## Schedule 4: Proposal form

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

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

Geraldine MacGibbon

Acting Director, Pharmaceuticals

C/- Michael Chung

Te Pātaka Whaioranga - Pharmac

By electronic transfer using GETS ([www.gets.govt.nz](http://www.gets.govt.nz))

Tēnā koutou

**Proposal for the supply of insulin pumps, insulin pump consumables or CGMs**

Set out below is information in support of our proposal. 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 Contact Details**
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| 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]* |

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

| 1. **Information About Our Organisation**
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| Type of entity (legal status)* Eg a New Zealand registered limited liability company
 |  |
| * City and country of residence of our company
 |  |
| Information about company size, structure, and annual turnoverInclude sales/product support staff relevant to this RFP.* **Attach** Organisational Chart.
 |  |
| Total number of New Zealand based staff* Include FTE for each section (eg 5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration)
 |  |
| Established locations within New Zealand * Include function of each location (eg head office, warehouse).
 |  |
| Company ownershipState ownership (eg public ownership)Include:* any parent companies and relationships
* names and percentage shareholdings of the major shareholders and directors
 |  |
| 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 our procurement. Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business.A Māori business for Government procurement 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 NZGPP, subject to any concerns you identify. | *[Yes / No]* *In line with this policy, Pharmac is committed to understand and support what roles Māori businesses play in our supply chain. You can add any further comment on how your company supports economic and social outcomes for Māori in question (h) below.* |
| Evidence of financial stability and ability to cover financial liabilities Include:* how you would cover your financial liabilities in the event of a major failure to supply (eg a recall)
* information about your financial stability (eg annual turnover, guarantor companies)
* **Attach** supporting evidence (eg annual financial report, Companies Register financial statement, insurance certificate, bank letter).
 |  |
| New Zealand Government Broader OutcomesProvide detail on how your Organisation supports social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement [Broader Outcomes](https://www.procurement.govt.nz/broader-outcomes/)).Provide detail on how your organisation:* supports New Zealand businesses, including Māori, Pasifika and regional businesses, as well as social enterprises if relevant
* supports improving conditions for New Zealand workers and support workforce diversity
* reduces emissions and waste.
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| 1. **Details of proposed products**
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| Please provide details of your proposed products in Attachment 1. You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state N/A. |

| 1. **Information about our ability to manage and support our proposed products**
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| Customer support hoursInclude:* standard support hours (NZ time) for customer support and orders
* any 24/7 troubleshooting support relevant to the proposed products
 | ***NB*** *Pharmac’s expectation is that 24/7 troubleshooting support would be provided* |
| Product support staffInclude information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education). |  |
| Training and education Include an overview of the training and education that would be regularly provided to diabetes specialist teams and other relevant staff based in Te Whatu Ora hospitals, other healthcare professionals, and patients, their whānau and/or caregivers for the proposed products including:* frequency
* location
* format
* content
* staff groups (eg hospital, community)
* other relevant information including how consumer and/or whānau voice have been incorporated into these materials
 | *For Te Whatu Ora hospital-based staff* |
| *For patients, whānau and/or caregivers* |
| *For other healthcare professionals* |
| Training and education materialsInclude training and education materials that would be provided to diabetes specialist teams and other relevant staff based in Te Whatu Ora hospitals, healthcare professionals, patients, whanau and caregivers using the proposed products. Please include any training and education materials specifically developed for younger people or for Māori, Pacific or disabled peoples with type 1 diabetes.  | *For Te Whatu Ora hospital based staff* |
| *For patients, whānau and/or caregivers* |
| *For other healthcare professionals* |
| As a publicly funded health entity, 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:  | *Views on the barriers to supporting equitable uptake of diabetes technologies, and achieving equitable health outcomes in the treatment of type 1 diabetes,* |
| *What your organisation is currently doing to partner with and support Māori, Pacific people, disabled people and other groups experiencing health inequities, achieve pae ora within the context of type 1 diabetes.*  |
| *Current resourcing, capabilities, or relationships with stakeholders and communities to help support the above.* |
|  *Future initiatives to support Māori, Pacific people, disabled people and other groups experiencing health inequities, achieve pae ora within the context of type 1 diabetes.* |
| Transition supportInclude an outline of the support that would be provided to diabetes specialist teams and other relevant staff based in Te Whatu Ora hospitals, healthcare professionals, patients and whānau transitioning to the proposed products, if these are not currently funded. | *For Te Whatu Ora hospital based staff* |
| *For patients, whānau and/or caregivers* |
| *For other healthcare professionals* |
| Complaints management processesInclude an overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes. |  |
| Information on other major markets for proposed product ranges.For each product range include:* type of market (eg private hospital, public hospital)
* any contracts held
* annual revenue
* any other relevant information
 |  |
| Other relevant information about ability to support the proposed products. |  |
| Any additional information Pharmac should consider under its Factors for Consideration Framework. |  |

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| 1. **Information about our compliance with regulations and standards**
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| Quality Management System(s) certification for your company**If Yes, attach evidence**Include relevant section(s) of standard where certification is not for full standard. | ISO 9001 | ISO 13485 | Other  |
| [Yes/No] | [Yes/No] | [specify] |
| Quality Management Systems(s) certification for manufacturer(s)**If Yes, attach evidence**Include:* manufacturer’s name
* relevant section(s) of standard where certification is not for full standard
 | ISO 9001 | ISO 13485 | Other  |
|  |  |  |
| Other relevant standards for the proposed productsList any other standards that are relevant to the proposed products including but not limited to:* AS/NZ standards
* ISO standards
* IEC standards

Describe the extent of compliance with the listed standard and the product range the standard applies to.**Attach** evidence of compliance where available.  | Standard | Compliance  | Evidence |
|  |  |  |
| Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product New Zealand, with additional information if required: |  |

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| 1. **Regulatory consents, technical specifications and evidence to support product(s)**
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| WAND registration number | *[please list all relevant WAND registration numbers in Attachment 1]* |
| Regulatory status in other jurisdictions | *[please provide evidence of regulatory approval status from international regulatory authorities if applicable e.g. FDA, TGA]* |
| Technical specifications of product | *[please provide this information in Attachment 1]* |
| Please provide clinical evidence to support the use of your proposed products for people with type 1 diabetes. Please include any evidence that demonstrates a health benefit for Māori, Pacific, and disabled peoples, or any other populations experiencing health disparities. This can be provided as a separate attachment. Please note name of attachment(s) in response column.  | ***NB*** *not required if you have previously submitted a funding application for your proposed products but you are able to submit additional supporting information.*  |
| Please provide an overview of your company’s product or R&D pipeline relating to products in their proposal over the next 4 years including estimated launch dates for the New Zealand market. Include any R&D for broader indications (ie type 2 diabetes). Pharmac is interested in learning about the use of diabetes technologies outside of type 1 diabetes |  |
| Please confirm that you will supply physical sample of the proposed product(s), to be provided within 10 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. **Software and Data**
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| Please outline the compatibility of your proposed products with smartphones, operating systems, personal computers and/or any other relevant device through which your proposed products may be operated or accessed.  |  |
| Please outline how any software updates or upgrades to software would be managed and rolled out to Te Whatu Ora hospitals, healthcare practices, healthcare professionals and end users.  |  |
| If your proposal includes the supply of proprietary third-party software, please provide details of the licensing agreement.Include exclusivity, expiry date, termination notice period. |  |
| If your proposal includes the supply of third-party software, please confirm that this will be provided at no cost to the end user.  |  |
| Please outline how any data generated through your proposed devices will be used and stored. Include details on who has access to this data and how this data can be accessed by users, caregivers, and/or healthcare professionals. Please include details of any privacy impact assessments you have conducted regarding the security of user data.  |  |
| Please outline how any cybersecurity risks associated with your proposed devices are identified and mitigated. Include:* how any new security vulnerabilities are identified, managed, and disclosed.
* how any security incidents would be contained and resolved
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| 1. **Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply**
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| **Stock Management** |
| Stock holding within New ZealandInclude any relevant information about how you would set and manage your stock levels in New Zealand for the proposed products. |  |
| Warehouse location(s) within New ZealandInclude if warehouse owned by company or owned by a logistics provider. |  |
| Recall managementInclude how a major recall of a proposed product(s) would be managed. |  |
| **Supply Chain** |
| Company role in supply chain | Manufacturer | Distributor |
| [Yes/No] | [Yes/No] |
| Distribution agreement(s) overviewInclude exclusivity, expiry date, termination notice period. | ***NB*** *Not required if you are the manufacturer and distributor of all proposed products.* |
| Manufacture to deliveryFor each product range, from start of manufacture to delivery. Please include:* steps
* who is involved
* timeframes
 |  |
| Previous supply performanceInformation about our previous supply performance, existing supply commitments and relevant expertise: |  |
| Alternative distribution channel(s)What alternative distribution channel(s) (if any) could your organisation access to support the localised distribution of your proposed products in hard-to-reach communities or populations? |  |
| **Potential supply issues and response to unexpected increase in demand**  |
| Key supply continuity risks and mitigationsFor each product range include the key risks to continuity of supply and the steps that will be taken to mitigate these risks. |  |
| Response to unexpected increase in demand Include:* any access to alternative international supply and timeframes
* communication with Te Whatu Ora Hospitals and other healthcare professionals
* communication with patients
* communication with Pharmac
* how stock is prioritised
* other relevant information
 |  |
| Information about our ability to ensure the continuity of supply of the proposed products, including other countries where the product is widely in use: |  |

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| 1. **Labour and human rights**
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| 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 our 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  |  |
| Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation  | Yes |  | No |  |
| Our organisation has systems to monitor compliance with these policies? | Yes |  | No |  |
| If you said yes to either of the two above questions, please attach or link.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. |  |
| 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 |  |
| 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? |  |
| Our organisation complies with recognised standards | Yes |  | No |  |
| 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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| Our Organisation has an environmental/sustainability policy? | Yes |  | No |  |
| Our Organisation has a sustainability report?  | Yes |  | No |  |
| If yes to either of the two above questions, please attach or link: |  |
| 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* |
| Our Organisation has received environmental/sustainability award(s) | Yes |  | No |  |
| If yes, provide details: |  |
| Our Organisation has received environmental fine/prosecution(s) | Yes |  | No |  |
| If yes, provide details: |  |
| Our Organisation has received environmental audit(s), or complies with a recognised standard? | Yes |  | No |  |
| 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 prices for each product you are intending to supply.All prices must be in New Zealand dollars and exclusive of GST. Please provide pricing details in Attachment 1.  |

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| 1. **Scope for negotiation**
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| Having considered the *Pharmac standard terms and conditions for the supply of pharmaceuticals* are there any special terms you would like to note up front? If yes, please compete Attachment 2. Please refer to the Out of Scope and Negotiation sections of the RFP for areas Pharmac will not negotiate on.It is Pharmac’s expectation that the terms of supply stated in Pharmac’s standard terms and conditions will apply to insulin pumps, consumables and CGMs with or without an AID system, however Pharmac acknowledges that special terms will need be added to the standard terms and conditions, for example including but not limited to:* ICT requirements for insulin pumps and CGMs with or without AID system functionality, for example:
	+ Software support services
	+ Security monitoring, disclosures and incident management
	+ Compliance with privacy laws, data sovereignty and associated policies, processes and guidelines
	+ Software upgrades and updates
	+ Software licensing
	+ Data security, including access and use of data, for example to Te Whatu Ora and patients
	+ Interoperability to associated devices and systems
* Supply in a dual-supply status arrangement

Please note that the above examples are indicative only and other special or alternative terms may be required to be added to the agreement as a result of the RFP process.Please note that completion of Attachment 2 or being selected as a preferred supplier does not guarantee Pharmac acceptance of all requested amendments included in Attachment 2.  |

Signed for and on behalf of **<insert name of supplier>** by

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**<Insert name>
<Insert designation>**