

17 December 2008

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RADIOLOGICAL CONTRAST MEDIA

PHARMAC invites proposals for the supply of Radiological Contrast Media 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 13 February 2009**.

If you have any questions about this RFP, please contact Andrew Davies at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely



Matthew Brougham
Chief Executive

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

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers for the supply or provision of pharmaceuticals which fall into any of the following product groups:

<i>Product group</i>	<i>Comment</i>
non-ionic monomer	a range of concentrations suitable for intravascular or other use
non-ionic dimer	a range of concentrations suitable for intravascular or other use
ionic monomer	concentration suitable for oral use
ionic dimer	
MR for intravascular use	
MR organ specific	
oral CT (non barium)	
oral CT (barium)	
oral general (barium)	bulk volume and individual patient preparation
barium enema	including kit for administration
intravenous for ultrasound	

2. Background to RFP

The background to this RFP is as follows:

In 2006 PHARMAC requested proposals, and entered into national agreements for the supply of a range of radiological contrast media to DHB Hospitals, some of which were listed with Hospital Supply Status (HSS). HSS is due to expire for these products on 30 June 2009. We are therefore seeking proposals for new national agreements for supply of radiological contrast media to DHB Hospitals.

Of the product groups for which we are seeking proposals, the following brands are currently listed on Section H:

<i>Product group</i>	<i>Currently listed brand</i>
non-ionic monomer	Omnipaque
non-ionic dimer	Visipaque
MR for intravascular use	Magnevist
MR organ specific	Multihance
oral CT (non barium)	Gastrografin, Ioscan

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

- Proposals involving only one of the product groups specified in clause 1, Schedule 1;
- Aggregated proposals involving more than one of the product groups specified in clause 1, Schedule 1;
- Proposals involving market exclusivity up to a maximum of 95% (such as Hospital Supply Status) for any pharmaceutical included in the product groups specified in clause 1, Schedule 1, given that any exclusivity or preferred supplier status ends on or before 30 June 2012;
- Proposals involving discount on invoice, caps, bonusing, rebates, or other expenditure risk sharing mechanisms (PHARMAC notes a DHB preference for effective prices being the list prices, however risk sharing mechanisms will be considered).

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

- Proposals involving greater than 95% market exclusivity (such as Hospital Supply Status) for a pharmaceutical included in the product groups specified in clause 1, Schedule 1.
- Proposals involving pharmaceuticals not included in any of the product groups specified in clause 1, Schedule 1.

Proposals submitted should include pricing options for various levels of market exclusivity, for example 80%, 90% and 95%. Proposals submitted should also include pricing options for a standard listing arrangement with no market exclusivity.

Proposals should include an outline of the delivery device requirement, if any, for the products included, and may include proposed terms for supply of the delivery device in addition to the contrast media product if applicable.

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 no later than 5.00 p.m. (New Zealand time) on **13 February 2009**. 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 **Andrew Davies**, either by facsimile (+64 4 460 4995) or email (andrew.davies@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(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 or any other clinical advisors the Evaluation Committee considers appropriate;
 - (iii) any advice from HPAC;
 - (iv) 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 Radiological Contrast Media 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 March 2009;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in April 2009;
 - (iii) consulting on a provisional agreement in April/May 2009;

- (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after May 2009,

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 July 2009.
- (c) Please note that if a proposal for Hospital Supply Status is accepted, the date of implementation may be later to allow for an orderly transition to any sole supply arrangement.

Schedule 3: Current listing and market information

The following information relates to the estimated market size for the currently listed products. The information is based on data supplied by DHB and is approximate and indicative only. The data used is not complete, so has been extrapolated based on population. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of these contrast media 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 encourages you to make use of any other sources that may be available to you. PHARMAC is not obliged to notify you in the event of any change to the figures below

Pharmaceutical	Year ending 30 June 2008 (mL)
Iohexol Inj 300 mg per ml (iodine equivalent) – pack sizes vary from 20 mL-500 mL	2,852,750
Iohexol Inj 350 mg per ml (iodine equivalent) - pack sizes vary from 20 mL-500 mL	3,727,150
Meglumine gadopentetate Inj 469 mg per ml (equivalent to 0.5 mmol per ml) – pack sizes between 10 mL and 20 mL	120,410
Iodixanol Inj 270 mg per ml (iodine equivalent) – pack sizes vary from 50 mL-100 mL	347,300
Iodixanol Inj 320 mg per ml (iodine equivalent) – pack sizes vary from 50 mL-200 mL	1,493,300
Gadobendate Dimeglumine Inj 0.5 g per litre) – pack sizes vary from 10 mL-20 mL	1,870
Meglumine diatrizoate with sodium amidotrizoate Oral soln 660 mg per ml, with sodium amidotrizoate 100 mg per ml, 100 ml	289,300
Sodium diatrizoate Powder for oral soln 3.705 g, 10 ml sachet	55,790*

*Units in Sachets

Schedule 4: Proposal form

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

[Supplier to insert date]

Chief Executive
C/- Andrew Davies
PHARMAC
PO Box 10-254
(or for courier delivery:
Level 9, Cigna House
40 Mercer Street)
Wellington
New Zealand

Dear Sir/Madam

Proposal for the supply of Radiological Contrast Media

In response to your request for proposals (RFP) dated 17 December 2008, we put forward the following proposal in respect of **[insert pharmaceutical]**.

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	
Strength [(e.g. 500mg)]	
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 PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

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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:

(h) Proposals/suggestions (e.g. pricing, risk sharing arrangements, 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: