# 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)**](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.

1. Our contact details:

|  |  |
| --- | --- |
| Name of supplier |  |
| Contact person |  |
| Address |  |
| Phone |  |
| Facsimile |  |
| Email address |  |

1. 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 |  |

1. Details of pharmaceutical manufacture:

***You should duplicate this table as necessary***

|  |  |
| --- | --- |
| [Chemical name] | |
| [Haemophilia Treatment e.g. rFVIII, rFIX, FEIBA, rFVlla] | |
| [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 |  |

1. Key features of our proposal

|  |
| --- |
|  |

1. 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 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) |  |

|  |  |  |
| --- | --- | --- |
| **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) |  |

1. 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.

|  |
| --- |
|  |

1. 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*** |  |

1. 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:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. 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.

|  |
| --- |
|  |

1. 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:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. Information about our previous supply performance and relevant expertise:

|  |
| --- |
|  |

1. Reasons why PHARMAC should accept our proposal:

|  |
| --- |
|  |

1. 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:

|  |
| --- |
|  |