) if it is possible to achieve the pricing point referred to in PTAC's funding recommendation; i.e. a daily cost that is no more expensive than the weighted combined average daily cost of the currently funded NSAIDs (see below); and

(b) if funding a selective COX-2 inhibitors without restrictions would be possible from within the available budget, noting that PHARMAC expects that a significant proportion of the existing COX-2 inhibitor private market would switch to a funded treatment if PHARMAC were to fund a COX-2 inhibitor.

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 oral tablet or capsule presentations of 'coxib' COX-2 inhibitors (e.g. celecoxib or etoricoxib but not meloxicam), to be listed without Special Authority or hospital restrictions (ie open listing).

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

(i) proposals that include a period of subsidy protection in the community and price protection in DHB hospitals and/or protection from delisting for a period of up to, but no more than, 3 years provided that the protection period does not extend beyond 30 June 2020;

(ii) 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, three years provided that the Sole Supply period does not extend beyond 30 June 2020;

(A) Proposals for sole supply should be at the 'coxib' class level. Sole Supply at the 'coxib' class level would mean that only one 'coxib' COX-2 inhibitor would be funded.

(B) For the avoidance of doubt, awarding sole supply to a single 'coxib' would not prevent a listing, or require the delisting of, a non-coxib COX-2 inhibitor such as meloxicam.

(iii) proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms; and/or

(iv) proposals that are subject to registration approval by Medsafe within a timeframe acceptable to PHARMAC.

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

(i) proposals that include pharmaceuticals other than oral tablet or capsule presentations of 'coxib' COX-2 inhibitors;

(ii) proposals that involve an end date for expenditure caps, rebates or other risk-sharing arrangements; and

(iii) proposals that have 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.

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

(e) Suppliers should provide PHARMAC with samples of the oral tablets or capsules of the 'coxib' COX-2 inhibitor/s 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 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 **5.00 p.m**. (New Zealand time) on **26 August 2016**. 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 or alternatively contact Chloë Dimock, Procurement Manager, by email at procurement@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 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 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 'coxib' COX-2 inhibitors 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 GETS, 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 the Factors 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.

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 'coxib' COX-2 inhibitors 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.

(k) PHARMAC is bound by obligations under law and the terms of this RFP are subject to those obligations.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in September 2016;

(ii) negotiating with submitter(s) of one or more preferred proposals in September/October 2016;

(iii) consulting on a provisional agreement in November 2016;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after January 2017;

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

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is March 2017.

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 potential funded market size of 'coxib' COX-2 inhibitors. 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 'coxib' COX-2 inhibitors 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.

Note that as PHARMAC does not currently fund any 'coxib' COX-2 inhibitors in the community, usage and expenditure is shown for the funded NSAID market.

1. Usage and expenditure on funded NSAIDs

Annual community expenditure on funded NSAIDs is currently approximately $7.6 million. Usage and expenditure for the funded oral NSAID preparations (excluding oral liquid) for the 2014 and 2015 calendar years is shown in the following table:

Chemical	presentation	2014		2015	
		Units(Caps/Tabs)	Expenditure ($NZ)	Units(Caps/Tabs)	Expenditure ($NZ)
Diclofenac sodium	Tab 50 mg dispersible	322,000	$29,000	618,000	$47,000
	Tab EC 25 mg	675,000	$27,000	684,000	$26,000
	Tab EC 50 mg	4,026,000	$129,000	3,714,000	$114,000
	Tab long-acting 100 mg	2,235,000	$189,000	2,063,000	$167,000
	Tab long-acting 75 mg	19,644,000	$963,000	19,346,000	$889,000
Ibuprofen	Tab 200 mg	50,617,000	$634,000	55,204,000	$522,000
	Tab 400 mg	369,000	$10,000		
	Tab 600 mg	46,000	$2,000		
	Tab long-acting 800 mg	11,777,000	$3,188,000	12,926,000	$3,461,000
Ketoprofen	Cap long-acting 100 mg	56,000	$12,000		
	Cap long-acting 200 mg	99,000	$43,000	126,000	$54,000
Mefenamic acid	Cap 250 mg	407,000	$10,000	417,000	$10,000
Meloxicam	Tab 7.5 mg	25,000	$9,000	22,000	$8,000
Naproxen	Tab 250 mg	3,673,000	$156,000	3,762,000	$148,000
	Tab 500 mg	7,594,000	$676,000	7,586,000	$624,000
	Tab long-acting 750 mg	1,616,000	$323,000	1,607,000	$321,000
	Tab long-acting 1 g	1,341,000	$313,000	1,395,000	$326,000
Sulindac	Tab 100 mg	37,000	$4,000	37,000	$6,000
	Tab 200 mg	61,000	$13,000	62,000	$19,000
Tenoxicam	Tab 20 mg	1,333,000	$315,000	1,171,000	$179,000
Total Expenditure			**$7,045,000**		**$6,921,000**

The current weighted combined average cost per day of the funded oral NSAIDs is $0.20.

Schedule 4: Proposal form

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

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- [Insert contact name

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

Dear Sir/Madam

Proposal for the supply of selective cyclooxygenase-2 (COX-2) inhibitors

In response to your request for proposals (**RFP**) dated 1 August 2016, we put forward the following proposal in respect of [***insert pharmaceutical***].

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. 100 mg)	
Form (e.g. capsule)	
Brand name	
Pack size (e.g. 60 capsules)	
Packaging type (e.g. blister pack)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	
Indications	

(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	
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 (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

(f) Information outlining likely daily cost, including information on recommended daily dose.

(g) 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	

(h) 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:

(i) Information about our ability to ensure the continuity of supply of the pharmaceutical:

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

(k) 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:

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