PHARMAC
Pharmaceutical Management Agency

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2 February 2015

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RECOMBINANT FACTOR VIII, RECOMBINANT FACTOR IX, RECOMBINANT FACTOR VIIa AND FACTOR VIII INHIBITOR BYPASSING FRACTION FOR HAEMOPHILIA

PHARMAC invites proposals for the supply of Recombinant Factor VIII, Recombinant Factor IX, Recombinant Factor VIIa and/or Factor VIII inhibitor bypassing fraction, in New Zealand (community and DHB hospitals).

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

- Schedule 1 specifies the pharmaceuticals 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 pharmaceuticals; 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 via the Government Electronic Tenders Service (GETS) no later than 5.00 p.m. on 6 March 2015.

If you have any questions about this RFP, please contact Sue Anne Yee, by email at sueanne.yee@pharmac.govt.nz or by telephone on +64 (0) 4916 7549 at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. **Pharmaceuticals**

PHARMAC is interested in considering any proposals from suppliers relating to the supply of:

- Recombinant Factor VIII (**rFVIII**);
- Recombinant Factor IX (**rFIX**);
- Recombinant Factor VIIa (**rFVIIa**); and/or
- Factor VIII inhibitor bypassing fraction,

collectively referred to as **Haemophilia Treatments** for the purpose of this RFP.

2. **Background to RFP**

The background to this RFP is as follows:

- Following a RFP in 2011, national contracts were put in place for the supply of Haemophilia Treatments to DHB hospitals.
- Following consultation with DHBs, PHARMAC made a decision to list these Haemophilia Treatments in Section B of the Pharmaceutical Schedule from 1 December 2013 and fund them from the Combined Pharmaceutical Budget (**CPB**). The National Haemophilia Management Group (**NHMG**) oversees the provision of these treatments and has discretion to manage expenditure up to an agreed funding provision from the CPB.
- The current price per unit of the Haemophilia Treatments currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule are summarised in the table below:

Pharmaceutical	Brand	Price per unit
Eptacog alfa [rFVIIa]	NovoSeven RT	$1,163.75 per mg
Moroctocog alfa [rFVIII]	Xyntha	$0.90 per IU*
Octocog alfa [rFVIII]	Kogenate FS	$1.00 per IU*
	Advate	$0.95 per IU*
Nonacog alfa [rFIX]	BeneFIX	$1.24 per IU*
Factor VIII inhibitor bypassing fraction	FEIBA	$3.28 per IU*

*Prices are subject to confidential rebates or discounts upon invoice.

- The Haemophilia Treatments are currently listed in Section B and H on the Pharmaceutical Schedule subject to the following restriction criteria:

Section B

For patients with haemophilia, whose treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Section H

When used in the treatment of haemophilia, treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

- Due to favourable pricing, the NHMG currently recommends using Xyntha first line for patients new to rFVIII, patients undergoing surgery, patients needing tolerisation, and where the treating clinician (**Treater**) feels it is clinically appropriate.

- As a result of the previous RFP in 2011, PHARMAC agreed to not alter funding terms for rFVIII prior to 1 July 2014. Given this period has come to an end, PHARMAC is looking to again secure the supply of Haemophilia Treatments, for a period of at least 3 years.

- Please note Novoseven RT has subsidy and delisting protection until 30 June 2016.

- PHARMAC is aware that a number of long-acting rFVIII and rFIX products are in development. Submitters should note that this RFP is not seeking proposals for the supply of long-acting rFVIII and/or rFIX products. Information available to PHARMAC indicates that there is uncertainty in relation to timing of Medsafe registration and submission of funding applications to PHARMAC for these long-acting factors. Once such steps have occurred we will make a decision on whether a competitive process is appropriate for these products. For the avoidance of doubt, any agreement resulting from proposals made in response to this RFP would not preclude the listing of long-acting rFVIII and rFIX products during the term of such agreement(s) or at any later date.

- Further detail on the types of proposals being sought as part of this RFP can be found in the section below.

3. Types of proposals sought

As stated, PHARMAC is interested in considering any proposal from suppliers relating to the supply of Haemophilia Treatments.

Proposals from suppliers may also include:

- rebates, including volume-based rebates;

- separate pricing arrangements, for example individual patient volume-based pricing (via rebate or otherwise) for the particular Haemophilia Treatment when used in specific clinical situations, i.e. patients undergoing surgery, patients experiencing significant bleeding episodes or patients requiring tolerisation; and

- subsidy and delisting protection for a period of up to 3 years.

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

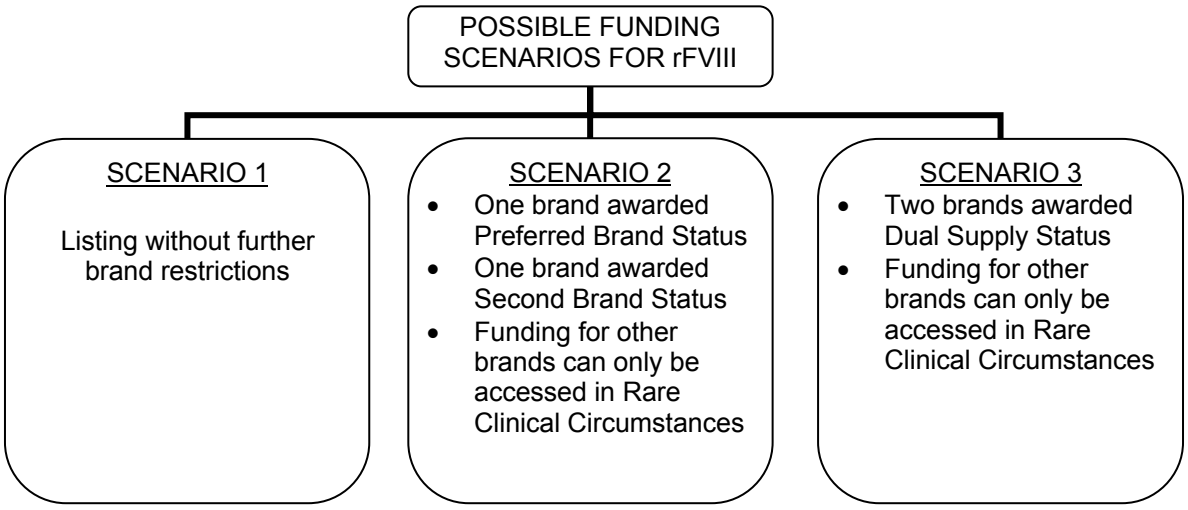
- proposals involving sole supply of rFVIII and rFIX;

- proposals involving treatments other than Haemophilia Treatments; and
- proposals for long-acting rFVIII and/or rFIX.

Additional terms specific to particular Haemophilia Treatments are detailed below.

Recombinant Factor VIII

PHARMAC is considering implementing one of the following funding scenarios for rFVIII as a result of this RFP:



In the event Scenario 2 or 3 is implemented, PHARMAC is proposing that a Haemophilia Advisory Panel (**Panel**) is established to determine which individual, or groups of, patients should have access to brands other than the brand(s) which has been awarded Preferred Brand Status or Dual Supply Status. The membership of the Panel would include clinicians who treat haemophilia.

The table below provides further detail on the types of bids being sought to enable PHARMAC to consider implementing one of the scenarios above. Suppliers submitting a proposal for the supply of rFVIII **MUST** submit a proposal form that includes information (including separate pricing information) for each of the five options detailed below:

Option	Type of Bid	Description of Funding Scenario for Bid
1	**Listing without further brand restrictions**	• Multiple brands would potentially be listed and there would be no enforced brand switching.
2	**Preferred Brand Status**	• The **Preferred Brand** would be the first treatment choice for current and new patients requiring rFVIII treatment in New Zealand. • The Preferred Brand would be used unless a change to the Preferred Brand would likely compromise appropriate treatment and care. • PHARMAC has received clinical advice that a proportion of patients (**High Risk Patients**) may not be able to be safely switched to an alternative brand and that they would require treatment, potentially long-term, with their existing or another brand of rFVIII. High Risk Patients may include patients in the following situations: o Patients who have a history of inhibitor development, who have undergone or are currently undergoing

		tolerisation; o Patients who have had an anaphylaxis reaction to a specific brand; and o Previously-untreated patients (PUPs) who have had less than 50 exposure days to treatment. • The Panel (see definition above) would determine which individual, or groups of, patients should have access to brands other than the Preferred Brand (in the event that PHARMAC decides to agree to a supply arrangement that involves a Preferred Brand). • In addition to clinical appropriateness, PHARMAC and the Panel would also take into account factors pertaining to supply security of rFVIII in New Zealand when deciding which brands individual, or groups of, patients would be treated with. • If Preferred Brand Status is awarded to a brand of rFVIII, it is likely that PHARMAC would award Second Brand Status (see definition below) to another brand. • In addition to funding a Preferred Brand and a Second Brand, PHARMAC may also agree to fund additional brands. Any funding of additional brands would be limited to a very small number of High Risk Patients in whom clinical circumstances render treatment with the Preferred Brand or Second Brand inappropriate (Rare Clinical Circumstances – see definition below). • PHARMAC is not able to define or provide assurances around supply percentage or volumes split between funded brands of rFVIII other than the proposed terms above.
3	**Second Brand Status**	• If PHARMAC agrees to a funding arrangement that involves a Preferred Brand, PHARMAC may (in its sole discretion) also agree to fund a Second Brand. • The Second Brand would be the second treatment choice for current and new patients requiring rFVIII treatment. A rFVIII brand would only be awarded Second Brand Status if another rFVIII brand is awarded Preferred Brand Status (as defined in section above). • This Second Brand would be the next treatment option for patients, including High Risk Patients, who cannot be treated with the Preferred Brand (see definition of High Risk Patients and Preferred Brand in section above). • The Panel (see definition above) would determine which individual, or groups of, patients would have access to this Second Brand. • In addition to clinical appropriateness, PHARMAC and the Panel would also take into account factors pertaining to supply security of rFVIII in New Zealand when deciding which brands individual, or groups of, patients would be treated with. • In addition to funding a Preferred Brand and a Second Brand, PHARMAC may also agree to fund additional brands. Any funding of additional brands would be limited to a very small number of High Risk Patients in whom clinical circumstances render treatment with the Preferred Brand or Second Brand inappropriate (Rare Clinical Circumstances – see definition below). • PHARMAC is not able to define or provide assurances around

		supply percentage or volumes split between funded brands of rFVIII other than the proposed terms above.
4	**Dual Supply Status**	• Two brands would be considered the preferred treatment choices. Clinicians and patients would be able to choose one of these two brands without further restriction. • In addition to the two brands holding Dual Supply Status, PHARMAC may also agree to fund additional brands. Any funding of additional brands would be limited to a very small number of High Risk Patients in whom clinical circumstances render treatment with the Preferred Brand or Second Brand inappropriate (Rare Clinical Circumstances – see definition below). • Access to additional brands which do not have Dual Supply Status would require approval from the Panel (see definition above). • PHARMAC is not able to define or provide assurances around supply percentage or volumes split between funded brands of rFVIII other than the proposed terms above.
5	**Rare Clinical Circumstances Funding**	• Access to these brands of rFVIII would be limited to a very small number of High Risk Patients who cannot be effectively or safely treated with the brands that have been awarded Preferred Brand Status, Second Brand Status or Dual Supply Status (as applicable). • Access to these treatments would require approval from the Panel. • PHARMAC is not able to provide assurances around the number of patients, if any at all, who would need to access specific rFVIII brands under this Rare Clinical Circumstances Funding scenario. • Suppliers may not have to hold stock if no patients have been initiated on the treatment but suppliers would need to provide information relating to lead times for supply. Once patients have been initiated on treatment, there would be obligations for ongoing supply.

For the supply of rFVIII, PHARMAC is also willing to consider proposals containing risk-sharing mechanisms in the event a patient develops inhibitors after a switch to a particular brand and requires additional treatment like tolerisation.

To help ensure supply security in some of the funding scenarios above, PHARMAC may require suppliers to hold a minimum of 4 months' supply of stock of rFVIII in New Zealand based on the forecast sales demand for the next four-month period. For the same reason, PHARMAC may also require suppliers to provide regular sales or stock reports to PHARMAC.

In the event of a funding scenario being implemented, following this RFP, that results in a brand change for some patients, there would be a transition period (with the length and terms of the transition period to be determined at PHARMAC's discretion) to allow clinicians and patients to coordinate a change to the new brand.

Recombinant Factor IX

PHARMAC is aware of competition in this market but PHARMAC is not willing to consider proposals containing brand-based restrictions for the funding of rFIX. This is to enable clinicians and patients to gain experience with any new brand of rFIX listed as a result of this RFP.

Recombinant Factor VIIa

Novoseven RT has subsidy and delisting protection until 30 June 2016 and any changes proposed for the listing of rFVIIa in response to this RFP would need to take this factor into consideration.

Additional supporting information

To support your bids for this RFP, PHARMAC also requests the following information to be included in your proposal form:

- International supply record including information about major markets your product is currently being supplied to, the volumes used and relevant supply terms, for example recent tenders awarded.

- Information relating to continuity of supply of product in New Zealand. This should include information on stockholding, minimum order size, delivery frequency and lead times for a stable demand situation, in the event of supply disruptions, and when there is an unexpected surge in demand for your product. Please include any specific measures you will take to secure stock for New Zealand from international production.

- Resources and activities to support clinicians and patients during and following a brand switch to your product if required.

- Details about planned distribution mechanisms including direct distribution to patients.

- Future plans (if any) of any change to your product, including changes in formulation, device or packaging.

Subject to all the terms above, PHARMAC is open to considering any other types of proposals involving Haemophilia Treatments you may wish to put forward. For the avoidance of doubt, PHARMAC may vary aspects of the supply arrangements set out above and may consider, at its sole discretion, any other alternative supply arrangements.

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) You cannot withdraw your proposal once submitted.

(c) All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than 5pm (New Zealand time) on **Friday, 6 March 2015.**

(d) If you have any enquiries about this RFP you should contact Sue Anne Yee, Senior Therapeutic Group Manager/ Team Leader (sueanne.yee@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) (if any).

(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.health.nz), to the extent applicable;

(ii) any clinical advice from PTAC or its relevant sub-committee;

(iii) any advice from relevant clinician and patient groups including the National Haemophilia Management Group and the Haemophilia Treaters Group; and

(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.

(e) Suppliers should provide PHARMAC with samples of the various presentations included in the proposal (and, if supply is intended to be in a different form from that sample pack, information about the form in which they will be supplied) within 7 business days of the deadline for submissions specified above.

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 the Board's delegate acting 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 the Board's delegate acting under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.

(d) If the Board or its delegate 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 delegate'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;

(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;

(viii) to readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC, its relevant sub-committee or other relevant groups 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 the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), District Health Boards, the National Haemophilia Management Group, the Haemophilia Treaters Group, the New Zealand Blood Service or the Haemophilia Foundation, including any of their officers or directors, 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. PHARMAC may, in its sole discretion, exclude your proposal if you do not comply with any of the terms contained in this RFP.

(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 Haemophilia Treatments by PHARMAC's apparent acceptance. Instead a separate agreement would need to be negotiated.

(i) It is possible that more than one supplier may be awarded a contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Haemophilia Treatments or restricts the terms that may be agreed with any other supplier.

(j) 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.

(k) 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, which for the avoidance of doubt includes the Panel and the NHMG and PTAC and its subcommittees, 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 2015;

(ii) negotiating with submitter(s) of one or more preferred proposals in April 2015;

(iii) consulting on a provisional agreement in May 2015;

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional agreement in or after June 2015,

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 August 2015.

Schedule 3: Current listing and market information

The following information relates to the estimated funded market size of Haemophilia Treatments. 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 these treatments 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.

Estimated market size for Recombinant Factor VIII, Factor IX, Factor VIIa and Factor VIII inhibitor bypassing fraction (units in IU unless otherwise specified)		
1 July – 30 June	**2012/13**	**2013/14**
Factor VIII (Octocog alfa)	17,337,240	16,727,500
Factor VIII (Moroctocog alfa)	4,735,000	6,014,500
Factor IX (Nonacog alfa)	1,836,250	2,143,500
Factor VIIa (Eptacog alfa - units in mg)	1,917	1,402
Factor VIII inhibitor bypassing fraction	787,000	945,500

Schedule 4: Proposal form

An electronic version of this form is available on GETS or on PHARMAC's website at www.pharmac.health.nz. You should expand or duplicate the boxes as necessary.

Submitters may submit a proposal involving multiple products (e.g. rFVIII and rFIX) and/or submit a separate proposal form for each product (e.g. a proposal form for rFVIII and a (separate) proposal form for rFIX).

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Sue Anne Yee
Senior Therapeutic Group Manager

By electronic transfer using GETS **(https://www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of Haemophilia Treatments

In response to your request for proposals (**RFP**) dated 2 February 2015, we put forward the following proposal for the following Haemophilia Treatments:

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, which for the avoidance of doubt includes all 5 options when submitting a proposal for Recombinant Factor VIII as stated in Schedule 1:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. risk sharing mechanisms, rebates, separate pricing arrangements, subsidy and delisting protections etc.(if any)):

Product	Proposal
Recombinant factor VIII Suppliers that submit bids for rFVIII must submit bids for ALL five types of bids below.	
rFVIII – Listing without further brand restrictions	
rFVIII – Preferred Brand Status	
rFVIII – Second Brand Status	
rFVIII – Dual Supply Status	
rFVIII – Rare Clinical Circumstances Funding	
Recombinant factor IX	
Recombinant factor VIIa	
Factor VIII inhibitor bypassing fraction	

(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	
Insert any other consents required for pharmaceutical	

(f) Information about our current supply arrangements, supply volumes and relevant supply terms in other major markets including recent tenders awarded:

(g) Information relating to continuity of supply of product in New Zealand. This should include information on stockholding, minimum order size, delivery frequency and lead times for a stable demand situation, in the event of supply disruptions and when there is an unexpected surge in demand for your product. Please include any specific measures you will take to secure stock for New Zealand from international production.

(h) Information about resources and activities we would make available or implement to support clinicians and patients during and following a brand switch to our product:

(i) Information about our planned treatment distribution mechanisms (including direct distribution to patients):

(j) Information about any future plans to change any aspect of our product, for example changes in formulation, device or packaging:

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

(l) Reasons why PHARMAC should accept our proposal:

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