

22 December 2008

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF LOW MOLECULAR WEIGHT HEPARIN

PHARMAC invites proposals for the supply of Low Molecular Weight Heparin (LMWH) on the Pharmaceutical Schedule 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 **Friday 20 February 2009**.

If you have any questions about this RFP, please contact **Stephen Woodruffe** at PHARMAC on (04) 916 7555 from 12 January 2009 (for questions before this 12 January please contact Greg Williams on (04) 916 7524).

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 seeking proposals for the supply of Low Molecular Weight Heparin.

2. Background to RFP

Currently three low molecular weight heparin chemicals (dalteparin sodium, enoxaparin sodium, and tinzaparin sodium) are listed in the Hospital Section (Section H) of the Pharmaceutical Schedule (they are all available via Discretionary Community Supply). However, no low molecular weight heparins are currently listed in the Community Section (Section B) of the Pharmaceutical Schedule.

We are seeking proposals from suppliers of low-molecular weight heparin for a listing in Section B as the sole funded brand of low-molecular weight heparin until 30 June 2012.

In addition to seeking a new listing of a single low-molecular weight heparin on Section B, we are also seeking proposals for Hospital Supply Status in Section H for each of the following chemicals:

- dalteparin sodium;
- enoxaparin sodium; and,
- tinzaparin sodium.

Sole Funded Brand of Low Molecular Weight Heparin in Section B

We are seeking proposals for one brand of low molecular weight heparin to be listed in Section B of the Pharmaceutical Schedule as the sole funded brand of low-molecular weight heparin.

This would mean that only one brand of low molecular weight heparin would be listed in Section B of the Pharmaceutical Schedule until 30 June 2011.

The listing in Section B would be under Special Authority Criteria to be determined by PHARMAC (we note that this would likely be similar to the current DCS criteria as below).

For the treatment of venous thromboembolism (VTE) for a maximum of 14 days or until a stabilised therapeutic INR is established.

For a maximum treatment period from the time of diagnosis to 8 weeks post partum for a confirmed thromboembolic event during pregnancy.

For prophylaxis of thromboembolism for patients considered high risk after consultation with a specialist from diagnosis of pregnancy to 8 weeks post partum.

For a maximum treatment period from diagnosis of pregnancy to 8 weeks post partum for women normally maintained on long-term oral anticoagulation who are at very high risk of thromboembolism.

For the treatment for a maximum of 7 days pre and post operatively for patients on oral anticoagulants requiring surgical intervention in a public hospital or until an appropriate therapeutic INR level is reached.

For a maximum of 14 days treatment in high-risk patients post pelvic, colo-rectal and major orthopaedic surgery.

For a maximum of 7 days treatment for patients with an acute coronary syndrome (ACS) awaiting further hospital intervention.

For a maximum of 14 days treatment post cardioversion in non anticoagulated patients with atrial fibrillation or until appropriate therapeutic INR level is reached.

For treatment of malignancy – associated venous thromboembolism.

Hospital Supply Status for Section H

We are also seeking proposals for Hospital Supply Status in Section H of the Pharmaceutical Schedule for each of the following low molecular weight heparin chemicals:

- daltaparin sodium;
- enoxaparin sodium; and,
- tinzaparin sodium.

Listings would likely be under the current DCS criteria (or a similar criteria), and would mean that one brand of daltaparin, one brand of enoxaparin, and one brand of tinzaparin would be listed in Section H of the Pharmaceutical Schedule until 30 June 2011.

3. **Types of proposals sought**

- PHARMAC is willing to consider proposals for the Section B listing of low molecular weight heparin and Section H listing of daltaparin sodium, enoxaparin sodium, or tinzaparin.
- Proposals should be for:
 - The sole funded brand of Low Molecular Weight Heparin in Section B of the Pharmaceutical Schedule, subject to Special Authority criteria to be determined by PHARMAC (likely similar to the current DCS criteria); and/or,
 - Hospital Supply Status for one or all of the relevant chemicals in Section H of the Pharmaceutical Schedule (subject to the current DCS criteria).
- Proposals do not need to be limited to the supply of low molecular weight heparin and may include any other pharmaceuticals or related products or programmes. However, if you submit a proposal(s) which includes other pharmaceuticals or related products or programmes then you are required to also submit an additional separate proposal which includes only your brand of low molecular weight heparin.
- If your brand of low molecular weight heparin became the sole funded brand of Low Molecular Weight Heparin in Section B and is also awarded Hospital Supply Status in

Section H, then the pricing for your brand would be the same in both Section B and Section H and would be the lower pricing of the two (if they differed in your proposal).

- For the avoidance of doubt, you may submit more than one proposal under this RFP.
- Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward, these may include:
 - caps, rebates, or other expenditure risk sharing mechanisms; and,
 - patient education or support services.

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 **Friday 20 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 at:

Level 9 Cigna House
40 Mercer Street
PO Box 10 254
Wellington 6001,

to the attention of **Stephen Woodruffe, Therapeutic Group Manager**, either by hand delivery, by courier or by post (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; and
 - (viii) to re-advertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee or any other clinical group 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, or any person or organisation contracted to provide services to the other parties specified in this clause 5(d) 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 nicotine patches and/or gum 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 February/March 2009;
 - (ii) seeking clinical advice on the proposals, if required, in March 2009;
 - (iii) negotiating with submitter(s) of one or more preferred proposals in February/March 2009;
 - (iv) consulting on a provisional agreement in April 2009;
 - (v) PHARMAC's Board or Chief Executive considering this provisional agreement in 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 1 July 2009.

Schedule 3: Current listing and market information

Currently no presentations of low molecular weight heparin are listed in the Community Section (Section B) of the Pharmaceutical Schedule. However, three presentations of low molecular weight heparins are currently listed in the Hospital Section (Section H) of the Pharmaceutical Schedule, and are available via Discretionary Community Supply (DCS) criteria, as shown below:

Enoxaparin Sodium	Dalteparin Sodium	Tinzaparin Sodium
(Current brand is Clexane)	(Current brand is Fragmin)	(Current brand is Innohep)
Inj 20 mg per 0.2 ml	Inj 2,500 IU per 0.2 ml	Inj 3,500 anti-Xa IU/0.35ml
Inj 40 mg per 0.4 ml	Inj 5,000 IU per 0.2 ml	Inj 4,500 anti Xa IU/0.45ml
Inj 60 mg per 0.6 ml	Inj 7,500 IU per 0.75 ml	Inj 10,000 anti Xa IU/0.5ml
Inj 80 mg per 0.8 ml	Inj 10,000 IU per 0.4 ml	Inj 14,000 anti Xa IU/0.7ml
Inj 100 mg per ml	Inj 10,000 IU per 1 ml	Inj 18,000 anti Xa IU/0.9ml
Inj 120 mg per 0.8 ml	Inj 12,500 IU per 0.5 ml	Inj 20,000 anti Xa IU/ml, 2ml
Inj 150 mg per ml	Inj 15,000 IU per 0.6 ml	
	Inj 18,000 IU per 0.72 ml	

Discretionary Community Supply (DCS) criteria

For the treatment of venous thromboembolism (VTE) for a maximum of 14 days or until a stabilised therapeutic INR is established.

For a maximum treatment period from the time of diagnosis to 8 weeks post partum for a confirmed thromboembolic event during pregnancy.

For prophylaxis of thromboembolism for patients considered high risk after consultation with a specialist from diagnosis of pregnancy to 8 weeks post partum.

For a maximum treatment period from diagnosis of pregnancy to 8 weeks post partum for women normally maintained on long-term oral anticoagulation who are at very high risk of thromboembolism.

For the treatment for a maximum of 7 days pre and post operatively for patients on oral anticoagulants requiring surgical intervention in a public hospital or until an appropriate therapeutic INR level is reached.

For a maximum of 14 days treatment in high-risk patients post pelvic, colo-rectal and major orthopaedic surgery.

For a maximum of 7 days treatment for patients with an acute coronary syndrome (ACS) awaiting further hospital intervention.

For a maximum of 14 days treatment post cardioversion in non anticoagulated patients with atrial fibrillation or until appropriate therapeutic INR level is reached.

For treatment of malignancy – associated venous thromboembolism.

Approximate DHB expenditure (including in hospital use for all DHBs and DCS expenditure for a number of DHBs) is outlined in the table below:

Chemical	Expenditure
Enoxaparin	\$6,700,000
Dalteparin	\$300,000
Tinzaparin	\$230,000
Total	\$7,230,000

Note that a low-molecular weight heparin listing in Section B of the Pharmaceutical Schedule is likely to affect DHB hospitals expenditure and that PHARMAC is not in a position to indicate what affect this would have.

PHARMAC makes no representation as to the accuracy of the above information or as to the level of sales or likely sales and, while PHARMAC has taken all reasonable care in preparing the information set out, it accepts no liability for any errors or omissions in the information and PHARMAC is not obliged to notify you in the event of any change to the information.

Schedule 4: Proposal form

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

[Supplier to insert date]

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

Dear Sir

Proposal for the supply of Low Molecular Weight Heparin

In response to your request for proposals (**RFP**) dated 22 December 2008, we put forward the following proposal in respect of **Low Molecular Weight Heparin**.

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(s) and their presentation:

Chemical name	
Strength	
Form (e.g injection)	
Brand name	
Pack size	
Packaging type	

(c) Key features of our proposal (including access):

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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 reductions, 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	

(f) Information about our ability to ensure the reliability and continuity of supply of the pharmaceutical over the sole subsidised supply period:

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

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- (h) Proposals (e.g. pricing, rebates, risk sharing arrangements, etc) regarding the pharmaceuticals (if any) 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) Please provide sample products and indicate if these have been provided or when they will be available: