

13 September 2011

Dear Supplier

REQUEST FOR PROPOSALS –SOLE SUPPLY OF CANDESARTAN

PHARMAC invites proposals for the sole subsidised supply of **candesartan** in New Zealand.

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

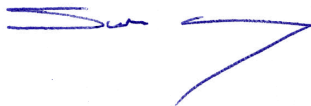
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated 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. (New Zealand time) on Monday 10 October 2011.

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 from suppliers for sole supply of candesartan in the community and DHB hospitals (Sections B and H of the Pharmaceutical Schedule).

2. Background to RFP

Two brands of candesartan tablets (4 mg, 8 mg, 16 mg and 32 mg) are currently listed in the Pharmaceutical Schedule. Candesartan is fully funded for patients in accordance with the following prices/subsidies (no rebates currently apply), Special Authority access criteria and daily dose restrictions:

Candesartan prices and subsidies:

Strength	Brands	Pack size	Price and Subsidy*
4 mg	Atacand	30	\$16.22
	Candestar		
8 mg	Atacand	30	\$19.30
	Candestar		
16 mg	Atacand	30	\$23.54
	Candestar		
32 mg	Atacand	30	\$38.50
	Candestar		

*Requires Special Authority approval and compliance with the daily dose restrictions

Candesartan Special Authority access criteria:

Candesartan

INITIAL APPLICATION
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick boxes where appropriate)

Patient with congestive heart failure
and

Has been treated with, and cannot tolerate, two ACE inhibitors, due to persistent cough
or

Has experienced angioedema on an ACE inhibitor at any time in the past or who have experienced angioedema (even if not using an ACE inhibitor) in the last 2 years

or

Patient with raised blood pressure
and

Use of fully funded beta blockers or diuretics are contraindicated; or not well tolerated; or insufficient to control blood pressure adequately at appropriate doses
and

Has been treated with, and cannot tolerate, two ACE inhibitors, due to persistent cough
or

Has experienced angioedema on an ACE inhibitor at any time in the past or who have experienced angioedema (even if not using an ACE inhibitor) in the last 2 years

Candesartan daily dose restrictions:

Tablet Strength	Daily dose restriction
4 mg	No more than 1.5 tab per day
8 mg	No more than 1.5 tab per day
16 mg	No more than 1 tab per day
32 mg	No more than 1 tab per day

In addition to the above Candestar has subsidy and delisting protection until 30 June 2012.

PHARMAC now seeks proposals for community and hospital sole supply of candesartan.

3. Types of proposals sought

- (a) PHARMAC is seeking proposals for sole subsidised supply of candesartan in the Community and the DHB hospitals (Sections B and H of the Pharmaceutical Schedule).
- (b) Proposals should be for the sole supply of candesartan for a period of up to, but not more than 3 years, with the sole supply period not starting before 1 July 2012. Please note that if a proposal for sole supply is accepted then:
 - (i) The sole supply period may not start from 1 July 2012 as there would be a transition period (the length and timing of any transition period would be determined at PHARMAC's sole discretion). In any transition period the successful supplier's brand would be listed in the Pharmaceutical Schedule alongside the current brands, until all brands (except the brand that has been awarded sole supply status) are delisted from the Pharmaceutical Schedule.
 - (ii) The supplier awarded sole supply, if their brand of candesartan is not already listed, could be listed at the current prices and subsidises as soon as practicable and prior to any sole supply and transition periods.
- (c) Suppliers should submit pricing for candesartan tablets under each of the following scenarios:
 - (i) Candesartan access remains restricted – however the dispensing restrictions would be removed and the Special Authority access criteria would be widened to the following:

INITIAL APPLICATION - ACE inhibitor intolerance Applications from any relevant practitioner. Approvals valid without further renewal unless notified. Prerequisites (tick boxes where appropriate) <input type="checkbox"/> Patient has persistent ACE inhibitor induced cough that is not resolved by ACE inhibitor retrial (same or new ACE inhibitor) or <input type="checkbox"/> Patient has a history of angioedema
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INITIAL APPLICATION - Unsatisfactory response to ACE inhibitor Applications from any relevant practitioner. Approvals valid without further renewal unless notified. Prerequisites (tick box where appropriate) <input type="checkbox"/> Patient is not adequately controlled on maximum tolerated dose of an ACE inhibitor

- (ii) Candesartan access is not restricted – both the dispensing restrictions and the Special Authority access criteria requirements would be removed making candesartan open listed with no restrictions.
- (d) Proposals should include the following:
- (i) the presentations and type of packaging;
 - (ii) the proposed prices;
 - (iii) information on the registration status of the product in New Zealand (proposals subject to registration approval by Medsafe are acceptable);
 - (iv) the supplier's own rationale for PHARMAC's acceptance of the proposal; and,
 - (v) a sample of the products.
- (e) Proposals may not include:
- (i) rebates;
 - (ii) expenditure caps;
 - (iii) 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; or
 - (iv) any products that are not included in this RFP.
- (f) Subject to the above, PHARMAC is open to considering any other types of proposals that 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 no later than **5.00 p.m. (New Zealand time) on 10 October 2011**. Late proposals will only be considered at PHARMAC's discretion.
- (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (d) All proposals must be submitted to **PHARMAC** to the attention of **Stephen Woodruffe**, Therapeutic Group Manager, either by facsimile (+64 4 460 4995) or email (stephen.woodruffe@pharmac.govt.nz). Email is preferred.

2. Evaluation

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal.
- (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 suppliers 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 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 either:
 - (i) the Board's or its Chief Executive's decision to accept a negotiated agreement; or
 - (ii) the termination of the RFP process.

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 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;
 - (vi) 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,
 - (vii) 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 yours or their proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or Chief Executive.
 - (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 candesartan 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 October/November 2011;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in October/November 2011;
 - (iii) consulting on a provisional agreement in November 2011;
 - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in November 2011/January 2012;

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

- (b) Please note that the date of sole supply implementation is at PHARMAC's discretion and may include an arrangement to allow for an orderly transition to a sole supply arrangement.

Schedule 3: Current listing and market information

The following information relates to the current listings and subsidised market size of candesartan tablets. The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or to the level of sales or likely sales of candesartan 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.

The number of candesartan tablets subsidised in the Community since July 2008 is shown below:

Presentation	July 2008 – June 2009	July 2009 – June 2010	July 2010 – June 2011
Tab 4 mg	2,614,811	2,838,655	3,099,693
Tab 8 mg	5,082,828	5,582,428	6,002,994
Tab 16 mg	4,318,238	4,898,072	5,499,148
Tab 32 mg	1,461,253	2,137,676	2,811,168

In the July 2010 to June 2011 financial year, candesartan equated to an expenditure of \$13.5 million. We note that the above data for the July 2010 to June 2011 period includes actual pharmacy claims but also some forecasted data for recent months where the pharmacy claiming data is not yet complete.

The number of candesartan tablets used in DHB hospitals since July 2008 are shown below:

Presentation	July 2008 – June 2009	July 2009 – June 2010	July 2010 – June 2011
Tab 4 mg	31,494	34,106	28,592
Tab 8 mg	60,135	60,875	58,170
Tab 16 mg	13,236	20,725	29,792
Tab 32 mg	1,492	2,010	1,532

Schedule 4: Proposal form

An electronic version of this form is available on request from stephen.woodruffe@pharmac.govt.nz.

You should expand the boxes as necessary.

[Supplier to insert date]

Stephen Woodruffe
PHARMAC
Level 9
Simpl House
40 Mercer Street
Wellington

By email: stephen.woodruffe@pharmac.govt.nz or facsimile (+64) 4 460 4995 (email is preferred).

Samples should be sent to the above address.

Dear Stephen

Proposal for the sole supply of Candesartan

In response to your request for proposals (**RFP**) dated 13 September 2011 we put forward the following proposal in respect of candesartan.

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:

Product	
Strength (eg 25 mg)	
Form (eg tablet)	
Brand name	
Pack size (tablets per pack)	
Packaging type (eg 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]	
<i>Insert any other consents required for pharmaceutical</i>	

(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) Proposals/suggestions regarding the product not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

- (i) Reasons why PHARMAC should accept our proposal:

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

- (k) Information regarding the provision of samples to PHARMAC (i.e. when PHARMAC can expect to receive product samples):