# Schedule 4: Proposal form

***An electronic version of this form is available* on GETS (**[**www.gets.govt.nz**](http://www.gets.govt.nz)**). You should expand the boxes as necessary.**

**[*Supplier to insert date***]

Director of Operations
PHARMAC
C/- Josh Wiles

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

Dear Madam

**Proposal for the supply of adalimumab**

In response to your request for proposals (**RFP**) dated **8 March 2021**, we put forward the following proposal in respect of adalimumab.

Set out below is further information in support of our proposal.

1. Our contact details:

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

1. Details of pharmaceutical presentation:

|  |  |
| --- | --- |
| Chemical name |  |
| Strength(s) (e.g. 40 mg) |  |
| Form(s) (e.g. subcutaneous injection) |  |
| Brand name |  |
| Pack size (e.g. 1 prefilled syringe) |  |
| Presentation (device type e.g. prefilled syringe/prefilled pen) |  |
| Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C) |  |
| Citrate free (Yes/No) |  |

1. Details of pharmaceutical manufacture:

|  |  |
| --- | --- |
| Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc) |  |
| Lead time (Time from notification of award to product being available to supply the New Zealand market) |  |
| Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA) |  |
| Batch size/s |  |
| Approximate manufacture time |  |
| Approximate time for shipping |  |

1. Information relating to if our adalimumab product is citrate containing (or not) and details of any plans to bring a citrate-free version to the NZ market (and timing of any such plans).

|  |
| --- |
|  |

1. Information relating to proposed presentation(s), and strength(s) of our adalimumab product including information regarding the suitability for all people using the currently funded strengths and presentations of adalimumab.

***Please include any attachments such as data sheets and/or transition plans with your proposal to support your response to this question***

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1. Confirmation that sample(s) of our adalimumab product, including packaging and artwork for all presentations, and strengths included in our proposal(s) will be supplied to PHARMAC within 10 business days from the dated specified in Schedule 2, clause 1 (b)

 Sample to be provided to PHARMAC – Mandatory **Yes/No\***

\*Delete as appropriate

1. Key features of our proposal:

|  |
| --- |
|  |

1. 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] |  |

1. Information relating to pricing for our adalimumab product ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (if any) is to be provided below:

***Please expand these boxes and add strengths to the below table as required***

|  |  |
| --- | --- |
|  | **Adalimumab** |
| Strength | Presentation type (device type e.g. prefilled syringe/prefilled pen) | Proposal |
|  |  |  |

1. Information relating to detail of the implementation and ongoing support we would provide for both clinicians and patients for our adalimumab product:

***Please include any attachments or additional information with your proposal to support your response to this question***

|  |
| --- |
| **Implementation and ongoing support**  |
| Education, training, and support resources for clinicians and patients |
|  |
| Related products for our adalimumab product for patients  |
|  |

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

|  |
| --- |
|  |

1. Information about our ability to ensure the continuity of supply of the pharmaceutical:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. Information about any support and resources we would provide to groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples (adults and children)

|  |
| --- |
|  |

1. Information about sustainability aspects of our company:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does our Organisation have an environmental/sustainability policy? | Yes |  | No |  |
| Does our Organisation have a sustainability report?  | Yes |  | No |  |
| If yes to either of the two above questions, please attach or link: |  |
| How does our Organisation contribute to environmental sustainability?  | *Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this Invitation* |
| Has our Organisation received any environmental/sustainability award(s)?  | Yes |  | No |  |
| If yes, provide details: |  |
| Has our Organisation received any environmental fine/prosecution(s)? | Yes |  | No |  |
| If yes, provide details: |  |
| Has our Organisation received any environmental audit(s) or does it comply with a recognised standard? | Yes |  | No |  |
| If yes, provide details: |  |

1. Reasons why PHARMAC should accept our proposal:

|  |
| --- |
|  |

1. Additional information that PHARMAC should consider when evaluating our proposal:

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1. Please include any additional information you consider relevant under PHARMAC’s [Factors for Consideration](https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/factors-for-consideration/) decision making framework:

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| --- |
|  |