

22 December 2010

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF RECOMBINANT FACTOR VIII, FACTOR VIIA,  
AND FACTOR IX**

PHARMAC invites proposals for the supply of Recombinant Factor VIII, Factor VIIa and Factor IX in New Zealand (to DHB Hospitals).

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

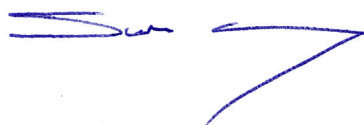
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current funded 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 **18 February 2011**.

If you have any questions about this RFP, please contact Andrew Davies (Email: [andrew.davies@pharmac.govt.nz](mailto:andrew.davies@pharmac.govt.nz); Ph: +64 4 9167 531) at PHARMAC.

We look forward to receiving your proposals.

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 any proposal from suppliers of Recombinant Factor VIII, which may also include proposals for Factor VIIa, and/or Factor IX.

### 2. Background to RFP

The background to this RFP is as follows:

- PHARMAC first contracted for the national supply of Recombinant Factor VIII in 2005 – prior to this DHBs contracted for their own purchases.
- National contracts are currently in place with three suppliers of Recombinant Factor VIII – the per unit list prices in Section H of the Pharmaceutical Schedule are as follows:

<b>Brand</b>	<b>Price per IU</b>
Xyntha	\$0.90
Advate	\$0.95
Kogenate FS	\$1.00

Note that some prices may be subject to confidential additional discounts beyond the prices itemised above.

- PHARMAC is looking to again secure the supply of Recombinant Factor VIII for a period of 2-3 years to ensure those in the haemophilia community are able to access appropriate, timely treatment. In addition we are interested in proposals for Factor VIIa and Factor IX.
- While PHARMAC is not willing to consider brand based restrictions for Factor VIII products, we are willing to consider Preferred Volume-based Pricing proposals, a special type of volume-based price discounting to encourage DHBs and the National Haemophilia Management Group to promote a particular brand of Factor VIII for new patients, or where brand consistency is deemed clinically less important.
- If a Preferred Volume-based Pricing proposal is agreed, it would be the only volume based pricing proposal accepted by PHARMAC. Such a proposal should only contain one Volume Tier, and we would expect the Volume Tier to be effective at volumes in excess to the supplier's current market share. This would mean the supplier could maintain one price for its current share, while offering a lower price to attract new patients.

### 3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

- proposals for Factor VIII, Factor VIIa, Factor IX; and Factor VIII inhibitor bypass fraction;
- proposals containing one or more of the above agents, and possibly including rebates, and/or discount on invoice arrangements;

In respect of Factor VIII, suppliers that offer a proposal for Preferred Volume-based Pricing MUST provide at least one proposal for listing on the Pharmaceutical Schedule that does not include Preferred Volume-based Pricing.

Note that, Subject to these restrictions, multiple proposals/combinations may be submitted.

PHARMAC is not willing to accept proposals for Sole Supply Status, Hospital Supply Status, or Dual Supply Status.

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 Friday, 18 February 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.

All proposals must be sent by email to [andrew.davies@pharmac.govt.nz](mailto:andrew.davies@pharmac.govt.nz).

### **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](http://www.pharmac.govt.nz)), to the extent applicable;
  - (ii) any clinical advice from PTAC or its relevant sub-committee;
  - (iii) any clinical or commercial advice from New Zealand Blood Service, DHB personnel, including the National Haemophilia Management Group, and the Ministry of Health;
  - (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 Recombinant Factor VIII 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 2011;
  - (ii) negotiating with submitter(s) of one or more preferred proposals in March-April 2011;
  - (iii) consulting on a provisional agreement in April-May 2011;
  - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after May 2011,

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 and current contractual obligations, the earliest that changes to the Pharmaceutical Schedule could be implemented is July 2011.
- (c) Please note that if a proposal involving a significant number of patients switching brands is accepted, the date of implementation may be later to allow for an orderly transition to any such arrangements.

### Schedule 3: Current listing and market information

The following information relates to the estimated funded market size of Recombinant Factor VIII. 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 Recombinant Factor VIII 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.

<b>Month</b>	<b>Total IU's purchased by DHB Hospitals</b>
July 2009	1,881,750
August 2009	2,050,250
September 2009	1,653,000
October 2009	2,069,750
November 2009	1,931,500
December 2009	2,072,750
January 2010	1,639,000
February 2010	1,359,000
March 2010	2,144,500
April 2010	1,966,250
May 2010	2,181,000
June 2010	1,847,250

#### 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). You should expand the boxes as necessary.

**[Supplier to insert date]**

Andrew Davies  
Procurement Initiatives Manager  
PHARMAC

By Email: [andrew.davies@pharmac.govt.nz](mailto:andrew.davies@pharmac.govt.nz)

Dear Andrew

#### Proposal for the supply of Recombinant Factor VIII

In response to your request for proposals (**RFP**) dated 22 December 2010, we put forward the following proposal in respect of Recombinant Factor VIII, Factor VIIa, and Factor IX.

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. 500 IU)	
Form (e.g. vial for reconstitution)	
Brand name	
Pack size (e.g. 1 vial)	
Packaging type	

- (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. 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)	
<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	
Insert any other consents required for pharmaceutical	

- (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 (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:

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

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