

27 October 2004

By Facsimile: 6 Pages

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RECOMBINANT FACTOR VIII

PHARMAC invites proposals for the supply of Recombinant Factor VIII to District Health Boards in New Zealand.

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

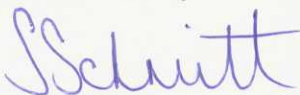
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP; and
- Schedule 3 specifies the information you need to include in your proposal.

If you wish to submit a proposal, you must submit it to PHARMAC no later than **5.00 p.m.** on **Wednesday 1 December 2004**.

If you have any questions about this RFP, please contact me on +64 4 916 7517.

We look forward to receiving your proposal.

Yours sincerely



Sarah Schmitt
Manager, Hospital Pharmaceuticals

Schedule 1: Description and rationale

1. Description of pharmaceutical

PHARMAC is interested in considering any proposal from current and/or potential suppliers of Recombinant Factor VIII.

2. Background to RFP

2.1 PHARMAC has been requested to conduct an RFP on behalf of the District Health Boards (DHBs) with support from the New Zealand Blood Service (NZBS) and District Health Boards New Zealand (DHBNZ).

2.2 The current factor VIII market incorporates the use of both blood derived and Recombinant Factor VIII. The current recommendations in place for treatment of haemophilia with factor VIII are under review. The results from this review are expected shortly although the result of this review may not significantly alter the market demand for Recombinant Factor VIII.

2.3 PHARMAC seeks proposals under each of the following market conditions for factor VIII:

- (a) where the ratio of blood derived to recombinant products remains unchanged (i.e. the status quo continues to apply) with natural market shifts;
- (b) where the ratio of blood derived to recombinant products is altered such that 30% of blood derived would be replaced with recombinant products and natural market shifts occur;
- (c) where the ratio of blood derived to recombinant products reduces over time such that the market would be intentionally driven from blood derived to recombinant products; and
- (d) where recombinant products are the predominant products with access to blood derived only available for those patients unable to use recombinant products (approximately 10% of patients).

2.4 PHARMAC is willing to consider proposals:

- for sole supply or preferred supply of Recombinant Factor VIII for a maximum of three years from acceptance of a contract, or a standard listing for an indefinite period to be agreed between the parties allowing other suppliers also to be listed;
- involving risk-sharing arrangements on expenditure, including rebates. PHARMAC is unwilling to accept proposals that would involve specified volumes;
- relating to the supply of recombinant blood products only. Aggregate proposals including other recombinant products in addition to Recombinant Factor VIII (for example, Recombinant Factor VIIa and Recombinant Factor IX) must be accompanied by a proposal for Recombinant Factor VIII alone.

Schedule 2: RFP Process

The following is indicative of the process that PHARMAC expects to follow in relation to the RFP. PHARMAC expects to follow the process in the sequence set out below.

Submission

1. You may submit more than one proposal. Each proposal will be considered as a separate proposal.
2. Proposals must be submitted no later than 5.00 p.m. (New Zealand time) on Wednesday 1 December 2004. Late proposals will only be considered at PHARMAC's discretion.
3. You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
4. All proposals must be submitted to PHARMAC at:

Level 14 Cigna House
40 Mercer Street
PO Box 10-254
Wellington 6001,

to the attention of Sarah Schmitt (Manager, Hospital Pharmaceuticals), either by hand delivery, by courier or by post (and not by facsimile or email).

Evaluation

1. Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff, NZBS staff, and DHB staff will evaluate each proposal to select its preferred proposal(s). The Evaluation Committee will seek any regulatory, legal, medical or other advice as it considers appropriate in assessing the proposals. The Evaluation Committee may request any further information from a supplier in relation to their proposal. Any such request does not indicate acceptance of that proposal.
2. The matters to be taken into account by the Evaluation Committee will include:
 - (a) 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;
 - (b) any clinical advice from the Ministry of Health, NZBS, PTAC or its relevant sub-committee; and
 - (c) any other matters that the Evaluation Committee considers to be relevant,provided that 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 ultimately at the sole discretion of the Evaluation Committee.
3. Each proposal will be evaluated on the basis that the price offered and/or expenditure entailed 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.
4. PHARMAC is not bound to select the lowest priced proposal or any proposal.

Negotiation

1. PHARMAC may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of one supplier's proposal would exclude acceptance of other proposal(s).
2. 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.
3. 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 the price.
4. 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.
5. 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).

Consultation and approval

1. Any provisional agreement will be conditional on consultation with suppliers and other interested parties, and on PHARMAC Board approval (or approval by PHARMAC's Chief Executive under delegated authority).
2. PHARMAC will not consider any counter-offers received during consultation.
3. 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.
4. 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).
5. The RFP process will be complete once PHARMAC has notified suppliers of either:
 - (a) the Board's or its Chief Executive's decision to accept a negotiated agreement; or
 - (b) the termination of the RFP process.

Miscellaneous

1. PHARMAC reserves the right:
 - (a) 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;
 - (b) not to accept any proposal;
 - (c) not to provide reasons for the acceptance or non-acceptance of any proposal;

- (d) to enter into an agreement or arrangement that differs in a material respect from that envisaged in this RFP letter;
 - (e) 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;
 - (f) to readvertise for proposals.
2. PHARMAC may consult or seek clinical advice from NZBS, 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.
 3. 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.
 4. You must not at any time initiate any communication with PHARMAC's directors, officers, staff or any members of any committees or staff from the Ministry of Health, the office of the Minister of Health, DHBs, DHBNZ, or the NZBS with a view to influencing the outcome of this RFP process. For the avoidance of doubt, your failure to comply with this restriction on communication will entitle PHARMAC, in its absolute discretion, to disqualify you from this RFP process.
 5. PHARMAC is not liable for any direct or indirect costs incurred in submitting a proposal.
 6. Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
 7. This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated. Further, PHARMAC is in no way contractually bound to follow the process outlined in this RFP, which is simply indicative.

Anticipated timetable

Following receipt of proposals, PHARMAC anticipates that the process of evaluation of proposals, negotiation and consultation on any provisional agreement, and implementation of any decision by the PHARMAC Board or the Chief Executive under delegated authority should be completed by 1 July 2005.

Schedule 3: Information to be included in the proposal

You are to provide the following information as part of your proposal:

- (a) name of supplier;
- (b) contact person;
- (c) contact details (address, telephone, facsimile, email address);
- (d) details of pharmaceutical(s) presentation proposed (please include a sample of pharmaceutical presentation and packaging with the proposal);
- (e) details of the key features of your proposal;
- (f) information relating to pricing (ex-manufacturer, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC(e.g. price in return for sole supply or risk sharing mechanisms);
- (g) evidence of market approval and any other consents required for the pharmaceutical(s);
- (h) information about resourcing and your ability to ensure the reliability and continuity of supply of the pharmaceutical(s);
- (i) information about your previous supply performance and relevant expertise;
- (j) proposals/suggestions regarding the pharmaceutical(s) not expressly identified in the RFP that you would like PHARMAC to consider as part of your proposal;
- (k) reasons why you consider PHARMAC should accept your proposal;
- (l) any particular information that you consider PHARMAC should take into account when evaluating your proposal;
- (m) details of your current and proposed distribution arrangements for the pharmaceutical(s); and
- (n) information relating to the current market share and pricing arrangements for the pharmaceutical(s).