

5 November 2009

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ATORVASTATIN

PHARMAC invites proposals for the supply of **atorvastatin** 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 no later than **5.00 p.m.** on **Monday 7 December 2009**.

If you have any questions about this RFP, please contact Stephen Woodruffe at PHARMAC on (04) 916 7555 or email stephen.woodruffe@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely



Steffan Crausaz
Acting Chief Executive

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

1. Pharmaceutical

PHARMAC is interested in considering proposals for the sole supply of **atorvastatin** on the Pharmaceutical Schedule.

2. Background to RFP

The background to this RFP is as follows:

- Atorvastatin tablets (10 mg, 20 mg, 40 mg and 80 mg) are currently listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority restriction for full subsidy:

Atorvastatin

<p>INITIAL APPLICATION Applications only from a relevant specialist or general practitioner. Approvals valid without further renewal unless notified.</p> <p>Prerequisites (tick boxes, and write the data requested in the space provided where appropriate)</p> <p><input type="checkbox"/> Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 years and</p> <p><input type="checkbox"/> Patient has severe documented intolerance to simvastatin (blood tests are not required) or</p> <p><input type="checkbox"/> Patient has been compliant with a dose of simvastatin of 80 mg per day for at least 2 months and</p> <p><input type="checkbox"/> Patient has venous CABG and LDL cholesterol test 1: ≥ 2 mmol/litre and LDL cholesterol test 2: ≥ 2 mmol/litre (at least 1 week after test 1) or</p> <p><input type="checkbox"/> Patient does not have venous CABG and LDL cholesterol test 1: ≥ 2.5 mmol/litre and LDL cholesterol test 2: ≥ 2.5 mmol/litre (at least 1 week after test 1)</p> <p>Note: To confirm that cholesterol levels are not still improving, two lipid tests must be carried out during treatment with simvastatin 80 mg, and have results for LDL cholesterol that have reduced by <10% in the second test. The tests must be carried out while the patient is in a fasted state (with the exception of patients with IDDM).</p> <p>The following indications of intolerance to simvastatin, are known as class effects for all statins, and hence are likely to mean that the patient may also be intolerant of atorvastatin:</p> <ul style="list-style-type: none">• Constipation, flatulence (may occur in >1% of patients)• Asthenia, abdominal pain, headache (may occur in >1% of patients)• Myopathy, rhabdomyolysis (may occur in <3% of patients)• Elevated serum transaminase levels (may occur in <1% of patients) <p>Statin have been shown to be generally well tolerated in clinical studies, with the rate of discontinuation due to adverse reactions being less than 5%, and similar to the discontinuation rate for patients taking a placebo.</p>

- The current prices and subsidies for atorvastatin tablets are as follows:

Strength	Brand	Pack size	Price	Subsidy	Subsidy with Special Authority approval
10 mg	Lipitor	30	\$18.32	\$4.03	\$18.32
20 mg	Lipitor	30	\$26.70	\$5.87	\$26.70
40 mg	Lipitor	30	\$37.02	\$8.14	\$37.02
80 mg	Lipitor	30	\$110.50	\$16.28	\$110.50

- A rebate arrangement applies to Lipitor 80 mg tablets dispensed in the community. The rebate has the effect of reducing the price of the 80 mg tablet to less than the price of two 40 mg Lipitor tablets.
- No subsidy or delisting protection currently applies to Lipitor.

3. Types of proposals sought

- (a) PHARMAC is willing to consider proposals that contain either of the following two structures (note suppliers may submit more than one proposal):
- Proposals for sole community and hospital supply status (hereinafter referred to as "**sole supply**") of the currently funded strengths of atorvastatin until 30 July 2012.
 - Proposals for community and hospital supply of all the currently funded strengths of atorvastatin with delisting protection until 30 July 2011. For the avoidance of doubt, if a proposal is accepted using this structure, then the relevant brand of atorvastatin would not be delisted from the Pharmaceutical Schedule prior to 30 July 2011; however it would not exclude other brands of atorvastatin being listed, and reference pricing being applied.
- (b) Proposals submitted under either of the above two structures may also include one or more of the following:
- Widening of access to atorvastatin via removal of the Special Authority restriction that currently applies to atorvastatin. If you submit a proposal for widening of access to atorvastatin, you must also submit a proposal for the current access (i.e., supply under the current Special Authority restriction).
 - Rebates.
 - Expenditure caps.
 - Staggered timing for implementation of price reductions.

- Listing of pharmaceuticals subject to registration approval by Medsafe. Note that any such proposal is required to include as much information as possible relating to the registration of the pharmaceuticals (such as the date of submission of application for registration to Medsafe, details of any requests for further information from Medsafe, and the anticipated timing of registration approval).
- (c) PHARMAC is not willing to consider the following types of proposals:
- Proposals that include pharmaceuticals other than atorvastatin.
 - 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.

Please note:

- If a proposal for sole supply of atorvastatin is accepted and the successful supplier's brand of atorvastatin is not currently listed in Section B of the Pharmaceutical Schedule, there may be a transition period where the successful supplier's brand is to be available for sale or supply and subsidised or purchased but would not be the sole subsidised brand of atorvastatin, or brand of atorvastatin with hospital supply status.
- Any transition period, including the timing of and relevant details of the transition, is at PHARMAC's absolute discretion.
- PHARMAC would be more likely to accept a proposal that included widening of access to atorvastatin (ie removing of the current atorvastatin Special Authority restriction) if the cost of atorvastatin, or marginal cost of atorvastatin (by way of an expenditure cap and rebate), is in line with, or lower, than the current simvastatin pricing on a dose equivalence basis.
- PHARMAC considers that the dose equivalence of atorvastatin and simvastatin is 1:2 (ie 10 mg atorvastatin = 20 mg simvastatin).

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 **Monday 7 December 2009**. Late proposals will only be considered at PHARMAC's discretion.
- (c) You must provide samples of the atorvastatin tablets that you would supply and the packaging you would supply them in with your proposal. If you are unable to provide samples by 7 December 2009, you should indicate in your proposal when samples will be provided. If you intend supplying atorvastatin in a different form or packaging from that sample, information about the form and packaging in which it will be supplied should also be provided.
- (d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (e) All proposals must be submitted to PHARMAC to the attention of **Stephen Woodruffe**, Therapeutic Group Manager, either by facsimile or email. **Email is preferred** (see page 1 for contact details).

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 basis on which the Evaluation Committee will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are to be determined by the Evaluation Committee at its sole discretion. The matters to be taken into account by the Evaluation Committee will, however, include:
 - (i) the decision criteria set out in PHARMAC's then current Operating Policies and Procedures (**OPPs**), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable;
 - (ii) any clinical advice from PTAC or its relevant sub-committee;
 - (iii) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).
- (c) 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.

- (d) 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, in which case you must supply that information within 10 business days of PHARMAC requesting it.
- (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.

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 PHARMAC's Chief Executive 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 PHARMAC's Chief Executive under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.
- (d) If the Board or the Chief Executive 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 the termination of the RFP process, whether because the Board or the Acting Chief Executive has approved one or more provisional agreements or otherwise.

6. **Miscellaneous**

- (a) PHARMAC reserves the right:
 - (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, or parties working on your behalf, 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 Chief Executive.
- (d) You, or parties working on your behalf, 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 atorvastatin 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**

Following receipt of proposals, PHARMAC anticipates:

- (a) the Evaluation Committee evaluating proposals in December 2009;
- (b) negotiating with submitter(s) of one or more preferred proposals in December 2009/January 2010;
- (c) consulting on a provisional agreement in January/February 2010; and
- (d) PHARMAC's Board or Chief Executive considering this provisional agreement in or after February/March 2010,

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.

Schedule 3: Current HMG CoA Reductase Inhibitors (Statins) listings and market information

The following information relates to the estimated market size of the various strengths of atorvastatin, simvastatin and pravastatin that are currently listed in Section B of the Pharmaceutical Schedule (atorvastatin and pravastatin are currently listed under Special Authority criteria).

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 any strengths of atorvastatin 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 and presentation	Number of tablets dispensed for the year ending June 30		
	2007	2008	2009
Atorvastatin			
Tab 10 mg	2,991,163	3,846,559	4,850,491
Tab 20 mg	4,596,081	5,511,298	6,855,544
Tab 40 mg	6,647,610	7,355,687	8,560,113
Tab 80 mg	Not subsidised	Not subsidised	31,548
Simvastatin			
Tab 10 mg	9,396,735	9,922,132	10,746,787
Tab 20 mg	45,358,584	46,896,902	50,342,025
Tab 40 mg	36,955,041	39,845,751	43,910,290
Tab 80 mg	2,056,170	2,781,831	3,712,324
Pravastatin			
Tab 10 mg	480	2,184	2,344
Tab 20 mg	1,275	5,167	8,696
Tab 40 mg	854	2,348	5,362

Schedule 4: Proposal form

An electronic version of this form is available on request from PHARMAC. You should expand the boxes as necessary.

[Supplier to insert date]

Chief Executive
C/- Stephen Woodruffe
Therapeutic Group Manager
PHARMAC
Level 9
40 Mercer Street
Wellington
New Zealand

By facsimile: (04) 460 4995

By email: stephen.woodruffe@pharmac.govt.nz

Dear Stephen

Proposal for the supply of atorvastatin

In response to your request for proposals (**RFP**) dated **5 November 2009**, we put forward the following proposal in respect of atorvastatin.

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	
Strengths (e.g. 5mg)	
Form (e.g. tablet)	
Brand name	
Pack size (e.g. 30's)	
Packaging type (e.g. blister)	

(c) Key features of our proposal:

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

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(e) 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	
Insert any information relevant to market approval or any other consents required for the pharmaceutical	

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

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

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(h) Reasons why PHARMAC should accept our proposal:

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

(j) Samples of the pharmaceuticals included in this proposal have been forwarded to PHARMAC (delete as appropriate): Yes/No. If No, please indicate when samples will be provided.