

27 August 2007

Dear Supplier

## REQUEST FOR PROPOSALS – SOLE SUPPLY OF OMEPRAZOLE

PHARMAC invites proposals for the supply of **omeprazole 10 mg, 20 mg, and 40 mg capsules/tablets, omeprazole 40 mg infusion and omeprazole 40 mg injection** 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 **21 September 2007**.

If you have any questions about this RFP, please contact **Mike Bignall** at PHARMAC by telephone (04) 916-7562 or email [mike.bignall@pharmac.govt.nz](mailto:mike.bignall@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 **omeprazole**.

### 2. Background to RFP

The background to this RFP is as follows:

- Omeprazole, at strengths of 10 mg per capsule (**cap 10 mg**), 20 mg per capsule (**cap 20 mg**), 40 mg per capsule (**cap 40 mg**) and 40 mg per injection (**inj 40 mg**), is currently listed fully subsidised in the Proton Pump Inhibitors sub-group of the Antiulcerants section of Section B of the Pharmaceutical Schedule.
- Omeprazole, at strengths of 10 mg per capsule (**cap 10 mg**), 20 mg per capsule (**cap 20 mg**), 40 mg per capsule (**cap 40 mg**), 40 mg per infusion (**inf 40 mg**) and 40 mg per injection (**inj 40 mg**), is currently listed in Part II of Section H of the Pharmaceutical Schedule.
- The current prices and subsidies for omeprazole are shown in Schedule 3.
- The pharmaceutical omeprazole is dispensed in very high volumes by both DHB hospitals and community pharmacies. It is estimated that in excess of 200,000 patients take omeprazole in New Zealand annually on a regular basis, and many more are prescribed it over a short time period such as acute situations and during hospital stays.
- Currently, there are two different brands of omeprazole listed on the Pharmaceutical Schedule, and two other brands are expected to be listed before any Sole Supply period would commence as a result of this RFP.
- PHARMAC now seeks proposals from suppliers for both sole subsidised supply of omeprazole in the community and hospital supply status for omeprazole (hereinafter referred to collectively as "**Sole Supply**"). Sole Supply would be for a period of two and a half years (from 1 January 2009 until 30 June 2011). We anticipate that a transition period would begin in 2008 with reference pricing being applied (where contractually possible) from 1 July 2008 and all listed brands of omeprazole that are unsuccessful in this RFP being delisted from the Pharmaceutical Schedule from 1 January 2009.

### 3. Types of proposals sought

3.1 PHARMAC seeks proposals from suppliers for any or all strength(s) and presentation(s) of omeprazole. For the avoidance of doubt, PHARMAC is prepared to consider proposals for the full current range of presentations of omeprazole, or for part of the range.

3.2 In addition, PHARMAC is willing to consider the following types of proposals:

- aggregated prices for two or more strengths and presentations of omeprazole, provided individual prices are supplied for each strength and presentation of

omeprazole. You must clearly indicate in your proposal your aggregated prices compared to your individual prices;

- proposals that include rebate arrangements. Please note that any rebate arrangement would be non-confidential, and that the proportion proposed to be rebated should be no more than 50% of the proposed gross listing price; and
- proposals requesting PHARMAC's support for priority assessment of registration with the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

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

- proposals that include pharmaceuticals other than omeprazole;
- proposals that include Sole Supply for some but not all of the presentations and strengths of omeprazole contained in the proposal;
- proposals that entail a manufacturer's surcharge (i.e. where the price is higher than the subsidy paid);
- proposals for the supply of any strength or presentation of omeprazole for only the community or hospital markets (i.e. proposals must be for supply to both markets and at the same prices for both markets) except in the case of omeprazole inf 40 mg, where bids for the hospital market only will be considered;
- proposals which include changes in the listing price within the Sole Supply period; and
- proposals which include bonusing mechanisms to pharmacies and/or wholesalers. For the avoidance of doubt, suppliers of omeprazole would not be prohibited from bonusing mechanisms, however bonusing mechanisms will not be considered as part of the evaluation of any proposal.

### 3.4 Please note:

- If a proposal for Sole Supply of omeprazole is accepted and the successful supplier's brand of omeprazole is not currently listed on the Pharmaceutical Schedule, there would be a minimum six 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 omeprazole in the community or the brand of omeprazole with hospital supply status.
- If a proposal for Sole Supply of omeprazole is accepted and the successful supplier's brand of omeprazole is currently listed on the Pharmaceutical Schedule, the supplier would be required to:
  - agree that its existing agreement in respect of omeprazole will be superseded by a new agreement; and

- change its existing price for omeprazole to the price specified in its proposal (or such other price as may be agreed with PHARMAC) from the start of the transition period under the new agreement.
- 3.5 Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.
- 3.6 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 and the final three months of the transition 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 21 September 2007**. Late proposals will only be considered at PHARMAC's discretion.
- (c) Proposals for non-registered formulations of omeprazole will be considered. PHARMAC may, at its discretion, recommend to Medsafe that a particular dossier is given priority assessment for registration. If a non registered proposal is submitted, the supplier must be prepared to submit a registration dossier to Medsafe within three weeks of being advised that it is the provisional best proposal.
- (d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (e) All proposals must be submitted to PHARMAC at **Level 14 Cigna House, 40 Mercer Street, Wellington 6143, New Zealand** to the attention of Mike Bignall, Therapeutic Group Manager, either by hand delivery, by courier or by post (and not by facsimile or email). In addition to, but not instead of, providing PHARMAC with a hard copy of all proposals by hand delivery, courier or post, submitters must also provide a copy of all proposals by facsimile (+64 4 460 4995) or email ([mike.bignall@pharmac.govt.nz](mailto:mike.bignall@pharmac.govt.nz)).

### 2. Evaluation

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff (including PHARMAC's Legal Counsel) 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](http://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 agreements for omeprazole; or

- (ii) the termination of the RFP process.

## 5. **Specific Features**

Any agreement with a successful supplier for supply of omeprazole will contain the following specific features:

- sole subsidised supply in Section B of the Pharmaceutical Schedule from 1 January 2009 until 30 June 2011;
- hospital supply status in Section H of the Pharmaceutical Schedule from 1 January 2009 until 30 June 2011 with a discretionary variance (DV) limit of not less than 1%; and
- if the successful supplier's brand of omeprazole is not already listed on the Pharmaceutical Schedule, a listing date on or close to 1 January 2008 but no later 1 July 2008.

## 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 re-advertise 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 any strength or presentation of omeprazole 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 September 2007 (including medical evaluation committee if required);
  - (ii) negotiating with submitter(s) of one or more preferred proposals in October 2007;
  - (iii) consulting on a provisional agreement in October 2007; and
  - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after November 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 January 2008.

### Schedule 3: Current listing and market information

#### Listing Information

The following information relates to the current listings in Sections B and H of the Pharmaceutical Schedule and the agreements with two suppliers for future listings before the proposed Sole Supply period commences:

Supplier	Form/strength(s)	Price	Brand Name	Listing Status
Affordable Healthcare	Cap 10 mg Cap 20 mg Cap 40 mg	\$2.99 per 28 \$4.27 per 28 \$5.01 per 28	Dr Reddy's Omeprazole	To be listed from 1 October 2007
AstraZeneca	Cap 10 mg Cap 20 mg Cap 40 mg Inj 40 mg per 10 ml, vial Inf 40 mg *	\$17.37 per 30 \$24.81 per 30 \$29.05 per 30 \$12.50 per 1 \$62.50 per 5	Losec	Listed
Pacific Pharmaceuticals	Cap 10 mg Cap 20 mg Cap 40 mg	\$6.28 per 30 \$6.28 per 30 \$9.50 per 30	Omezol	Listed
Rex Medical	Cap 20 mg Inf 40 mg	\$6.28 per 30 \$10.00 per 1	Omeprazole – Rex	To be listed subject to registration

\* Note that this presentation is only listed in Section H of the Pharmaceutical Schedule

We note that a rebate applies for Losec capsules and that a price/volume adjustment applies for Omezol and Omeprazole-Rex.

#### Market Information

The following information relates to the estimated subsidised market size of omeprazole in the community, and estimated market size of omeprazole being sold to DHB Hospitals (although note PHARMAC does not currently have a percentage of market share for omeprazole in relation to sales to DHB Hospitals). 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 form or strength of omeprazole in the community or to DHB Hospitals 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 entity	Percentage market share (prescriptions) in the community in the period May 2006 to April 2007
Omeprazole	86% of all proton pump inhibitors (lansoprazole, omeprazole and pantoprazole)

The number of subsidised units (capsules or injections) for omeprazole in the community for the years ending June 2005, June 2006 and April 2007 is shown below:

<b>Pharmaceutical/form/ strength</b>	<b>Year End June 2005</b>	<b>Year End June 2006</b>	<b>Year End April 2007</b>
Omeprazole cap 10 mg	4,027,024	4,404,036	3,900,420
Omeprazole cap 20 mg	57,108,375	63,506,670	58,615,217
Omeprazole cap 40 mg	9,540,091	11,795,231	11,756,297
Omeprazole inj 40 mg	916	1,115	964

The number of units (capsules, infusions or injections) for omeprazole purchased by DHB Hospitals for the years ending June 2005, June 2006 and April 2007 is shown below:

<b>Pharmaceutical/form/ strength</b>	<b>Year End June 2005</b>	<b>Year End June 2006</b>	<b>Year End April 2007</b>
Omeprazole cap 10 mg	18,384	15,880	20,889
Omeprazole cap 20 mg	1,025,731	1,101,127	1,073,353
Omeprazole cap 40 mg	64,204	83,194	129,404
Omeprazole inf 40 mg	16,539	17,385	20,035
Omeprazole inj 40 mg	30,435	35,609	37,787

#### Schedule 4: Proposal form

*An electronic version of this form is available on PHARMAC's website at [www.pharmac.govt.nz](http://www.pharmac.govt.nz) or can be emailed to you on request. You should expand the boxes as necessary.*

**[Supplier to insert date]**

Acting Chief Executive  
C/- Mike Bignall  
PHARMAC  
PO Box 10-254  
(or for courier delivery:  
Level 14, Cigna House  
40 Mercer Street)  
Wellington  
New Zealand

Dear Mike

#### Proposal for the supply of omeprazole

In response to your request for proposals (**RFP**) dated 27 August 2007, we put forward the following proposal in respect of omeprazole.

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:

[Repeat for each strength and presentation of omeprazole – cap/tab 10 mg, cap/tab 20 mg, cap/tab 40 mg, inf 40 mg, inj 40 mg]

Chemical name	Omeprazole
Strength (e.g. 20 mg)	
Presentation (e.g. oral dosage)	
Form (e.g. capsule)	
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:

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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)	
<b>OR</b> Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
<b>OR</b> Expected date of dossier submission to Medsafe	
<b><i>Insert any other consents required for pharmaceutical</i></b>	

(f) Information about our ability to ensure the continuity of supply of the pharmaceutical and to hold sufficient stock to supply 100% of the market before the Sole Supply period commences:

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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: