PHARMAC
Pharmaceutical Management Agency

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30 April 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF NON-INVASIVE VENTILATION EQUIPMENT, OXYGEN CONCENTRATORS, RESPIRATORY GAS HUMIDIFIERS AND ASSOCIATED PRODUCTS

PHARMAC invites proposals for the supply of non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products ("NIV Products") to New Zealand DHB hospitals.

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

- Schedule 1 sets out the background to the RFP and the range of products included and types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 specifies the information and evidence you need to include in your proposal; and
- Schedule 4 and Attachments 1, 3 and 4 contain the forms in which you are to provide the details of your proposal.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than 5.00 p.m. on 8 June 2018

If you have any questions about this RFP, please post these on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

Schedule 1: Background to RFP and types of proposals sought

1. Background to RFP

(a) *PHARMAC's role in Medical Devices*

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the District Health Boards (DHBs). In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC.

Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operation Policy Framework, DHBs are required to comply with the Pharmaceutical Schedule as determined by PHARMAC.

(b) *Reasons for running the RFP*

PHARMAC is taking a phased approach to its activity in medical devices. Following consultation feedback received in September 2016, PHARMAC has expanded its medical devices scope to cover respiratory care equipment and consumables. Due to the complexity and size of this category PHARMAC has divided the category into the following three sub-categories for the purpose of procurement activity:

- Respiratory equipment and consumables (including respiratory suction products) ("**Respiratory Products**")
- Non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products ("**NIV Products**")
- Invasive ventilation equipment

In April 2017, PHARMAC issued a Request for Proposal for listing agreements for the supply of Respiratory Products to DHB hospitals.

This RFP is for listing agreements for the supply of NIV Products to DHB hospitals.

A further procurement process will be undertaken for invasive ventilation equipment in the future.

(c) Impact of RFP

PHARMAC intends to establish national listing agreements **("National Contracts")** with suppliers to secure the supply of NIV Products used by DHB hospitals in both hospital and community settings **("DHB Hospitals").** It is expected that NIV Products subject to a National Contract will be listed in Section H, of the Pharmaceutical Schedule. National Contracts would not be exclusive of other suppliers, and it is possible that multiple suppliers of equivalent NIV Products will be listed, where appropriate.

There may be some medical devices associated with, but not exclusive to, NIV Products that were submitted in the Respiratory Products RFP. Suppliers who currently have medical devices associated with NIV Products submitted under the Respiratory RFP may choose to submit additional proposals via this RFP or to extend their product ranges, for consideration.

2. Expected outcome of the RFP

(a) PHARMAC intends to establish National Contracts with suppliers of NIV Products to:

(i) list a range of NIV Products available for use by DHB Hospitals in Section H, of the Pharmaceutical Schedule;

(ii) secure future supply of NIV Products for DHB Hospitals at competitive prices;

(iii) secure a range of options for DHB Hospitals to access NIV Products, including supply arrangements that meet DHB Hospital requirements;

(iv) ensure access to an appropriate level of clinical support, education and training for relevant DHB Hospital health professionals;

(v) ensure access to an appropriate level of technical support for other relevant DHB Hospital personnel, including but not limited to, clinical engineers;

(vi) engage and establish relationships with new and current suppliers of NIV Products; and

(vii) move commercial arrangements for NIV Products into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available to DHB hospitals.

(b) PHARMAC recognises that the use of medical devices touches a wide group of patients and health professionals; therefore, in the event a National Contract is entered into with a supplier as an outcome of this RFP process, and the NIV Products are listed in Section H of the Pharmaceutical Schedule:

(i) The listing shall be non-exclusive and will include pricing and details of NIV Products;

(ii) It will be discretionary for DHB Hospitals to procure the NIV Products from the supplier, however where they do, DHB Hospitals will be expected to procure these NIV Products under the National Contract;

(iii) It is anticipated that multiple suppliers of NIV Products will be listed, where appropriate;

(iv) Any resultant National Contract will be between the supplier and PHARMAC. DHBs will be able to procure under the National Contract, effective from the listing date, and will not be required to individually approve the agreement for it to come into effect;

(v) There may be alternative options for procuring NIV Products, such as various loan options, that are included in the National Contract that are not included in Pharmaceutical Schedule listing.

(c) Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to act in accordance with the Pharmaceutical Schedule.

3. **Scope of NIV Products**

(a) PHARMAC is willing to consider proposals that involve NIV Products for listing in Section H of the Pharmaceutical Schedule for use by DHB Hospitals; and the following products are considered **'in scope'** of this RFP:

(i) Non-invasive positive pressure ventilation devices (NIPPV) including:

- Fixed pressure devices (CPAP's)
- Auto adjusting pressure devices (APAP's)
- Fixed within range for inspiratory and expiratory pressures devices (BPAP's)
- Variable pressure devices (VPAP's);

(ii) Non-invasive negative pressure ventilation devices (NPV);

(iii) NIPPV and NPV specific consumables and associated products including but not limited to:

- masks, and mask cushions, liners and frames
- forehead spacers, pads, supports and pillows
- nasal prongs and nasal pillow cushions
- tubing, hoses, and connectors
- chin straps, headgear, headgear clips and accessories
- hose holders, clamps
- carry bags and cases
- spare parts and replacement batteries
- filters
- water chambers
- exhalation diffusors
- product holders and stands
- other products associated with the use and care of NIV Products

(iv) Associated respiratory gas humidifiers and their associated consumables and accessories;

(v) Oxygen concentrators and their associated consumables and accessories.

(b) What PHARMAC considers as **'out of scope'** for this RFP includes but is not limited to the following:

(i) Invasive ventilation devices and associated products;

(ii) NIV Products already specifically listed in Part II of Section H of the Pharmaceutical Schedule;

(iii) General respiratory consumables not associated with NIV Products; or

(iv) Any other medical device categories.

4. **Types of proposals sought**

(a) PHARMAC is willing to consider the following types of proposals:

(i) Proposals for the supply of NIV Products to DHB Hospitals;

(ii) Proposals for the supply of NIV equipment with purchasing options that meet the current and future requirements of DHB Hospitals;

(iii) Proposals with a single price per supply option;

(iv) Alternative pricing options, provided the proposal also includes a pricing option as per 4 (a) (iii) above;

(v) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed NIV Products during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHBs within a reasonable timeframe.

(b) Proposals must meet all the mandatory information and evidence requirements as set out in the responses column in Schedule 3.

(c) PHARMAC is **not** willing to consider proposals:

(i) for cross category bundles of products; or

(ii) sole supply arrangements.

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

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) All RFPs must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single submission.

   (c) All proposals must be submitted to PHARMAC via GETS no later than 5.00 p.m. (New Zealand time) on **8 June 2018.** Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

   (d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

   (e) If you have any enquiries about this RFP, you should submit them via GETS (www.gets.govt.nz).

2. **Evaluation**

   (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).

   (b) The Evaluation Committee will evaluate proposals in light of 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 (FFC) that form part of PHARMAC's current Operating Policies and Procedures, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

   (c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those FFC which relate directly to these aspects will be given greatest weight by the Evaluation Committee but all FFC are important.

   (d) The information to be taken into account in applying the decision mechanism by the Evaluation Committee will be at its discretion, however it will include:

      (i) information provided by you in accordance with Schedule 3 and 4 of this RFP;

      (ii) information and evidence requirements as set out in Schedule 3 of this RFP;

(iii) ability to provide the appropriate level of product support, including but not limited to:

(A) clinical training and education in the use and handling of products;

(B) training and education in equipment cleaning and maintenance (where applicable);

(C) technical support for clinical engineers (where applicable);

(D) information for patients;

(E) supply chain to support sustainable provision of products; and

(F) equipment tracking, maintenance and repair (where applicable).

(iv) provision of DHB usage data where applicable, and reference sites and referees;

(v) any advice received from relevant clinicians and/or DHB staff;

(vi) any information received from reference sites and referees; and

(vii) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

(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) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **PHARMAC may request further information**

(a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to) detailed information about your company structure, credit status and any other relevant company information.

(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 judgment, this would not be unfair to any other party.

4. **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) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of medical devices, which are available as a download (Attachment 2) from GETS, will apply.

(c) You **must** complete and submit Attachment 3 of this RFP as part of your proposal by declaring that you have read and understood PHARMAC's standard terms and conditions for the supply of medical devices, and where you disagree with any of the standard terms and conditions, include comments about the terms and conditions you would seek to amend during any negotiation.

(d) 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, as a result of the impact that other negotiated terms may have on price.

(e) 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.

(f) 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).

5. **Consultation and approval**

(a) Any provisional agreement will be conditional on consultation with DHBs and other interested parties, 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 the FFC in PHARMAC's then current OPPs.

(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 accept a negotiated agreement; or

(ii) the termination of the RFP process.

6. **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 it notifies suppliers affected by those changes;

(ii) not to 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 in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals 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; and

(viii) to re-advertise for proposals.

(b) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(c) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC, with a view to influencing the outcome of this RFP process.

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

(e) You must limit the information provided to that which is requested in Schedule 3 and 4 and Attachments 1, 3 and 4 and provide it succinctly and clearly. Please do not provide brochures or additional information (e.g. PEHNZ forms and presentations) unless specifically requested to do so in this RFP document.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

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

(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 NIV Products by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever 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) It is possible that more than one supplier may be awarded a contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of NIV Products or restricts the terms that may be agreed with any other supplier.

(k) PHARMAC will consider your proposal and information exchanged between the parties 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, the Ministry of Health and DHBs (**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; or

(ii) in the course of consultation on a provisional agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that agreement; or

(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 purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in 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.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the PHARMAC internal Evaluation Committee evaluating proposals from July 2018;

(ii) negotiating with submitter(s) of one or more preferred proposals from August to December 2018;

(iii) consulting on a provisional agreement(s) from September 2018

(iv) PHARMAC's Board, or the Board's delegate, considering provisional agreement(s) in or after October 2018; and

(v) NIV Products being listed as agreements are approved following consultation.

provided that the above time frames 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 anticipated to be 1 December 2018.

8. Governing Law

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

Schedule 3: Information and evidence to be included in your proposal

Please include the following information and evidence in your proposal. Proposals that do not include mandatory responses will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

Requirement	**Evidence / Information**	**Response**
Pricing, types and sizes of products, and procurement options	Detailed information about all proposed NIV Products and any related conditions or proposed terms as set out in **Attachment 1** (and **Schedule 4** as needed). **Any proposed NIV Products that do not include a price will not be considered by PHARMAC (unless noted as free of charge or supplier provided at no cost to the DHB).**	Mandatory
Spare parts and accessories pricing and details	Details of proposed spare parts or specialised accessories required throughout the service life of any proposed NIV equipment as set out in **Attachment 1** (and **Schedule 4** as needed) Applicable where your proposal includes NIV equipment offered for outright purchase.	Mandatory (where applicable)
WAND registration	All proposed NIV Products must be WAND registered. WAND registration number must be provided for all NIV Products set out in **Attachment 1**. Please **do not** provide WAND documents.	Mandatory
International compliance	Evidence of international compliance certificates must be provided (eg. ARTG, CE Mark) for all NIV Products set out in **Attachment 1.** Please **attach** copies of certificates.	Mandatory
GS1 (GTIN) and UNSPSC	Provide codes for each proposed NIV Product as set out in **Attachment 1.**	Desirable
Biocompatibility	Indicate if NIV Products contain latex as set out in **Attachment 1**. Provide any further relevant biocompatibility information of skin contact products in **Schedule 4**. Applicable where your proposal includes long term skin contact NIV Products.	Mandatory Mandatory (where applicable)

Requirement	Evidence / Information	Response
DHB current usage data – equipment only	Provide sales data, including volume and spend, by DHB. **in an excel format,** for the 3 years to 31 March 2018 for all NIV equipment items submitted in Attachment 1. Applicable where you have supplied proposed NIV equipment, such as positive airway pressure machines, oxygen concentrators and active humidifiers, to DHB Hospitals in the time period stated. Include products under any type of supply arrangement, if any such supply has had ownership arrangements other than DHB outright ownership at time of purchase please state the terms.	
DHB current usage data – all NIV Products	Provide sales data, including volume and spend, by DHB, **in an excel format,** for the period 1 April 2017 to 31 March 2018 for all line items submitted in Attachment 1. Applicable where you have supplied a proposed NIV Product to DHB Hospitals in the time period stated.	Mandatory (where applicable)
Current Equipment supply arrangements by DHB	Provide detailed information by DHB about the current purchasing models under which you supply NIV equipment to DHB Hospitals. Applicable where you have supplied NIV equipment to DHB Hospitals over the last 3 years to 31 March 2018	Mandatory (where applicable)
Equipment purchasing models, including outright purchase, lease, rent and any other arrangement you would like to have considered with respect to the provision of equipment	Provide detailed information about all purchasing options for NIV equipment you would like considered for your proposal as set out in **Attachment 1** and **Schedule 4.** Applicable if your proposal includes NIV equipment	Mandatory (where applicable)
Current DHB Hospital contracts	Provide details of DHB Hospital contracts in place including expiry as set out in **Schedule 4**, and any additional cost and volume information not already included in **your sales data excel spreadsheet.** Applicable where you currently have an agreement with DHB Hospital(s) to provide NIV Products.	Mandatory (where applicable)
	Provide details of any NIV Products or supply options currently provided to DHB Hospitals that you have **not**	

Requirement	Evidence / Information	Response
	included in this proposal, and rationale for this, as set out in **Schedule 4**. Applicable where your proposal does not include all NIV Products and supply options that you currently provide to DHB Hospitals (contracted or non-contracted)	Mandatory (where applicable)
Financial analysis of your proposal	Provide an overview of how your proposed pricing compares to the contracted/non-contracted pricing currently offered to DHBs, as set out in **Schedule 4.** Include a detailed financial impact analysis of your proposal for each DHB based on current usage patterns; to be **attached** in an Excel document named: ***<Company name>* Financial impact analysis for NIV Products** showing the volume of all NIV Products sold for the period, 1 April 2017 to 31 March 2018, with price paid by the DHB Hospital and new price applicable based on your proposal. Applicable where a proposed NIV Product is currently supplied to DHB Hospital(s)	Mandatory (where applicable)
Distribution and supply arrangements	Provide information relating to your ability to ensure continuity of supply of products to DHB Hospitals; as set out in **Schedule 4**.	Mandatory
Other major markets	Provide information about NIV Product supply in other major markets, reference sites and referees as set out in **Schedule 4**. Applicable where your NIV Product supply experience is for countries other than New Zealand DHBs.	Mandatory (where applicable)
Organisational information	Provide information about your organisation as set out in **Schedule 4**. Your response must include information about your ability to manage liability in the event of a major product recall or failure to supply event as described in Part 6 of PHARMAC's standard terms and conditions for the supply of medical devices – refer to Attachment 2.	Mandatory
Safety, performance and standards	Provide information about the extent to which you meet the standards set out in **Schedule 4.** Whether a standard is applicable, or not, will depend on the type of NIV Product you have included in your proposal, and your role (if any) in ongoing interaction with the NIV Product, including but not limited to maintenance and repairs, fleet management, cleaning and reprocessing. It is mandatory that you complete this section in **Schedule 4.**	Mandatory (where applicable)

Requirement	Evidence / Information	Response
Quality management systems	Indicate whether or not your organisation and relevant parties in your supply chain conform to ISO 9000-Quality management or ISO 1345:2016 Medical devices quality management systems as set out in **Schedule 4**.	Desirable
	Provide information about your current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods, as set out in **Schedule 4.**	Mandatory
	Provide information about your business continuity planning in relation to unexpected events that could impact your ability to support ongoing supply of your NIV Products.	Mandatory
DHB Hospital education and training requirements	Provide a statement of your understanding of DHB Hospital educational requirements and your experience in providing training and product support for the proposed NIV Products, as set out in **Schedule 4**.	Mandatory
	Provide information about your ability to support DHB transition to your NIV Products, as set out in **Schedule 4.** Please **attach** an example of a detailed transition plan.	Mandatory Mandatory
	Provide information about the operating manuals and other instructions and guides that would be provided to DHB Hospitals that procure your proposed NIV Products, as set out in **Schedule 4.** Please **do not** provide full operating manuals for any proposed NIV equipment. A copy of a brief example troubleshooting guide for proposed NIV equipment will be acceptable.	Mandatory
Patient information	Provide information about patient instructions and/or educational resources that would be provided to DHB Hospitals to support your proposed NIV Products, as set out in **Schedule 4**. Please **do not** provide copies of all available patient information resources. A copy of an example patient brochure or similar will be acceptable. Applicable where your proposal includes NIV equipment intended for use in home settings.	Mandatory (where applicable)
Consignment stock arrangements	Provide information related to your ability to support consignment products as set out in **Attachment 1** and **Schedule 4**.	Mandatory (where applicable)

Requirement	Evidence / Information	Response
	Applicable where a proposed NIV Product is available on consignment.	
Servicing, warranties and cleaning	Provide details for service agreements, warranties, cleaning and reprocessing instructions for NIV equipment included in proposal, as set out in **Schedule 4**. Provide details of NIV equipment life expectancy and expected product upgrade cycle. Applicable where your proposal includes reusable equipment for outright purchase and/or single patient use consumables or equipment that requires cleaning during use, and/or where your proposal requires DHB Hospital management of reusable lease equipment.	Mandatory (where applicable)
Waste reduction and recycling	Provide information about manufacturing waste reduction policies and New Zealand recycling processes relevant to your proposed NIV Products, as set out in **Schedule 4**.	Desirable
Continuity of patient care	Provide information on your willingness and ability to provide congruent NIV Products to non-DHB providers, (eg. ACC) as set out in **Schedule 4**.	Desirable
Working with PHARMAC and other stakeholders	Provide information about how you envisage working with PHARMAC and other key stakeholders, as set out in **Schedule 4**.	Mandatory

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
c/- Maree Hodgson
Senior Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products

In response to your request for proposals (**RFP**) dated 30 April 2018 we put forward the following proposal in respect of non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products **("NIV Products")**

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 1, 3 and 4 as part of your proposal.

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

(a) Our contact details:

Full legal trading name in NZ	
Key Contact person	
Address	
Phone	
Mobile phone	
Facsimile	
Email address	

(b) Key features of our proposal and associated services available:

(c) Information relating to pricing ($NZ, GST exclusive) inserted in Attachment 1, including any related conditions or proposed terms:

(d) Information about the biocompatibility of our proposed skin contact products, in addition to the latex status as set out in Appendix 1:

[Including information about any reported adverse events relating to biocompatibility/allergies/sensitivities]

(e) Information relating to NIV equipment included in proposal, in addition to that set out in Appendix 1:

[[Delivery lead in time]

[Product support, training and education]

[Other relevant information]

(f) Information by DHB about NIV equipment supply arrangements to DHB Hospitals

[Supply models offered currently]

[reason for continuing or not continuing to offer these models in the proposal]

(g) Additional information relating to current NIV equipment supply options, including but not limited to outright purchase, lease, rent and rent to buy arrangements:

[Any differences between current arrangements with DHB Hospitals and proposed arrangements]

[if fleet options offered:

- *Limitations and/or consumable requirements per device and or per DHB Hospital*
- *Contingencies for peaks in demand*
- *Assumptions used to estimate fleet size requirements*
- *Delivery and retrieval timeframe(s)*
- *Delivery, receipt and pre-use procedures*
- *Management and operational arrangements including equipment tracking*
- *Respective supplier and DHB responsibilities for fleet management*
- *Risk and liability during key exchange and activity points]*

[Product support, training and education]

[Termination terms and conditions]

[Other relevant information about the arrangement(s) being proposed]

(h) Information about current contracts we have in place with DHB Hospitals, in addition to that included in Appendix 1:

[Expiry dates]

[Additional cost and volume data/information]

[Other relevant information about current contracts in place with DHB Hospitals]

*[NIV Products or procurement options currently provided to DHB Hospitals that are **not** included in proposal, and reason for this]*

(i) Financial analysis of our proposal:

[Overview of how proposed pricing compares to that currently offered to DHB Hospitals and total National cost impact of your proposal]

*[**Attach** detail in Excel format as requested in schedule 3]*

(j) Information about our proposed distribution and supply arrangements including our ability to ensure continuity of supply to DHB Hospitals:

[Whether you are a manufacturer or distributor of the proposed NIV Products]

[Terms of any distribution agreements, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement]

[Description of supply chain used to bring stock to NZ]

[Details of distribution and stock-holding for New Zealand – including but not limited to amount of stock held and warehouse/distribution centre location(s) where it is held]

[Delivery frequency and lead in times, including under stable demand situations, in the event of supply disruptions, and when there is an unexpected surge in demand]

[Specific measures to secure stock for New Zealand from international production, including information about agreements in place with other parties in supply chain and notice periods required for any changes]

[Information relating to the manufacturing sites used to produce the products you propose, including but not limited to country of origin, whether one site has end to end production or if products are sent to other sites for finishing e.g. packaging, sterilisation etc]

[Any freight and delivery costs to DHB Hospitals – noting a preference for Free into Store arrangements]

[Other relevant supply chain arrangements]

(k) Information about our other major markets and previous supply performance:

[Private New Zealand market(s)]

[International markets]

[Recent tenders awarded]

[Reference sites where proposed products are used in similar ways and settings to DHBs,

and sales volumes for 1 Apr 2017 – 31 Mar 2018] *[Contact details for one clinical, one procurement and one technical (eg. clinical engineer) referee for non-NZ DHB sites]*

(l) Information about our organisation:

[Organisational structure in NZ and globally (if applicable)] *[information about your ability to manage liability in the event of a major product recall or failure to supply event as described in Part 6 of PHARMAC's standard terms and conditions for the supply of medical devices – refer to Attachment 2]* *[Management, technical skills, experience and qualifications of staff in relation to the proposed NIV Products]* *[Customer support hours for repairs, troubleshooting and advice]* *[Other relevant information about organisation]* *[Where any of the requested information has been provided to PHARMAC within the last twelve months in response to a previous Request for Proposal, provide the name and date of the RFP and detail any changes]*

(m) Information about our compliance with safety and performance standards:

Standard	Information about the extent to which we conform with the standard	Conformance evidence **attached**?
AS/NZS IEC 60601-1: 2015 Medical electrical equipment – General requirements for basic safety and essential performance	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*
AS/NZS 3200.1.1:1995 Approval and test specification – Medical electrical equipment – General requirements for safety – Collateral Standard – Safety requirements for medical electrical systems	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*
AS/NZS 3200.1.2:2015 Medical electrical equipment – Part 1.2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*
AS/NZS 3551:2012 Management programs for medical equipment	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*
AS/NZS 4187:2014 Reprocessing of reusable medical devices in health	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*

service organizations		
IEC standards and/or other relevant standards *[Specify standard]*	*[include reference to relevant NIV Product(s)]*	*[Yes/No/NA]*

(n) Information about our Quality Management Systems

[Information about conformance to ISO 900 Quality management or ISO 1345:2016 Medical devices quality management systems. ***Attach*** *evidence where available]*

[Information about our current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods]

[Information about our business continuity planning in the event of an unexpected impact on our ability to supply our products, eg IT failure, manufacturing plant or product QC failure, force majeure event]

(o) Our understanding of DHB educational requirements and our experience in providing training and product support for the NIV Products submitted:

Clinical staff and technical personnel

(p) Information about our ability to support DHB transition to our NIV Products:

[Overview of transition support with detailed transition plan ***attached****]*

(q) Information about operating manuals, instructions and guides that would be provided for the safe and appropriate use, and maintenance, of our NIV Products

[Overview of content of operating manuals, instructions and guides for the range of NIV Products proposed for clinical and technical personnel. Please ***do not*** *include copies of full equipment operating or service manuals]*

(r) Information about our instructions and/or educational resources for patients

[Overview of patient information resources for NIV Products intended for use in home settings]

(s) Information about our current (and/or proposed) consignment stock management system:

[Risk and liability arrangements]

[Responsibility for stock management including storage requirements, stock-takes,

replenishment, discrepancy resolution]

[Auditing arrangements]

[Other relevant consignment stock management information]

*[Provide detail in **Attachment 1** of which products a consignment model would apply to]*

(t) Details of our warranties and services for maintenance, servicing and calibration for reusable equipment:

[NIV equipment life expectancy and expected product upgrade cycle]

[Warranty information in addition to that included in Attachment 1, including warranties for repairs and spare parts]

[Frequency of calibration and maintenance]

[Performed by DHB clinical engineers on-site, or off-site service centre]

[Replacement and repair policies]

[Duration of availability of spare parts after date of delivery]

[Duration of availability of maintenance, servicing and calibration services after date of delivery]

[Cost of respective services including within the warranty period and following expiry of the warranty period]

[Training of DHB staff (eg. clinical engineers)]

[Other relevant information about maintenance, servicing and calibration services]

(u) Information about equipment cleaning reprocessing:

[Cleaning requirements during same patient use, including any specialised cleaning equipment and products]

[Reprocessing requirements between patients, including any specialised reprocessing equipment and products]

[Other relevant information about cleaning and reprocessing]

(v) Information about manufacturing waste reduction policies and within New Zealand recycling processes:

(w) Information about our willingness and ability to provide congruent NIV Products and procurement options to healthcare providers funded by non-DHB entities, to enable continuity of patient care:

[eg. ACC, non-DHB community service and/or palliative care providers, other]

(x) Information about how you envisage working with PHARMAC and other key stakeholders:

[including how patients could obtain ongoing consumable requirements where DHB Hospitals provide initial NIV Products]

(y) Proposal/suggestions (eg. pricing, risk sharing arrangements) regarding the medical device not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(z) Reasons why PHARMAC should accept our proposal:

(aa) Additional information that PHARMAC should consider when evaluating our proposal:
