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Pharmaceutical Management Agency

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23 July 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RECOMBINANT FACTOR VIII, RECOMBINANT FACTOR IX AND BYPASSING AGENTS FOR THE TREATMENT OF HAEMOPHILIA

PHARMAC invites proposals for the supply of Recombinant Factor VIII, Recombinant Factor IX and bypassing agents (Recombinant Factor VIIa and FEIBA) in New Zealand.

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

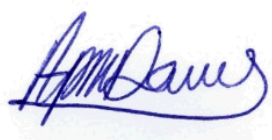
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated 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 via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than 5.00 p.m. on 20 August 2018.

If you have any questions about this RFP, please post these on GETS. Responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely



Andrew Davies
Director of Operations (acting)

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 of:

Currently funded presentations

- Recombinant Factor VIII (**rFVIII**) – short half-life (SHL);
- Recombinant Factor IX **(rFIX)** – SHL;
- Recombinant Factor VIIa (**rFVIIa**);
- Factor eight inhibitor bypassing fraction [activity] (FEIBA),

Not currently funded presentations

- Recombinant Factor VIII (**rFVIII**) – extended half-life (EHL)
- Recombinant Factor IX (**rFIX**) – EHL

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

2. Definitions of terms used in the RFP

(a) **Preferred Brand Status:** One brand is selected as the first treatment choice for current and new patients requiring treatment for haemophilia in New Zealand.

(b) **Rare Clinical Circumstances Brand(s) Status:** One or more brands are selected as the rare clinical circumstances brand(s) for high risk patients who cannot be effectively or safely treated with the brand that has been awarded Preferred Brand Status. High-risk patients for rFVIII are likely to fulfil the following criteria:

- previously had high titre inhibitor levels
- are undergoing active or have undergone immune tolerance therapy
- have a known product allergy
- have recently commenced therapy (Previously Untreated Patients or PUPs)
- live in the same residential setting with other people with haemophilia who are unable to switch, as it would be safer to have only one brand kept in the household.

(c) **Sole Subsidised Supply Status**: One supplier is selected as the only supplier of a given Treatment and Presentation as outlined in section 5.

(d) **Bundling:** A proposal is received for the supply of multiple Haemophilia Treatments that must be considered collectively.

(e) **Multiple supply:** Two or more suppliers are awarded contracts to supply a Haemophilia Treatment with equal access.

(f) **Prophylaxis:** Long or medium-term routine and scheduled infusion of recombinant products with the goal of reducing the frequency of spontaneous musculoskeletal haemorrhage (bleeding) in patients with haemophilia.

(g) **Open listing:** Haemophilia Treatments listed in the Pharmaceutical Schedule without PHARMAC imposed clinical restrictions for all patients with haemophilia, whose treatment is delegated to the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

3. Background to RFP

The background to this RFP is as follows:

Funding history of haemophilia treatments

The National Haemophilia Management Group (**NHMG**) was established in 2006 and is responsible, on behalf of 20 DHBs, for management oversight of a national haemophilia service in New Zealand. The Haemophilia Treaters Group (**HTG**) is made up of clinicians who are involved in the clinical management of patients with haemophilia in New Zealand, and collaborates closely with the NHMG. Since 2007, PHARMAC has managed haemophilia treatment procurement activities for DHBs in close collaboration with the NHMG and the HTG.

In July 2013, the Government decided that expenditure on most haemophilia treatments, including rFVIII, rFIX, rFVIIa and FEIBA, should be part of the Combined Pharmaceutical Budget managed by PHARMAC on behalf of DHBs. In performing its statutory function of making decisions about which haemophilia treatments will be funded, PHARMAC works closely with the NHMG and the HTG.

Current funding arrangements

In February 2015, PHARMAC issued an RFP for the funding of the haemophilia treatments (rFVIII, rFIX, rFVIIa and FEIBA) rFVIII EHL and rFIX EHL products were specifically excluded from the scope of the RFP.

Note that the 2015 RFP included the option of Second Brand Status, where one brand is selected as the second treatment choice for current and new patients requiring treatment for haemophilia in New Zealand. For the avoidance of doubt, this current RFP will not include the option of Second Brand Status.

Following the RFP, PHARMAC awarded three contacts for the supply of rFVIII SHL, which resulted in the nomination of a Preferred Brand, a Second Brand and a Rare Clinical Circumstances Brand.

A Haemophilia Treatments Panel was established by PHARMAC in 2015 to consider applications for funded access to the brands of rFVIII SHL with Second Brand Status and Rare Clinical Circumstances Brand Status.

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
Moroctocog alfa [rFVIII]	Xyntha	$0.84 per IU*
Octocog alfa [rFVIII]	Kogenate FS	$0.95 per IU*
	Advate	$1.15 per IU
Nonacog alfa [rFIX]	BeneFIX	$1.24 per IU*
Nonacog gamma [rFIX]	RIXUBIS	$1.15 per IU
Eptacog alfa [rFVIIa]	NovoSeven RT	$1,178.30 per mg
Factor VIII inhibitor bypassing fraction	FEIBA NF	$2.90 per IU

*Prices are subject to confidential rebates.

Current access arrangements

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

Brand	Restriction Criteria
FEIBA	For patients with haemophilia, whose treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.
RIXUBIS	
BeneFIX	
NovoSeven RT	
Xyntha	Preferred Brand of rFVIII SHL for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.
Kogenate FS	Second Brand of rFVIII SHL for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel. Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz.
Advate	Rare Clinical Circumstances Brand of rFVIII SHL for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel. Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz

Further information is available on the PHARMAC website https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/haemophilia-treatments/

Reason for running the RFP

The purpose of this RFP is to:

(a) Secure competitive pricing for the supply of Haemophilia Treatments;

(b) secure supply of Haemophilia Treatments for approximately another three years, possibly extending for two additional periods of one year each; and

(c) determine if funded access to rFVIII EHL and rFIX EHL Haemophilia Treatments would be possible from within the available budget and, if so, to progress funding and secure supply of EHL Haemophilia Treatments via the RFP process.

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its Operating Policies and Procedures (**OPPs**) with reference to the Factors for Consideration.

Relevant clinical advice

PHARMAC has obtained clinical advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Haematology Subcommittee of PTAC. Meeting minutes can be found on PHARMAC's website.

22 November 2013 the Haematology Subcommittee noted that EHL treatments are currently undergoing registration overseas and considered preliminary information on their efficacy.

1 October 2014 the Haematology Subcommittee noted different models for the supply of rFVIII, and considered that a supply model similar to the one in Australia could be suitable for the New Zealand context.

16 March 2016 the Haematology Subcommittee considered newly available information on rFVIII EHL subsequent to the Subcommittee's previous discussion in 2013 of these treatments.

On 11 & 12 August 2016 PTAC recommended that rFVIII EHL and rFIX EHL be listed in the Pharmaceutical Schedule, only if cost-neutral to the currently listed preferred brand of short-acting products.

On 4 October 2017 the Haematology Subcommittee recommended that an EHL treatment be funded for haemophilia A, with a low priority, and EHL rFIX be funded for haemophilia B with a medium-high priority.

4. Scope

PHARMAC is seeking proposals for the following range of Haemophilia Treatments:

- **rFVIII**
    - Short half-life (SHL)
    - Extended half-life (EHL)
- **rFIX**
    - Short half-life (SHL)
    - Extended half-life (EHL)

- **<u>Bypassing fraction</u>**
    - FEIBA
        - <14 days predicted use
        - >14 days predicted use
    - rFVIIa
        - <14 days predicted use
        - >14 days predicted use

Out of scope products

PHARMAC considers the following products to be out of scope of this RFP:

- haemophilia treatment options beyond those specified in this RFP;
- proposals involving sole supply or other protections of products beyond those specified as in scope;
- haemophilia treatment products for patients in exceptional circumstances which may be available by application to PHARMAC under NPPA;
- EHL treatments for non-prophylaxis (on-demand) use.

PHARMAC has a preference that Haemophilia Treatments identified as in scope of this RFP are supplied in a range of strengths suitable for treating the patient population.

Please note that while it is PHARMAC's intention to award contracts to supply for the full range of products detailed above, funding of any EHL Haemophilia Treatments will depend on budget availability. One potential outcome of this RFP is that PHARMAC may choose not to award contracts for the supply of EHL treatments. In addition, please note where both SHL treatments and EHL treatments are awarded PHARMAC may choose to list these in the Pharmaceutical Schedule at different times.

5. Types of proposals sought

The table below details the supply and access arrangements PHARMAC intends to award as a result of this RFP.

Treatment	Presentation	Supply Arrangement Offered	Access Arrangements
rFvIII	Short half-life	Preferred Brand and Rare Clinical Circumstances Brand(s)	Preferred Brand: open listing Rare Clinical Circumstances Brand(s): access delegated to Haemophilia Treaters Group on a named patient basis and prespecified criteria for high-risk patients, with PHARMAC and NHMG informed of NHI and approval category.
	Extended half-life	Sole Subsidised Supply	Open listing for Prophylaxis only
rFIX	Short half-life	Sole Subsidised Supply	Open listing
	Extended half-life	Sole Subsidised Supply	Open listing for Prophylaxis
Bypassing agents (FEIBA and rFVIIa)	<14 days predicted use	Multiple Supply	Open listing for two or more brands
	>14 days predicted use (extended half-life)	Preferred Brand and Rare Clinical Circumstances Brand(s)	Preferred Brand: be open listing Rare Clinical Circumstances Brand(s): access delegated to Treaters Group on a named patient basis if there are strong clinical reasons why the Preferred Brand cannot be used, with PHARMAC and NHMG informed of NHI and approval category.

PHARMAC is willing to consider the following types of proposals (with the following mandatory requirements):

(a) Proposals **MUST** only be for the access arrangements specified in the table above for an approximate 3-year initial term until 30 June 2022, with PHARMAC retaining the sole right to extend the access arrangements for two additional one-year periods (until 30 June 2023, then 30 June 2024).

(b) Suppliers wishing to submit proposals **MUST** submit proposals that would cover the entire haemophilia treatment market in New Zealand.

(c) Suppliers wishing to submit proposals for supply of rFVIII SHL and rFIX SHL **MUST** include pricing under two scenarios, one where EHL treatments are awarded/listed and one where they are not. This includes any proposed bundling arrangements if applicable (therefore multiple bundling arrangements may be required within your proposal).

(d) Proposals that include supply of rFVIII SHL and bypassing agents (rFVIIa and FEIBA) >14 days predicted use **MUST** include pricing for both Preferred Brand Status and Rare Clinical Circumstances Brand(s) Status.

(e) Proposals that involve bundling arrangements **MUST** be limited to the range of Haemophilia Treatments considered in scope of this RFP.

(f) Proposals that involve bundling arrangements, provided that a supplier who submits a proposal including bundling arrangements **MUST** also submit individual pricing for each Haemophilia Treatment included in the bundle capable of being accepted on its own.

(g) Proposals that include supply of rFVIII SHL **MUST** include a similar range of strengths as the currently funded strengths.

(h) Proposals that include the following:

- expenditure caps, rebates or other risk-sharing arrangements;
- proposals that include a ‘hard cap’, where a 100% rebate exists over a certain level of expenditure, provided that the proposal also includes an alternative bid with a flat rebate structure of one net price per unit regardless of expenditure;
- proposals that include a ‘soft cap’, where a rebate of less than 100% exists over a certain level of expenditure, or a tiered pricing structure where the level of rebate is linked to certain levels of expenditure.

(i) Proposals that include pharmaceuticals that have not yet gained all necessary Consents. Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate their ability to obtain those consents within a time frame acceptable to PHARMAC.

(j) Individual patient volume pricing for bypassing agents.

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

(i) proposals that include pharmaceuticals other than those identified as in scope of this RFP;

(ii) proposals including sole subsidised supply of rFVIII SHL;

(iii) proposals including sole subsidised supply of Bypassing agents (FEIBA and rFVIIa)

(iv) proposals that involve foreign currency exchange rate clauses or prices linked to any index; and

(v) two-part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

(l) Suppliers should provide PHARMAC with samples of the Haemophilia Treatments included in their proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within 10 business days from the dated specified in Schedule 2, clause 1 (b).

Please note that contractual arrangements resulting from this RFP will supersede and replace any existing agreement(s) between a supplier and a DHB(s) for the supply of Haemophilia Treatments. In addition, following the conclusion of this RFP suppliers will not be able to enter into future agreements with DHBs for the supply of Haemophilia Treatments other than those agreements established by PHARMAC.

Transition Period

In the event that this RFP results in patients being required to switch to a brand other than their current brand of Haemophilia Treatment, PHARMAC may implement a transition period and may maintain the listing and funding of any outgoing suppliers or brands to allow a well-managed transition

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 to PHARMAC via the Government Electronic Tenders Service (GETS) no later than 5:00pm (New Zealand time) on 20/08/2018. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

   (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

   (d) If you have any questions about this RFP, you should submit them on GETS. Responses to questions will be published on GETS.

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 Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the Factors for Consideration (**Factors**) that form part of PHARMAC's then current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

   (c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.

   (d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

      (i) price and NPV costs and savings;

      (ii) market approval and any other required consents and standards;

      (iii) information provided by you in accordance with Schedule 4 of this RFP;

      (iv) Haemophilia Treatments offered in a range of strengths suitable for the patient population;

      (v) appropriate labelling, packaging and instructions for use;

(vi) lead times;

(vii) any clinical advice from PTAC or its relevant Subcommittee;

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

(ix) education and training for use;

(x) previous supply performance and relevant expertise;

(xi) financial resources of the company;

(xii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(e) 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.

(f) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **PHARMAC may request further information**

(a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal.

(b) If PHARMAC requests further information from or about you, it is not obliged to request the same or any other information from or about any other party, provided that in PHARMAC's judgment this would not be unfair to any other party.

4. **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) PHARMAC is willing to negotiate reasonable stock-holding requirements with any suppliers of a Rare Clinical Circumstances Brand depending on the expected usage of the product.

(f) 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).

5. **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.

6. **Miscellaneous**

(a) PHARMAC reserves the right, having regard to probity principles:

(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, 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 Subcommittee 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 you and/or they submit any 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's directors or officers, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), District Health Boards, the NHMG, HTG or Treatment centres with a view to influencing the outcome of this RFP process.

(e) You agree that PHARMAC is to be party to any Haemophilia Treatment pricing arrangements (including free stock etc) offered or entered into with the NHMG, the HTG, treatment centres or an individual clinician during the RFP period that are additional to your proposal offered in this RFP.

(f) You must pay your own costs for preparing and submitting your proposal.

(g) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(h) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP.

(i) 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 and instead a separate agreement needs to be negotiated.

(j) 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.

(k) 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.

(l) 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.

7. **Anticipated timetable**

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in September 2018;

(ii) negotiating with submitter(s) of one or more preferred proposals in September/October 2018

(iii) consulting on a provisional agreement(s) in October/November 2018

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after November/December 2018

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 March 2019.

(c) Please note that if a proposal for sole supply 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 size of the estimated subsidised market size for the following Haemophilia Treatments:

- rFVIII SHL
- rFIX SHL
- FEIBA
- rFVIIa

As EHL Haemophilia Treatments are not currently subsidised PHARMAC does not have information regarding the size of the market, or usage of these treatments.

2017 calendar year subsidised Haemophilia Treatment usage.				
Pharmaceutical	**Strength**	**Vials**	**iu/mg**	**Gross expenditure (per iu/mg)**
rFVIII	250 (iu)	2,627	656,750	$ 581,123
	500 (iu)	6,962	3,481,000	$ 2,984,100
	1000 (iu)	8,877	8,877,000	$ 7,579,000
	2000 (iu)	3,483	6,966,000	$ 5,851,440
	3000 (iu)	424	1,272,000	$ 1,068,480
rFVIII Total		*22,373*	*21,252,750*	*$ 18,064,143*
rFIX	250 (iu)	44	11,000	$ 13,280
	500 (iu)	168	84,000	$ 102,855
	1000 (iu)	713	713,000	$ 868,460
	2000 (iu)	1,074	2,148,000	$ 2,600,160
	3000 (iu)	199	597,000	$ 740,280
rFIX Total		*2,198*	*3,553,000*	*$ 4,325,035*
Bypassing Fraction (FEIBA	500 (iu)	90	45,000	$ 130,500
	1000 (iu)	505	505,000	$ 1,464,500
	2500 (iu)	25	62,500	$ 181,250
	1 (mg)	206	206	$ 242,729.80
	2 (mg)	135	270	$ 318,141.00
	5 (mg)	5	25	$ 29,457.50
Bypassing Fraction Total		*966*	*613,001*	*$ 2,366,578*
Total		**25,537**	**25,418,751**	**$24,755,756**

The above 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 the Haemophilia Treatments identified above and, while PHARMAC has taken all reasonable care in preparing the information set out above, 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 above.

Schedule 4: Proposal form

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

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Josh Wiles
Procurement Manager

By electronic transfer via 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 23 July 2018, 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:

You should duplicate this box as necessary

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

(a) Details of pharmaceutical manufacture:

You should duplicate this table as necessary

[Chemical name]	
[Haemophilia Treatment e.g. rFVIII, rFIX, FEIBA, rFVIIa]	
[Presentation e.g. Short half-life, Extended half-life, >14 days predicted use, <14 days predicted use]	
Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(c) Key features of our proposal

(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) is to be provided below:

Scenario 1: Short-half-life and Extended half-life treatments awarded		
Haemophilia Treatment	Presentation	Proposal
rFVIII	SHL (Preferred Brand)	
	SHL (Rare Clinical Circumstances Brand)	
	EHL	
rFIX	SHL	
	EHL	
FEIBA	<14 days predicted use	
	>14 days predicted use, (Preferred Brand)	
	>14 days predicted use, (Rare Clinical Circumstances Brand)	
rFVIIa	<14 days predicted use	
	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	

Scenario 2: Short-half-life treatments only are awarded		
Haemophilia	Presentation	Proposal

Treatment		
rFVIII	SHL (Preferred Brand)	
	SHL (Rare Clinical Circumstances Brand)	
rFIX	SHL	
FEIBA	<14 days predicted use	
	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	
rFVIIa	<14 days predicted use	
	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	

Scenario 1: Short-half-life and Extended half-life treatments awarded (bundling arrangements)		
Haemophilia Treatment	Presentation	Proposal
rFVIII	SHL (Preferred Brand)	
	SHL (Rare Clinical Circumstances Brand)	
	EHL	
rFIX	SHL	
	EHL	
FEIBA	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	
	>14 days predicted use (Preferred Brand)	
rFVIIa	<14 days predicted use	

	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	

Scenario 2: Short-half-life treatments only are awarded (bundling arrangements)		
Haemophilia Treatment	Presentation	Proposal
rFVIII	SHL (Preferred Brand)	
	SHL (Rare Clinical Circumstances Brand)	
rFIX	SHL	
FEIBA	<14 days predicted use	
	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	
rFVIIa	<14 days predicted use	
	>14 days predicted use (Preferred Brand)	
	>14 days predicted use (Rare Clinical Circumstances Brand)	

(e) For proposals including extended half-life treatments please provide details of your reference standard, testing required to verify this and anything you intend to do to support testing facilities to complete this.

(f) Evidence of market approval and any other required consents:

You should duplicate this table as necessary

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	

(g) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required:

(h) Information about our current supply arrangements (including existing supply commitments), supply volumes and relevant supply terms in other major markets including recent contracts awarded:

(i) Information relating to continuity of supply of Haemophilia Treatments in New Zealand (and risk mitigation strategies in that regard). 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.

(j) 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:

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

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

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

(n) Reasons why PHARMAC should accept our proposal:

(o) Additional information that PHARMAC should consider when evaluating our proposal. Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework: