PHARMAC
Pharmaceutical Management Agency

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16 December 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF METOPROLOL SUCCINATE TO DHB HOSPITALS AND/OR TO COMMUNITY PHARMACIES

PHARMAC invites proposals for the supply of metoprolol succinate controlled-release tablets (metoprolol) 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 in relation to community supply and/or hospital supply, you must submit it to PHARMAC via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **4 pm** (New Zealand time) on **Friday 27 January 2017**.

If you have any inquiries about this RFP you should submit them via GETS or alternatively contact Matthew Wolfenden, Procurement Manager, by email procurement@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of metoprolol succinate controlled release tablets.

2. Background to RFP

Clinical

Metoprolol succinate is a selective beta-blocker (it acts via the beta-1 receptor) indicated for patients with hypertension, angina, heart failure, cardiac arrhythmias (such as supraventricular tachycardia), myocardial infarction and a number of other minor indications.

Previous RFT (April 2015)

PHARMAC previously issued a Request for Tender (RFT) for the supply of metoprolol succinate and metoprolol tartrate to DHB hospitals and/or community pharmacies, on 20 April 2015. Following evaluation and consultation, in July 2015, PHARMAC notified of its decision to award Sole Supply Status in the Community and Hospital Supply Status in DHB hospitals, to AFT Pharmaceuticals Limited for its Metoprolol-AFT CR brand of metoprolol succinate, from 1 July 2016 until 30 June 2018.

Current Situation

Ongoing disruption to the continuity of supply of Metoprolol-AFT CR has occurred over the past 6-12 months, causing significant inconvenience to patients and pharmacy. PHARMAC has been working with AFT and other suppliers to organise additional stocks of metoprolol succinate to ensure continuity of supply.

PHARMAC now currently lists and fully funds the following presentations of metoprolol succinate in Section B and Section H of the Pharmaceutical Schedule, without restriction.

Chemical and presentation	Brand	Pack Size	Subsidy and price (ex-man., ex. GST)
Metoprolol succinate Tab long-acting 23.75 mg	Metoprolol-AFT CR	90	$2.39
	Myloc CR	30	$0.80
Metoprolol succinate Tab long-acting 47.5 mg	Metoprolol-AFT CR	90	$3.48
	Betaloc CR	30	$7.50
Metoprolol succinate Tab long-acting 95 mg	Metoprolol-AFT CR	90	$5.73
	Betaloc CR	30	$7.50
Metoprolol succinate Tab long-acting 190 mg	Metoprolol-AFT CR	90	$11.54
	Myloc CR	30	$3.85

Notwithstanding the outcome of the RFT issued in April 2015, PHARMAC is now in a position to open a new competitive process to seek bids for sole and dual supply of metoprolol succinate tablets in both the community and DHB hospitals; so that PHARMAC may assess the options available to secure continuity of supply for metoprolol succinate in New Zealand going forward.

Timing

The exact timing of any proposed change to the listing of metoprolol succinate on the Pharmaceutical Schedule is to be confirmed as at the date of this RFP, but as an indication, suppliers should note that a change may occur before the previously awarded sole supply period is due to expire on 30 June 2018. In any event the timings of any proposed change will be clearly communicated to the market with reasonable notice.

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals for metoprolol succinate controlled-release tablets and/or capsules of the following strengths:

- 23.75 mg; 47.5 mg; 95 mg and 190 mg.

For listing on the Pharmaceutical Schedule without any restrictions or Special Authority criteria; **and** either:

- Sole Supply Status and Hospital Supply Status, with a DV Limit of 1%, as an Additional Stock Pharmaceutical (ASP[1]) to run until 30 June 2020; **or**
- Dual Supply Status and Hospital Dual Supply Status, with a total combined Dual DV Limit of 1%, to run until 30 June 2020.

Suppliers must submit proposals for both sole and dual supply scenarios described above.

PHARMAC is willing to consider proposals that include rebates as part of this RFP.

In the event any proposal is awarded either:

- Sole Supply Status and Hospital Supply Status, the anticipated commencement of this status would be agreed between the preferred supplier and PHARMAC at the time of negotiating the provisional agreement; or
- Dual Supply Status and Hospital Dual Supply Status, the anticipated commencement of this status would be agreed between the preferred supplier and PHARMAC at the time of negotiating the provisional agreement.

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

- where your brand of metoprolol succinate does not currently hold all necessary consents required for supply in New Zealand (including Ministry of Health market approval);
- cross-deal or bundling arrangements with other pharmaceuticals; or
- 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.

In addition to the desired outcome of this RFP as stated above, PHARMAC notes that the prescribing patterns of metoprolol succinate internationally may differ to the

[1] ASP means a Pharmaceutical for which the supplier of any successful Sole Supply Status proposal would be required to hold additional stock and to report on the level of that additional stock each quarter.

prescribing patterns in New Zealand. In the event that PHARMAC takes any steps to influence prescribing patterns in New Zealand during any sole or dual supply arrangement as set out in this RFP, to be more aligned with international usage (or otherwise), PHARMAC shall consult with you prior to taking any such action and shall act in good faith with you in respect to impacts our activities may have on any national total market volume or unit volumes.

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

Schedule 2: RFP process

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

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted to PHARMAC **via the Government Electronic Tenders Service (GETS)** no later than **4.00 p.m.** (New Zealand time) on **Friday 27 January 2017**. 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 inquiries about this RFP you should submit them via GETS or alternatively contact Matthew Wolfenden, Procurement Manager, by email 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; and

(ii) 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.

(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 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 supplier(s) 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 readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, the Minister of Health or District Health Boards, with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your proposal.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of metoprolol succinate 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 **February 2017**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **February 2017**;

(iii) if applicable consulting on a provisional agreement by **March 2017**;

(iv) PHARMAC's Board or its delegate considering the provisional agreement in or after **March 2017**,

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, any date of changes to the Pharmaceutical Schedule shall be determined at the time of negotiating any provisional agreement.

(c) Please note that if a proposal for sole or dual supply is accepted, the date of implementation may be later to allow for an orderly transition to any sole supply arrangement.

7. **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: Market information

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

Chemical Name	Presentation	Unit Subsidy	Distribution	1 July 2013 – 30 June 2014	1 July 2014 – 30 June 2015
				Units	Units
Metoprolol succinate	23.75 mg (long-acting) tablet	$0.032	Community	19,826,398	20,493,883
			Hospital	168,095	168,078
	47.5 mg (long-acting) tablet	$0.047	Community	34,392,627	34,502,033
			Hospital	294,223	289,550
	95 mg (long-acting) tablet	$0.08067	Community	24,917,686	24,570,618
			Hospital	146,805	142,023
	190 mg (long-acting) tablet	$0.15533	Community	6,113,722	5,854,071
			Hospital	11,850	9,794

Schedule 4: Proposal Submission Form

An electronic version of this form is available on GETS or on PHARMAC's website at www.pharmac.govt.nz. You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Matthew Wolfenden

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

Dear Sir

Proposal for the supply of metoprolol succinate to DHB hospitals and/or to community pharmacies

In response to your request for proposals (**RFP**) dated 16 December 2016, we put forward the following proposal in respect of metoprolol succinate.

Set out below is further information in support of our proposal.

(a) Our contact details (i.e., who communications relating to the attached bid(s) should be made to):

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of pharmaceutical presentation(s):

Chemical name	
Strength (e.g. 10 mg)	
Form (e.g. tablet or capsule)	
Brand name	
Pack size (e.g. 30 tablets)	
Packaging type (e.g. Blister pack)	
Date of market approval (please attach copy of Medsafe Gazette notice)	
Lead time (Months)	
The manufacturer(s) of the finished product (and name and location of the packaging site, if different)	
The manufacturer(s) of the active ingredients	
Alternative manufacturers of the finished product and active ingredients (if any)	

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

(d) Information about our company structure:

(e) Information about our management and technical skills:

(f) Information about our financial resources:

(g) Information about our, or our supplier's, existing supply commitments:

(h) Information about our quality assurance processes (where applicable):

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

(j) Our proposed distribution and supply arrangements for metoprolol:

(k) Key features of our proposal:

(l) Information about our previous supply performance and relevant expertise:

(m) Information that would be relevant to PHARMAC's assessment of our proposal in light of the Factors for Consideration:

(n) Any additional information that PHARMAC should consider when evaluating our Proposal:

Signed for and on behalf of **<insert name of tenderer>** by

_____
<Insert name>
<Insert designation>