5 September 2007

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ALENDRONATE SODIUM

PHARMAC invites proposals for the supply of alendronate sodium 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 19 October 2007.

If you have any questions about this RFP, please contact Sean Dougherty at PHARMAC by telephone on (04) 916 7534 or email sean.dougherty@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Matthew Brougham
Acting Chief Executive
Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of products containing alendronate sodium (hereinafter referred to as “alendronate”).

2. Background to RFP

The background to this RFP is as follows:

- The following presentations of alendronate are currently listed on the Pharmaceutical Schedule, under Special Authority restriction in respect of community supply, for the prevention and treatment of osteoporosis and for the treatment of Paget’s disease of the bone (as applicable):

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Price and subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate sodium tab 40 mg</td>
<td>Fosamax</td>
<td>30</td>
<td>$133.00</td>
</tr>
<tr>
<td>Alendronate sodium tab 70 mg</td>
<td>Fosamax</td>
<td>4</td>
<td>$35.91</td>
</tr>
<tr>
<td>Alendronate sodium tab 70 mg</td>
<td>Fosamax Plus</td>
<td>4</td>
<td>$35.91</td>
</tr>
<tr>
<td>with cholecalciferol 2800 iu</td>
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<td></td>
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</tbody>
</table>

- The following presentation of alendronate has previously been (but is not currently) listed on the Pharmaceutical Schedule:

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Brand</th>
<th>Pack size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate sodium tab 10 mg</td>
<td>Fosamax</td>
<td>30</td>
</tr>
</tbody>
</table>

- The following Special Authority restriction applies to the prescribing and dispensing of alendronate sodium tab 70 mg and alendronate sodium tab 70 mg with cholecalciferol 2800 iu in the community:

SA0797 Special Authority for Subsidy

Initial application — (Underlying cause – Osteoporosis) only from a relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

1. History of one significant osteoporotic fracture demonstrated radiologically and documented bone mass density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5); or

2. History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological
reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or

3 History of two significant osteoporotic fractures demonstrated radiologically; or

4 Documented T-Score ≤ -3.0.

Initial application — (Underlying cause – glucocorticosteroid therapy) only from a relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The patient is receiving systemic glucocorticosteroid therapy (≥ 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months and has either; and

2 Either:

2.1 documented BMD ≥ 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -1.5); or

2.2 history of one significant osteoporotic fracture demonstrated radiologically.

Renewal only from a relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is continuing systemic glucocorticosteroid therapy (≥ 5 mg per day prednisone equivalents).

Notes:

a) Evidence used by National institute for Clinical Excellence (NICE) guidance indicates that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score ≤ -2.5, and therefore do not require BMD measurement for treatment with bisphosphonates.

b) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

c) In line with the Australian guidelines for funding alendronate, a vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

The following Special Authority restriction applies to the prescribing and dispensing of alendronate sodium tab 40 mg in the community:

SA0467 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Paget’s disease; and

2 Any of the following:

2.1 Bone or articular pain; or
2.2 Bone deformity; or
2.3 Bone, articular or neurological complications; or
2.4 Asymptomatic disease, but risk of complications due to site (base of skull, spine, long bones of lower limbs); or
2.5 Preparation for orthopaedic surgery.

Renewal only from a relevant specialist. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

- Under the terms of the supply agreement with the current supplier, Fosamax 70 mg is protected from subsidy reduction in respect of community supply until 1 January 2009.

- PHARMAC now seeks proposals for both sole subsidised supply of alendronate in the community and hospital supply status for alendronate (hereinafter referred to collectively as "sole supply"). Proposals for sole supply of alendronate may include the supply of the currently available range of presentations, a range smaller than that currently available, or the supply of presentations that are not currently marketed in New Zealand. For the avoidance of doubt:
  - proposals for sole supply of alendronate do not need to include the supply of all of the currently available presentations; and
  - from the beginning of the sole supply period, PHARMAC would delist from the Pharmaceutical Schedule all listed presentations of alendronate supplied by suppliers that are unsuccessful in this RFP.

- PHARMAC understands that some suppliers may not be able to supply a 40 mg presentation (currently subsidised for the treatment of Paget’s disease of the bone), and accordingly PHARMAC is also willing to consider proposals for sole supply of alendronate where PHARMAC would have the option of subsidising one or more other suppliers’ brands of alendronate sodium in a 40 mg presentation.

3. Types of proposals sought

3.1 PHARMAC is willing to consider the following types of proposals:
  - proposals that involve sole supply of alendronate, for a period of no more than two and a half years, provided that the end of the sole supply period does not extend beyond 30 June 2011, and that the sole supply period does not commence prior to 1 January 2009;
  - proposals that involve sole supply of alendronate only for the purposes of treating and preventing osteoporosis (i.e. excluding the 40 mg presentation for Paget’s disease of the bone), for a period of no more than two and a half years, provided that the end of the sole supply period does not extend beyond 30 June 2011, and that the sole supply period does not commence prior to 1 January 2009; and
  - proposals that involve wider, or derestricted, access to alendronate.

3.2 PHARMAC is not willing to consider the following types of proposals:
• caps, rebates, or other expenditure risk sharing mechanisms;

• proposals that include pharmaceuticals other than alendronate (for the avoidance of doubt, proposals may include combination preparations that include alendronate and another pharmaceutical);

• 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; and

• parity pricing, whereby PHARMAC may reduce the subsidy payable for a pharmaceutical in a particular therapeutic sub-group to the level of the subsidy payable for a pharmaceutical in any other sub-group.

3.3 Please note:

• If a proposal for sole supply of alendronate is accepted and the successful supplier's brand of alendronate is not currently listed on the Pharmaceutical Schedule, there would be a minimum five months' transition period where the successful supplier's brand is to be available for supply and subsidised but would not be the sole subsidised brand of alendronate in the community or the brand of alendronate with hospital supply status.

• If a proposal for sole supply of alendronate is accepted and the successful supplier's brand of alendronate is currently listed on the Pharmaceutical Schedule, the supplier would be required to agree that its existing agreements in respect of alendronate will be superseded by a new agreement.

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

3.5 Please ensure that your proposal provides information about how you plan to have sufficient stock available before the sole supply period commences to enable you to supply 100% of the market during the sole supply period.
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 19 October 2007. 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 Sean Dougherty, Therapeutic Group Manager either by hand delivery or by courier to Level 14, Cigna House, 40 Mercer Street, Wellington, or by post to PO Box 10-254, Wellington 6143 (and not by facsimile or email).

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. **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).

4. **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.

5. **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 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 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 alendronate 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.

6. **Anticipated timetable**

   (a) Following receipt of proposals, PHARMAC anticipates:

      (i) the Evaluation Committee evaluating proposals in October 2007;
      
      (ii) seeking clinical advice on proposals in October/November 2007;
      
      (iii) negotiating with submitter(s) of one or more preferred proposals in November 2007;
      
      (iv) consulting on a provisional agreement in November 2007;
      
      (v) PHARMAC’s Board or Chief Executive considering this provisional agreement in or after December 2007,

   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, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 February 2008.
(c) Please note that due to the agreement in place with the current supplier of alendronate, it is likely that the earliest time that a sole supply period could begin for a different supplier is 1 April 2009.
Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of alendronate. 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 alendronate 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 table below illustrates the number of units (tablets) of alendronate that were subsidised for use in the community in each of the last three financial years.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tab 10 mg</td>
<td>594,198</td>
<td>395,618</td>
<td>0</td>
</tr>
<tr>
<td>Tab 40 mg</td>
<td>113,718</td>
<td>103,658</td>
<td>76,648</td>
</tr>
<tr>
<td>Tab 70 mg</td>
<td>1,403,428</td>
<td>2,002,558</td>
<td>2,653,810</td>
</tr>
<tr>
<td>Tab 70 mg with cholecalciferol 2800 iu</td>
<td>0</td>
<td>0</td>
<td>2,551</td>
</tr>
</tbody>
</table>

Please note:

- Alendronate tab 10 mg was delisted from the Pharmaceutical Schedule on 1 April 2006; and
- Alendronate tab 70 mg with cholecalciferol 2800 iu was listed in the Pharmaceutical Schedule on 1 June 2007.

The table below illustrates the number of units (tablets) of alendronate that were purchased for use in DHB hospitals in each of the last three financial years.

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Tab 10 mg</td>
<td>4,304</td>
<td>2,670</td>
<td>420</td>
</tr>
<tr>
<td>Tab 40 mg</td>
<td>840</td>
<td>1,020</td>
<td>1,470</td>
</tr>
<tr>
<td>Tab 70 mg</td>
<td>7,841</td>
<td>12,072</td>
<td>15,620</td>
</tr>
<tr>
<td>Tab 70 mg with cholecalciferol 2800 iu</td>
<td>0</td>
<td>0</td>
<td>120</td>
</tr>
</tbody>
</table>
Dear Sir

Proposal for the supply of alendronate sodium

In response to your request for proposals (RFP) dated 5 September 2007, we put forward the following proposal in respect of alendronate.

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

(a) Our contact details:

<table>
<thead>
<tr>
<th>Name of supplier</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Facsimile</td>
<td></td>
</tr>
<tr>
<td>Email address</td>
<td></td>
</tr>
</tbody>
</table>

(b) Details of pharmaceutical presentation:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength (e.g. 70 mg)</td>
<td></td>
</tr>
<tr>
<td>Form (e.g. tablet)</td>
<td></td>
</tr>
<tr>
<td>Brand name</td>
<td></td>
</tr>
<tr>
<td>Pack size</td>
<td></td>
</tr>
<tr>
<td>Packaging type (e.g. blister)</td>
<td></td>
</tr>
</tbody>
</table>
(c) Key features of our proposal:

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

(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 |

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

(g) Information about our previous supply performance and relevant expertise:
(h) Proposals/suggestions (e.g. pricing, etc) regarding the pharmaceutical 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: