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11 July 2023

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INSULIN PUMPS, INSULIN PUMP CONSUMABLES AND CONTINUOUS GLUCOSE MONITORING (CGM) DEVICES

Pharmac invites proposals for the supply of insulin pumps, insulin pump consumables and continuous glucose monitoring (CGM) devices in the New Zealand subsidised community market.

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

- Schedule 1 specifies the products 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 products.
- 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 4:00 pm (New Zealand time) on **Friday 18 August 2023.**

If you have any questions about this RFP, please post these on GETS or alternatively contact Pharmac by email at **procurement@pharmac.govt.nz**. Responses to all questions will be anonymised and published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Geraldine MacGibbon
Acting Director, Pharmaceuticals

Schedule 1: Products, background to RFP and types of proposals sought

Definitions

For the purpose of this RFP document, unless the context otherwise requires:

"**AID system**" means an automated insulin delivery system;

"**CGMs**" means is-CGMs and/or rt-CGMs inclusive of sensors, transmitters, readers and any other consumables necessary for the operation of the device;

"**is-CGMs**" means intermittently-scanned continuous glucose monitors;

"**rt-CGMs**" means real-time continuous glucose monitors; and

"**type 1 diabetes**" means type 1 or pancreatogenic[1] diabetes.

1. Products

Pharmac invites proposals from suppliers of insulin pumps, insulin pump consumables, and CGMs, for people with type 1 diabetes.

The intention of this RFP is to secure supply of of insulin pumps, insulin pump consumables, and CGMs, for people with type 1 diabetes. Insulin pumps and insulin pump consumables are currently funded on the Pharmaceutical Schedule. CGMs are not currently funded. The funding of CGMs through this RFP will depend on the bids received and the amount of available funding from Pharmac's fixed budget.

2. Background to RFP

Type 1 diabetes is a chronic condition caused by the inability of the pancreas to produce insulin, which then affects blood glucose control. Treatment for type 1 diabetes requires subcutaneous administration of insulin with dosing guided by blood glucose levels. Insulin can be delivered via continuous subcutaneous insulin infusion (CSII) via an insulin pump or via a multiple daily injection (MDI) regimen.

The current funded standard of care for blood glucose testing in New Zealand is self-monitoring via finger-prick testing and a blood glucose monitor. We understand that the pain and effort associated with finger-prick testing can be a psychological barrier which can reduce adherence, especially if multiple tests a day are required.

CGMs measure blood glucose levels without the need for blood samples, and send this information to a smart-phone or reader device automatically. Some CGMs also include alarms to let the person know when blood glucose levels move too high or low. Is-CGMs must be scanned by a reader device to display blood glucose levels while readings from rt-CGMs are displayed in real-time without the need for scanning.

Some CGMs can be paired with an insulin pump to create an AID system. This uses an algorithm to automatically delivers and adjust basal insulin doses based on the blood glucose readings from the CGM.

The advice we have received from our clinical advisors is that funding CGMs would substantially reduce the burden of disease for people with type 1 diabetes, given the

[1] For the purposes of this document, pancreatogenic diabetes mellitus is any form of diabetes resulting from pancreatic disease and a subsequent loss in insulin-producing cells. It includes permanent neonatal diabetes and diabetes secondary pancreatitis, cystic fibrosis, pancreatic cancer, and pancreatectomy.

central importance of glycaemic control in reducing the risk of complication. As such, the primary objective of this RFP is to see whether we are able to fund CGMs for people with type 1 diabetes within the funding available from Pharmac's fixed budget.

Pharmac's role within the sector

The Pae Ora (Healthy Futures) Act 2022 (the Act) took effect on 1 July 2022 and shapes the reform of the health sector in Aotearoa New Zealand. Its vision is that all New Zealanders achieve pae ora (healthy futures). Achieving pae ora means that people and their whānau will live longer in good health, have improved health and quality of life, are part of healthy, inclusive and resilient communities, and live in environments that sustain their wellbeing.

As a government health entity, Pharmac is to give effect to the principles of te Tiriti o Waitangi (as set out in section 6 of the Act) and be guided by the health sector principles (as set out in section 7 of the Act), including equity, engagement, and the promotion of health and wellbeing.

This RFP includes sections for suppliers to outline how they can support Pharmac and the broader health system give effect to the principles of te Tiriti, that is, tino rangatiratanga (self-determination), ōritetanga (equity), whakamaru (active protection), kōwhiringa (options), and pātuitanga (partnership).

We expect suppliers to include information in their proposals as to how they would partner with priority populations (ie Māori, Pacific, and disabled peoples) to enable them to fully realise the benefits from access to diabetes technologies. :

How this RFP supports New Zealanders achieve pae ora

Diabetes is identified as one of Pharmac's Hauora Arotahi – Māori health areas of focus. We understand that access to diabetes technologies can significantly improve health outcomes, particularly for Māori, Pacific and disabled peoples with type 1 diabetes.

While type 1 diabetes is more common in non-Māori and non-Pacific populations, Māori and Pacific people with type 1 diabetes are more likely to experience diabetic complications such as cardiovascular disease. We are also aware that Māori and Pacific people receive insulin pumps at a lower rate than non-Māori and non-Pacific people, and are less likely to be continued on insulin pump therapy once initiated.

Through this RFP we are aiming to secure supply of, and fund, CGMs for people with type 1 diabetes. We understand that CGMs would benefit all people with type 1 diabetes but that the people with the greatest health need (including Māori, Pacific people and disabled people) would likely benefit the most. We also intend to revise and simplify the eligibility criteria for insulin pumps and consumables as we understand the current eligibility criteria may act as a barrier to access for many people.

However, we know that eligibility criteria are only one of the factors that influence whether people access treatments and whether they fully realise the benefit of the treatments once they have access. This is why we are seeking information from suppliers about how they are able to support the onboarding of these technologies in priority populations.

Pharmac understands that there is emerging evidence supporting the use of CGMs for people with type 2 diabetes, a condition which disproportionately impacts Māori and Pacific peoples. As Pharmac has not yet received or assessed a funding application for CGMs in type 2 diabetes, we are not in a position to consider funding CGMs for people with type 2

diabetes through this RFP. However, the outcome of this RFP would not prevent Pharmac from considering funding of CGMs for type 2 diabetes in the future and we would be pleased to assess a funding application for CGMs for people with type 2 diabetes. Funding applications can be made at any time via the PharmConnect portal.

Currently funded products

Pharmac funds two insulin pumps with their associated range of consumables, which are listed on the Pharmaceutical Schedule. Insulin pumps and consumables are funded subject to eligibility criteria. Confidential rebates apply to the funded insulin pump and insulin pump consumables, which reduce their net prices versus the prices listed on the Pharmaceutical Schedule.

Pharmac also funds the CareSens brand of blood glucose meters and test strips as a result of a 2017 procurement process for these products. These products are **not** included within the scope of this RFP.

Links to details of currently funded insulin pumps, insulin pump consumables, blood glucose meters, and blood glucose test strips are included below.

Therapeutic Group Subcategory	Chemical name
Insulin pumps	Insulin pump
Insulin pump consumables	Insulin pump cartridge Insulin pump infusion set (steel cannula) Insulin pump infusion set (steel cannula, straight insertion) Insulin pump infusion set (Teflon cannula) Insulin pump infusion set (Teflon cannula, angle insertion with insertion device) Insulin pump infusion set (Teflon cannula, angle insertion) Insulin pump infusion set (Teflon cannula, straight insertion with insertion device) Insulin pump infusion set (Teflon cannula, straight insertion) Insulin pump reservoir
Blood glucose testing	Blood glucose diagnostic test meter Blood glucose diagnostic test strip Blood glucose test strips (visually impaired)
Dual blood glucose and blood ketone testing	Dual blood glucose and blood ketone diagnostic test meter

Pharmac does not fund any CGM for type 1 diabetes. One of the aims of this RFP is to be able to progress the funding of CGMs for people with type 1 diabetes.

Refer to section 3 below ‘Scope and types of proposals sought’ below for specifics on what products are in scope of this RFP.

Pharmacology and Therapeutics Advisory Committee (PTAC) and Advisory Committee Advice

Pharmac has received funding applications for CGMs for people with type 1 diabetes in the community setting. We have received positive clinical advice recommendations from the Diabetes Advisory Committee for two CGMs (Abbott Freestyle Libre system and the Dexcom G6 system), and one AID (MiniMed 780G System) for the treatment of type 1 diabetes.

In addition to the funding applications received, Pharmac is aware of multiple CGMs currently available in New Zealand or overseas.

Pharmac sought additional clinical advice regarding insulin pumps, insulin pump consumables, CGMs, AID systems and eligibility criteria from the Diabetes Advisory Committee in April 2023, to help inform this RFP. The records from this meeting relevant to this RFP are available here.

This RFP provides a fair opportunity for any CGM to achieve a listing on the Pharmaceutical Schedule. It also provides an opportunity to consider the market for insulin pumps and consumables alongside the market for CGMs and maximise the value we could secure for New Zealanders.

Reasons for running the RFP

Pharmac considers that significant health benefit could be gained through funding CGMs for the treatment of type 1 diabetes, and we are aware of significant competition in this market.

With regards to insulin pumps and consumables, the last RFP for these products was run in 2012. Insulin pumps and CGMs can be used together in an AID system and there is competition in this market.

Therefore, we consider that an RFP that includes insulin pumps and consumables along with CGMs within the same procurement process may help secure the greatest value for New Zealanders.

The primary objectives of this RFP are to:

- determine whether the funding of CGMs for people with type 1 diabetes is possible from the available funding from Pharmac's fixed budget
- address a significant unmet health need, especially amongst Māori and Pacific people who experience poorer health outcomes from type 1 diabetes
- secure long-term supply of a range of clinically suitable insulin pumps, insulin pump consumables and CGMs.

A secondary objective of this RFP is to secure pricing that would support any future assessment of CGMs for people with type 2 diabetes.

Any provisional agreement will be conditional on consultation 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).

Any 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 Pharmac's decision-making framework as outlined in its then OPPs with reference to the Factors for Consideration.

Intended outcome of the RFP

Through this RFP, Pharmac intends to contract with suppliers to secure supply of a range of suitable insulin pumps, insulin pump consumables and CGMs as set out below.

Pharmac would seek to secure supply of:

- **up to two** suppliers of CGMs in one of the following scenarios:
    - a scenario that would result in up to two suppliers with one type (brand) of CGM for each supplier.
    - a scenario that would result in up to two suppliers with more than one type (or brand) of CGM for each supplier.
- **up to two** suppliers of insulin pumps and consumables, where each supplier would be eligible to supply one type (or brand) of insulin pump and associated consumables. In this scenario, **at least one** insulin pump would require to be compatible with at least one of the funded CGMs as outlined above.

Insulin pumps, insulin pump consumables, and CGMs would be listed in Section B of the Pharmaceutical Schedule only, and would be funded subject to the proposed eligibility criteria described below.

Products would not be listed in Section H of the Pharmaceutical Schedule via this RFP process. However, under Schedule Rule 3.6 Te Whatu Ora hospitals would be permitted to purchase devices included in this RFP for inpatient use subject to the eligibility criteria in Section B of the Pharmaceutical Schedule.

The anticipated outcome of this RFP is a 'dual-supply status' scenario for insulin pumps, insulin pump consumables, and CGMs. This means two suppliers could be contracted to supply each of the insulin pumps and associated consumables, and two suppliers could be contracted to supply CGMs. Dual-supply status would apply:

- to CGMs for a period of **4 years** from the date of listing on the Pharmaceutical Schedule
- to insulin pumps for a period of **3 years and 9 months** following the end of the transition period
- to insulin pump consumables for a period of **3 years** following the end of the transition period

For insulin pumps and consumables, the dual-supply status would result in each of the contracted suppliers supplying one type (brand) of insulin pump alongside a range of associated consumables.

For CGMs, dual-supply status may result in each of the contracted suppliers being able to supply **a range** of different types (brands) of CGMs from their portfolio. This would mean

that there could potentially be more than two CGM devices listed on the Pharmaceutical Schedule.

As a part of the RFP, we are seeking information on supplier's product pipelines for both CGMs and insulin pumps to understand potential product upgrades that may be available for people with type 1 diabetes. We would be willing to consider allowing product upgrades during the dual-supply status period. However, this would be subject to mutual agreement between the supplier and Pharmac. Any replacement product would be required to have the equivalent (or better) compatibility options as the superseded product and may require clinical assessment depending on the nature of the product upgrade. Replacement products would be required to be listed under the same commercial terms as the original product.

The award of dual-supply status would result in the contracted suppliers being collectively assured of at least 90% of the funded market but would not be provided any assurance of individual market share. This means that through the Alternative Brand Allowance (ABA) of 10%, other brands of insulin pumps and consumables or CGMs could be funded for use in up to 10% of the funded market. Pharmac retains its discretion as to who could access funding for an alternative brand and how funded access to it would be enabled. Funded access to an ABA brand could be via a listing on the Pharmaceutical Schedule or via Pharmac's exceptional circumstances framework.

As a result of this RFP, Pharmac would retain the right at its sole discretion to widen funded access to insulin pumps, insulin pump consumables or CGMs at any time during the dual-supply status period.

Please note that up to four suppliers could be awarded dual-supply status as a result of this RFP (two for insulin pumps and consumables and two for CGMs).

Subject to the proposals received as a result of this RFP, Pharmac reserves the right:

(a) not to progress any proposals submitted in response to the RFP; or

(b) to evaluate proposals submitted in accordance with the terms of this RFP.

Eligibility criteria

In an effort to simplify and future-proof the eligibility criteria for insulin pumps and insulin pump consumables and CGMs, the following proposed criteria have been drafted with advice from Pharmac's Diabetes Advisory Committee and input from the New Zealand Society for the Study of Diabetes (NZSSD).

The proposed changes to the current criteria include:

- the individual criteria for HbA1c, severe hypoglycaemia and permanent neonatal diabetes would be combined into a single criterion.
- the specific HbA1c threshold requirements for people with elevated HbA1c and those experiencing severe unexplainable hypoglycaemia would be removed.
- references to clinical guidance or standards would be removed as we do not consider these to be relevant to the targeting of funding to those who would benefit the most from insulin pump therapy.

The proposed criteria are intended to be indicative and may be amended following consideration of any consultation feedback or further advice from the Diabetes Advisory

Committee, PTAC and/or other expert advisors. Pharmac reserves the right to amend the criteria as part of this RFP process.

Insulin pumps would be subject to the following proposed Special Authority criteria:

> **Initial application** – (type 1 diabetes) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:
> All of the following:
> 1. Patient has type 1 or pancreatogenic* diabetes; and
> 2. Patient has been evaluated by a diabetes multidisciplinary team for their suitability for insulin pump therapy; and
> 3. Either:
> 3.1. Both:
> 3.1.1. Has adhered to an intensive MDI regimen using analogue insulins for at least three months; and
> 3.1.2. Any of the following:
> 3.1.2.1. Severe unexplained nocturnal hypoglycaemia; or
> 3.1.2.2. One or more severe unexplained hypoglycaemic events requiring assistance; or
> 3.1.2.3. Chronically raised HbA1c despite optimal MDI therapy; or
> 3.2. In the opinion of the treating specialist a trial with an MDI regimen would be unsuitable and clinically inappropriate
> *This includes permanent neonatal diabetes or patients with insulin deficiency secondary to cystic-fibrosis or pancreatectomy.
>
> **Renewal** – (type 1 diabetes) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:
> Both:
> 1. Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
> 2. There is objective evidence of maintained improvement in glycaemic control from baseline.

A rule of a maximum of one funded device per patient over a four year period would continue to apply to insulin pumps. Insulin pump consumables would be subject to the same Special Authority criteria described above, however both initial and renewal applications would be valid for 2 years rather than 3 months.

CGMs would be subject to the following Special Authority criteria:

> **Initial application** (type 1 diabetes) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criterion:
> 1. Patient has type 1 or pancreatogenic* diabetes.
>
> *This includes permanent neonatal diabetes or patients with insulin deficiency secondary to cystic-fibrosis or pancreatectomy.
>
> **Renewal – (type 1 diabetes)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
> Both:
> 1. Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
> 2. Time spent in the target glycaemic range has improved compared with baseline.

3. Scope and types of proposals sought

<u>Pricing and proposal structure</u>

a) Suppliers **MUST** submit proposals for community supply of insulin pumps and consumables, and/or CGMs in accordance with the funding scenarios and subject to the eligibility criteria described above.

b) Proposals for insulin pumps **MUST** also include proposals for the associated consumables.

c) Proposals **MUST** include an overview of your company's product and R&D pipeline with a description of any new updated or upgraded products that could potentially be launched during the dual-supply status period and under the same commercial terms as your proposal.

d) Proposals that include products that are not currently registered on the Web Assisted Notification of Devices (WAND) Database **MUST** include estimated registration and supply dates.

e) Proposals **MAY** include bids with a flat rebate structure (which may be confidential) of one price per unit regardless of unit volume or expenditure.

f) Suppliers **MAY** submit multiple proposals for the supply of insulin pumps, consumables, and/or CGMs.

g) For proposals where a supplier submits a range of CGMs, the supplier **MUST** also include separate proposals for each CGM.

h) Proposals for CGMs or insulin pumps with AID system functionality **MUST** be all-inclusive, ie must include the price of any software or algorithms required for use in an AID system. Suppliers **MUST** provide the details of any software licencing agreements at Pharmac's request.

Proposal validity period

i) All proposals **MUST** remain valid for 12 months from the submission deadline. Respondents must honour the terms and conditions stated in their proposals. Changes to pricing, terms, or conditions post-submission may result in disqualification. Pharmac may seek clarifications or engage in limited negotiations during the validity period.

Term

j) Proposals **MUST** include a period of dual-supply status for each product included in the proposal, with an Alternative Brand Allowance of 10%, following the transition period in the case of insulin pumps and consumables (see below)

k) The period of dual-supply status for each product would be as follows:

   i) A period of four years for CGMs;

   ii) three years and nine months for insulin pumps; and

   iii) three years for insulin pump consumables.

l) All proposals for insulin pumps and consumables **MUST** include a transition period of:

   i) **three months** between listing the new brand of insulin pump and the commencement of any dual-supply status period,

   ii) **12 months** between listing the new brand of insulin pump consumables and the commencement of any dual-supply status period,

noting that these periods may be subject to negotiation following evaluation of proposals.

Consents and supporting evidence

m) Suppliers **MUST** be able to legally supply their proposed products in New Zealand as evidenced by WAND registration number. Where WAND is not applicable to a proposed product, suppliers **MUST** state the reason why it is not applicable. Where a product is not registered on WAND, suppliers **MUST** demonstrate their ability to obtain WAND registration within a timeframe acceptable to Pharmac.

n) Proposals **MUST** include evidence of international compliance certification for any proposed products. The name of the certifying body and certificate number **MUST** be included for each proposed product and suppliers **MUST** attach a copy of all relevant certificates.

o) Proposals **MUST** include relevant clinical evidence to enable clinical assessment of the device's technical operating functions.

Transition and ongoing support

p) Proposals **MUST** include information outlining the support that would be provided to implement the proposal, particularly any initiatives that would contribute to equitable access and outcomes for Māori, Pacific people, disabled people and other populations experiencing health disparities.

q) Proposals **MUST** include information regarding any aspects of the product(s) provided that would contribute to equitable health outcomes.

r) Proposals that would result in a change in the listed brand of insulin pumps and consumables **MUST** provide information regarding the support that would be provided by the supplier to support the change.

s) Proposals for CGMs **MUST** include information regarding the education and support that would be provided to support the successful introduction and equitable uptake and use of CGMs.

Data privacy and security

t) Proposals **MUST** include information about how any data connected to the proposed products is managed including who is able to access the data, what this data is used for, how patient consent would be sought, where this data is stored and any relevant data security protocols.

4. Out of scope proposals

Pharmac is not willing to consider the following types of proposals:

a) Proposals involving pharmaceuticals or devices other than insulin pumps, consumables or CGMs.

b) Proposals that include a requirement to widen funded access to insulin pumps and/or consumables.

c) Proposals for insulin pumps and consumables, or CGMs for any eligibility criteria other than described above.

d) Proposals for insulin pumps that do not also include the associated insulin pump consumables.

e) Proposals for supply of other pharmaceuticals or devices (funded or unfunded)

f) Proposals that include cost-offsets on other pharmaceuticals or devices .

g) Proposals that include any rebate structure other than a flat price per unit rebate.

h) Proposals that include a 'hard cap', where a 100% rebate exists over a certain level of expenditure.

i) Proposals that include cost-offsets on pharmaceuticals or devices that are indicated as a future procurement opportunity on GETS by Pharmac.

j) Proposals that ask for part-funding or subsidy.

k) Proposals that involve an end date for rebates.

l) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.

m) Two-part pricing arrangements, whereby Pharmac may make an upfront payment (in addition to any ongoing subsidy) in return for the listing of products on specific terms.

n) Proposals for supply of the hospital market[2].

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

5. Widened access

Notwithstanding this RFP, Pharmac would retain the right at its absolute sole discretion to widen access to insulin pumps, insulin pump consumables or CGMs.

This could include the possibility of widening access to other population groups, such as people with type 2 diabetes, following consideration of any relevant funding applications and subject to available funding from within Pharmac's fixed budget.

6. Samples

Suppliers **MUST** provide Pharmac, upon request, with physical samples of the product(s) (and, if the supplied product is intended to differ from the provided samples in any way, information about the differences must be supplied) within a reasonable timeframe of such a request.

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[2] Products would not be listed in Section H of the Pharmaceutical Schedule via this RFP process. However, Te Whatu Ora hospitals would be permitted to purchase devices included in this RFP for inpatient use subject to the eligibility criteria in Section B of the Pharmaceutical Schedule.

7. Supplier Code of Conduct

The New Zealand Government is committed to sustainable and inclusive government procurement and has outlined the expectations of all suppliers in the Supplier Code of Conduct. Pharmac expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.

8. Intellectual Property

Pharmac makes no representation as to the intellectual property status of any product included in this RFP including but not limited to in relation to method(s) of manufacture, processes, or software. It is the responsibility of the supplier to ensure its product does not infringe any third-party intellectual property rights. Pharmac accepts no liability for any intellectual property infringement that might occur because of this RFP process or Pharmac's acceptance of a proposal.

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 **4:00 pm (New Zealand time) on Friday 18 August 2023**. 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) Subject to Schedule 1, paragraph 3(i), you cannot withdraw your proposal, once submitted, while the RFP process is continuing.

d) In preparing your proposal you acknowledge and agree that in submitting your proposal you will rely on your own knowledge, skill, and independent advice or assessment of the market size for insulin pumps, insulin pump consumables and CGMs, and Pharmac is to have no liability in that regard.

e) If you have any questions about this RFP, please submit these via GETS. If you need to get in touch via email, then please email Pharmac at procurement@pharmac.govt.nz. Responses to questions will be anonymised and published on GETS.

2. Evaluation

a) Following the deadline for submitting proposals, Evaluation Committees comprising Pharmac staff and relevant external advisors will evaluate each proposal to select its preferred proposal(s). Please note that any third party who attends an Evaluation Committee meeting would be required to enter into a confidentiality agreement with Pharmac prior to any attendance. Pharmac **would not** share any pricing information with third parties, even with a confidentiality agreement in place.

b) The Evaluation Committees will evaluate proposals considering 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 that form part of Pharmac's then current Operating Policies and Procedures (OPPs), as published on Pharmac's website (www.pharmac.govt.nz), to the extent applicable.

c) Pharmac anticipates that the evaluation will occur in two stages. The first stage will involve a Technical and Consumer Evaluation Committee comprising Pharmac staff and external advisors including consumer representatives and clinical experts. This stage will evaluate the clinical and technical features and suitability of the proposed products. Pricing will not be assessed during this stage of evaluation. The second stage will involve a Pharmac Evaluation Committee comprising Pharmac staff, which will assess the proposals against the Factors for Consideration described above.

d) The information to be considered in applying the Factors for Consideration by the Pharmac Evaluation Committee will be at its discretion, however it will include:

(i) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below.

(ii) any advice from the Pharmacology and Therapeutic Advisory Committee (PTAC), or relevant specialist advisory committee, any relevant healthcare professionals or professional groups, any relevant consumers or consumer organisations or health sector agencies. This may include specific clinical advice regarding relative risks and benefits of proposals including clinical benefits, risks and implementation considerations following the closing of this RFP.

(iii) any other matter or information that the Pharmac Evaluation Committee considers to be relevant (provided that Pharmac will notify such matters and allow an opportunity for submitters of proposals to address them) having regard to probity principles.

(iv) previous supply performance and relevant expertise.

(v) information regarding the support that would be provided to ensure successful and equitable introduction of funded CGMs into the New Zealand health sector.

(vi) information about how the implementation support provided within a proposal would contribute to equitable access and outcomes for Māori, Pacific, populations experiencing health disparities and populations with disabilities.

(vii) information regarding any aspects of the product that would contribute to equitable health outcomes.

(viii) information regarding the support that would be provided to support the introduction of CGM and any change in funded insulin pump and consumables brand.

(ix) 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) For the purpose of fiscal evaluation for this RFP, Pharmac would assess any pricing offered as commencing from 1 April 2024 unless otherwise specified by the supplier. Suppliers may offer proposals that include a listing or price change prior to this date, however, any fiscal impact from this earlier/price change would not be included in Pharmac's primary fiscal evaluation of proposals. If two or more proposals were determined by Pharmac to be similar, having considered all the Factors for Consideration, Pharmac may undertake a secondary fiscal evaluation where we may consider the impact of earlier list date/price changes.

g) Pharmac is not bound to select the lowest priced proposal(s) or any proposal.

3. Pharmac may request further information

a) Pharmac may request further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to):

(i) detailed information about your company structure, credit status and any other relevant company information

(ii) any other additional information about your proposed products

(iii) any other information regarding the implementation support requested and described above.

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 judgement this would not be unfair to any other party.

Please note that Pharmac may seek advice from PTAC, or relevant specialist advisory committee, any relevant professional organisations, consumer groups, health care professionals and/or any other relevant expert advisors about your product including evaluation of any product samples.

4. Clinical advice and prioritisation

a) Following evaluation of proposals Pharmac may seek clinical advice from PTAC, relevant specialist advisory committees or other parties if required.

b) Pharmac may rank preferred proposal(s) on our Options for Investment list if required. If proposal(s) are not able to be progressed from the available funding from within Pharmac's fixed budget, Pharmac reserves the right not to accept any proposals and terminate the RFP process in respect to either insulin pumps, insulin pump consumables, and/or CGMs.

5. 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) Negotiation will proceed on the basis that Pharmac's standard terms and conditions for supply of pharmaceuticals will apply. These are included as an attachment to this RFP. Pharmac acknowledges that special terms may need to be negotiated with a supplier for any product specific requirements.

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, because 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) 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).

6. Consultation and approval

a) Any provisional agreement will be conditional on consultation 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 Pharmac's decision-making framework as outlined in its then OPPs with reference to the Factors for Consideration.

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 approve a negotiated agreement

(ii) The termination of the RFP process.

7. 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 Pharmac notifies suppliers affected by those changes.

(ii) to not 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 letter.

(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 to consult. In this situation, we may ask you to adapt and resubmit your proposal considering consultation, or alternatively we may request that a new proposal 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 advice from PTAC, any relevant specialist advisory committee(s), or any other parties at any stage of the RFP process. Pharmac will notify you if the advice results in any changes to the terms of the RFP.

c) Subject to Pharmac's prior consent, you must not initiate or engage in any communication with other suppliers in relation to this RFP, whether before or after submitting your proposal(s), until such time as a provisional agreement is approved by Pharmac's Board or the Board's delegate.

d) You must not initiate or engage in any communication with Pharmac, Manatū Hauora (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), Te Whatu Ora, Te Aka Whai Ora, Whaikaka or any of their officers or directors, or advisors to Pharmac with a view to influencing the outcome of this RFP process. Failure to comply with this clause will entitle Pharmac, in its sole discretion, to disqualify you from this RFP process.

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

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

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) 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 insulin pumps, insulin pump consumables, or CGM devices by Pharmac's apparent acceptance and instead a separate agreement needs to be negotiated.

i) Pharmac is not liable in any way 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.

j) 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, external advisors, Manatū Hauora, Te Whatu Ora, Whaikaha. and Te Aka Whai Ora (**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.

(ii) during consultation on a provisional agreement with a supplier.

(iii) in publicly notifying any approval by the Pharmac Board of that agreement.

(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 purpose described in sub-clauses (i) to (iv) above. You

acknowledge, however, that it is for Pharmac to decide, at 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.

8. Anticipated timetable

a) Following the close of the RFP, Pharmac anticipates:

(i) the Pharmac Evaluation Committee evaluating proposals in September 2023

(ii) negotiating with submitter(s) of one or more preferred proposals in October to November 2023

(iii) consulting on provisional agreement(s) in December 2023 to January 2024

(iv) Pharmac's Board, or the Board's delegate, considering provisional agreement(s) in or after February 2024,

provided that the above timeframes 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 1 April 2024.

c) Please note that if a proposal for dual supply is accepted, the date of implementation may be later to allow for a managed transition to any dual supply arrangement.

9. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Market information

Usage data:

Usage data from 2020 to 2023 for insulin pumps, insulin pump consumables, blood glucose testing meters and blood glucose testing strips is available in Attachment 3.

Anticipated patient uptake:

Based on advice from our clinical experts, New Zealand data sources, a number of commercial assumptions and modelling, we consider that the number of people who may access insulin pumps and CGMs each year in New Zealand could be as shown in the tables below. This includes an increase in uptake in insulin pumps associated with the proposed eligibility criteria changes outlined on pages 7-8.

Table 1: Anticipated individual uptake of CGMs and Pumps

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Eligible individuals	17,700	18,400	19,200	20,000	21,000
CGM uptake rate	25%	52%	56%	59%	63%
Individuals receiving CGMs	4,500	9,700	10,700	11,900	13,200
Individuals receiving insulin pumps	4,500	5,900	7,100	8,300	9,600
Percent receiving insulin pumps	25%	32%	37%	41%	46%

The 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 insulin pumps, consumables or CGMs. While Pharmac has taken all reasonable care in preparing the information set out below, 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 our estimates of the market size.

PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

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)

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*]

1. Our Contact 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]*

2. Our Point of Contact	
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	

3. Information About Our Organisation	
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 turnover Include 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 ownership State ownership (eg public ownership) Include:	

3. Information About Our Organisation	
• 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 Outcomes Provide detail on how your Organisation supports social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes).	

3. Information About Our Organisation	
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.	

4. Details of proposed products
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.

5. Information about our ability to manage and support our proposed products	
Customer support hours Include: • 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 staff Include 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	*For Te Whatu Ora hospital-based staff* *For patients, whānau and/or caregivers*

5. Information about our ability to manage and support our proposed products	
• staff groups (eg hospital, community) • other relevant information including how consumer and/or whānau voice have been incorporated into these materials	*For other healthcare professionals*
Training and education materials Include 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.

5. Information about our ability to manage and support our proposed products	
	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 support Include 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 processes Include 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.	

5. Information about our ability to manage and support our proposed products	
Any additional information Pharmac should consider under its Factors for Consideration Framework.	

6. Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, <u>attach</u> evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
Quality Management Systems(s) certification for manufacturer(s) **If Yes, <u>attach</u> 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 products List 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. **<u>Attach</u>** 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:			

7. Regulatory consents, technical specifications and evidence to support product(s)

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]*

8. Software and Data	
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	

9. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply		
Stock Management		
Stock holding within New Zealand Include 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 Zealand Include if warehouse owned by company or owned by a logistics provider.		
Recall management Include 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) overview Include exclusivity, expiry date, termination notice period.	***NB*** *Not required if you are the manufacturer and distributor of all proposed products.*
Manufacture to delivery For each product range, from start of manufacture to delivery. Please include: • steps • who is involved • timeframes	
Previous supply performance Information 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 mitigations For 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:	

10. Labour and human rights				
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.	

11. Environmental Sustainability				
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:				

12. Pricing and Terms of Supply

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.

13. Scope for negotiation

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

_____
<Insert name>
<Insert designation>