## Schedule 4: Proposal form

An editable version of this form is available on the GETS listing for this RFP

**<Respondent to Insert Date>**

Director, Pharmaceuticals

C/- Sam Bright, Procurement

Te Pātaka Whaioranga | Pharmac

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Tēnā koe

**Proposal for the supply of Lenalidomide and/or Pomalidomide**

In response to your Request for Proposals (RFP) dated 24 August 2023, we put forward the following proposal in respect of **lenalidomide and/or pomalidomide**

You may expand the boxes below to suit the content of your response, please remove any guidance in *[square brackets].*

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| 1. **Our Company Details**
 |
| Trading name:  | *[insert the name that you do business under]* |
| Full legal name (if different): | *[if applicable]* |
| Physical address: | *[if more than one office – put the address of your head office]* |
| Business website: | *[URL address]* |
| Type of entity (legal status): | *[sole trader / partnership / limited liability company / other please specify]* |
| Registration number: | *[if your organisation has a registration number insert it here e.g. NZBN number]* |
| Does your organisation identify as being a Māori business? Pharmac is committed to the Government’s progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori businesses.As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through this procurement. One aspect is understanding what roles Māori businesses have in the pharmaceutical supply chain and how we can support Māori businesses in those roles.Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business.A Māori business for Government procurement reporting purposes is:* one that has at least 50% Māori ownership, or
* a Māori Authority as defined by Inland Revenue.

Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac’s supplier’s database and will be reported to New Zealand Government Procurement (NZGP), subject to any concerns you identify (see below). | *[Yes / No]* *As part of adopting a progressive procurement policy, Pharmac are committed to understand and support what roles Māori businesses play in our supply chain* |
| Pharmac is required to report to NZGP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting [requirements](https://www.procurement.govt.nz/procurement/improving-your-procurement/frameworks-reporting-and-advice/reporting-on-progressive-procurement-policy/). Please indicate either ‘Yes’ or ‘No’ as to whether you agree to Pharmac reporting on your organisation’s status. If you indicate ‘No’, please provide reasons for our consideration.  | *[Yes / No]*  |

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| 1. **Our Points of Contact**
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| Contact person: | *[i.e., who communications relating to the response(s) should be made to]* |
| Position: |  |
| Phone number: |  |
| Mobile number: |  |
| Email address: |  |
| Secondary contact person: |  |
| Position: |  |
| Phone number: |  |
| Email address |  |

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| 1. **Information About Our Organisation**
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| 1. Information about our Organisation structure:
 | *[you may embed organisational charts or similar]* |
| 1. Information about our management and technical skills:
 |  |
| 1. Information about our financial resources:
 |  |
| 1. Information about our, or our supplier’s, previous supply performance, and ability to ensure continuity of supply of the proposed product(s)
 |  |
| 1. Information about our quality assurance processes:
 |  |
| 1. The New Zealand Government is committed to sustainable and inclusive government procurement and the [Supplier Code of Conduct](https://www.procurement.govt.nz/assets/procurement-property/documents/supplier-code-of-conduct.pdf) outlines the Government’s expectations of suppliers in this respect, please outline:
* how your Organisation meets or exceeds the expectations set out in the Supplier Code of Conduct
 |  |
| 1. Please outline how your Organisation support social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement [Broader Outcomes).](https://www.procurement.govt.nz/broader-outcomes/)

Please also outline how your organisation:* Supports New Zealand businesses, including Māori, Pacific, and regional businesses, as well as social enterprises (if relevant)
* Supports improving conditions for New Zealand workers and support workforce diversity
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| 1. **Details of pharmaceutical presentation (duplicate this table for more than one pharmaceutical)**
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| 1. Chemical name
 |  |
| 1. Brand name
 |  |
| 1. Strength(s)
 | *[e.g. mg]* |
| 1. Form
 | *[e.g. capsule, tablet]*  |
| 1. Pack size
 | *[see page 11 of RFP for requirements around multiple pack sizes]* |
| 1. Packaging type
 |  |
| 1. Shelf life and storage
 | *[include months from date of manufacture and temperature to be stored at]* |
| 1. Labelling and images
 | *[please embed file(s) into your response form or upload to GETS as clearly named file(s) separate to the response form(s)]* *Minimum specification requirements for images:** *On a plain background (preferably white)*
* *Minimal shadows and good lighting*
* *Ideally images should include, pack exterior, sheet of units or similar, close up of unit*
* *Separate images for different strengths or pack sizes*
* *The product should take up 80% of the photo*
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| 1. **Details of pharmaceutical manufacture (duplicate this table for more than one pharmaceutical)**
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| 1. Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)
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| 1. Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body
 | *[e.g. TGA, FDA, MHRA]* |
| 1. Batch size/s
 |  |
| 1. Lead time (time from final notification of award to product being available to supply the New Zealand market)
 |  |
| 1. Approximate manufacture time
 |  |
| 1. Approximate time for shipping
 |  |

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| 1. **Evidence of market approval and any other required consents (duplicate this table for more than one pharmaceutical)**
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| 1. Evidence for market approval and any other required consents, include date of market approval
 | *[please attach copy of Medsafe Gazette notice, either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]* |
| 1. For any proposed products without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:
 | *[N/A if product is approved by Medsafe]* |
| 1. For any proposed products without market approval and where the dossier has **not** been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:
 | *[N/A if product is approved by Medsafe]* |
| 1. Insert the details of any other consents required for the proposed products and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:
 | *[N/A if product is approved by Medsafe]* |
| 1. Please confirm that you will supply physical sample of the proposed products, to be provided within 12 business days of Pharmac’s request.
 | *[whether or not Pharmac requires a sample will be determined upon initial evaluation of your proposal, please wait to hear from us]* |

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| 1. **Risk management programme**
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| 1. Risk management programme – link to application/programme
	1. Please include a link to, and any instructions for accessing, your programme that Pharmac would be able to register for and access in a “test” environment, allowing for multiple logins representing a prescriber, dispenser and patient.
2. You may embed instruction documents or similar, or upload to GETS as a clearly named appendix to your response.
 |  |
| 1. Risk management programme – data management and privacy
2. Please outline how any data held by the risk management programme will be used and stored. Include details on who has access to this data, who can request access and where the system and data is held (server location)
3. Please include details of any privacy impact assessments you have conducted regarding the security of user data.
 |  |
| 1. Risk management programme – support and promotion
	1. support successful introduction of this system into New Zealand pharmacies and hospitals. Please detail what technical support is offered in terms of troubleshooting access, any training and education initiatives that may be tailored to prescriber, dispenser and patient.
	2. Please detail the compatibility of your risk management programme with the existing programme as this would contribute to the implementation of this within the New Zealand health system.
	3. If you have launched your risk management programme in other markets please detail any learnings from this experience
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| 1. **Context surrounding proposed products and capability to support the product(s).**
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| 1. Key features of our proposal
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| 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(s), including other countries where the product is widely in use; any additional information about our, or our suppliers existing supply commitments.
 |  |
| 1. Information relating to the education and support plan (if applicable) for the introduction of your product(s) with regards to Te Whatu Ora Hospitals, healthcare professionals, individuals and their whānau transitioning to the proposed product(s). And relevant information regarding the launch of your pharmaceutical in other jurisdictions.
 | *[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]* |
| 1. Information relating to training and education materials that would be provided to Te Whatu Ora Hospitals, healthcare professionals, individuals and their whānau and caregivers using the proposed products. Consider ability to make patient materials available in multiple languages.
 | *[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]* |
| 1. Include information about the location, experience and qualifications of any staff that would be involved in supporting the proposed products (including those providing training and education).
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| 1. Please outline how your Organisation would support improving access and responsible use of these medicines (eg services and resources that would be offered).
 |  |
| 1. How would you support implementation of your proposal to ensure that access to treatment is equitable and contributes to equitable outcomes, specifically for Māori, Pacific and disabled peoples (but also for communities who have been underserved by the health system, including those living rurally or people who’ve been refugees).
 |  |
| 1. Pharmac is committed to embedding Te Tiriti o Waitangi within our work, achieving health equity as a starting point, and supporting communities to promote and improve wellbeing.

We are therefore interested in learning about your organisation’s:1. views on the barriers to achieving equitable outcomes for Māori and our other priority populations and what you consider your organisation’s role within the wider health sector in overcoming these barriers
2. current resourcing, capabilities, infrastructure and/or initiatives to support Māori, Pacific peoples, disabled people and other groups experiencing health inequities to achieve pae ora.
3. current relationships with stakeholders and communities to help support the above
4. future initiatives to support Māori, Pacific people, disabled people and other groups experiencing health inequities achieve pae ora
 |  |
| 1. Any other reasons why Pharmac should accept our proposal
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| 1. Any additional information Pharmac should consider under its [Factors for Consideration Framework:](https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/factors-for-consideration/)
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| 1. **Labour and human rights**
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| 1. Visibility over our supply chain

Please select one of the below options and explain why you have selected this option:**High:** we have mapped the full supply chain for key products and services used by our organisation and have identified key suppliers at all levels of your supply chain.**Moderate**: we have identified major suppliers and have partially or fully mapped the supply chains for key products and services of our supply chain.**Developing**: we have identified major suppliers. We have very limited or no visibility of our supply chains for key products and services of our supply chain. **Other**: summary of the current status of our supply chain visibility  |  |
| 1. Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation
 | Yes |  | No |  |
| 1. Our organisation has systems to monitor compliance with these policies
 | Yes |  | No |  |
| 1. If you said yes to either of the two above statements, please attach or link to the supporting information.

If the answer is no, please provide information on what your organisation is doing, or plans to do, to manage modern slavery and worker exploitation risk. |  |
| 1. Our organisation performs due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains
 | Yes |  | No |  |
| 1. If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns.

If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future? |  |
| 1. Our organisation complies with recognised standards
 | Yes |  | No |  |
| 1. If yes, please identify the standard and outline the degree to which your organisation complies.
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| 1. **Environmental Sustainability**
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| 1. Does your organisation have an environmental/sustainability policy?
 | Yes | *[delete one]* | No | *[delete one]* |
| 1. Does your organisation have a sustainability report?
 | Yes | *[delete one]* | No | *[delete one]* |
| 1. If yes to either of the two above questions, please attach or link:
 |  |
| 1. How does your organisation contribute to environmental sustainability?
 | *[Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP]* |
| 1. Has your organisation received any environmental/sustainability award(s)?
 | Yes | *[delete one]* | No | *[delete one]* |
| 1. If yes, provide details:
 |  |
| 1. Has your organisation received any environmental fine/prosecution(s)?
 | Yes | *[delete one]* | No | *[delete one]* |
| 1. If yes, provide details:
 |  |
| 1. Has your organisation received any environmental audit(s), or does it comply with a recognised standard?
 | Yes | *[delete one]* | No | *[delete one]* |
| 1. If yes, provide details:
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| 1. **Pricing and Terms of Supply**
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| * As outlined in the RFP, you are required to submit pricing for the bid options that make up a proposal.
* All prices must be in New Zealand dollars and exclusive of GST.
* Each row is for one strength and pack size of a pharmaceutical, add more rows and bid options as required, see page 11 for mandatory strengths and pack sizes.
* The pricing is per pack, in line with what could be listed on the Pharmaceutical Schedule, but any rebate would apply on a per unit basis, i.e. the price is divisible by the pack size to have a per unit price.
* Please refer to page 10 for information on when it is mandatory to include bid options for a smaller market, where you are bidding on a larger market, in summary:
	+ if you have a bid for widened access to lenalidomide, you **MUST** provide a bid for current access.
	+ If you are bidding for an award of both lenalidomide and pomalidomide you **MUST** bid on each pharmaceutical separately
* You may duplicate the tables below in order to submit more than one bid for a given bid option.
* **Lead time definition**: This is the time in months or weeks from the date of Pharmac notifying you that the response has been accepted without any further consultation or decisions pending to the date that you are able to make the product available in the NZ supply chain.
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| **Bid Option 1: Award of lenalidomide for current access criteria** |
| **Item –** (Chemical Entity, Form and Strength) | **Brand name**  | **Units (Pack Size)** | **List price (Pack)** | **Net price (Pack)** | **% Rebate** | **Lead Time** |
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| *[Any comments in relation to bid]* |

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| **Bid Option 2: Award of lenalidomide for current and widened access (must also provide an individual bid for bid option 1)** |
| **Item –** (Chemical Entity, Form and Strength) | **Brand name**  | **Units (Pack Size)** | **List price (Pack)** | **Net price (Pack)** | **% Rebate** | **Lead Time** |
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| *[Any comments in relation to bid]* |

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| **Bid Option 3: Award of pomalidomide for relapsed/refractory multiple myeloma** |
| **Item –** (Chemical Entity, Form and Strength) | **Brand name**  | **Units (Pack Size)** | **List price (Pack)** | **Net price (Pack)** | **% Rebate** | **Lead Time** |
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| *[Any comments in relation to bid]* |

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| **Bid Option 4: Award of lenalidomide for current access criteria AND funding of pomalidomide for relapsed/refractory multiple myeloma (must also provide individual bids for bid options 1 and 3)** |
| **Item –** (Chemical Entity, Form and Strength) | **Brand name**  | **Units (Pack Size)** | **List price (Pack)** | **Net price (Pack)** | **% Rebate** | **Lead Time** |
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| *[Any comments in relation to bid]* |

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| **Bid Option 5: Award of lenalidomide for current access criteria AND widened access AND funding of pomalidomide for relapsed/refractory multiple myeloma (must also provide individual bids for bid option 1, 2 and 3)** |
| **Item –** (Chemical Entity, Form and Strength) | **Brand name**  | **Units (Pack Size)** | **List price (Pack)** | **Net price (Pack)** | **% Rebate** | **Lead Time** |
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| *[Any comments in relation to bid]* |

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| **Having considered the *Pharmac standard terms and conditions for the supply of pharmaceuticals* and the *Pharmac Principal Supply Status template terms* are there any special terms you would like to note up front? Please refer to the Out of Scope and Negotiation sections of the RFP for areas Pharmac will not negotiate on.**  |
|  |