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26 April 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RESPIRATORY EQUIPMENT AND CONSUMABLES (INCLUDING RESPIRATORY SUCTION)

PHARMAC invites proposals for the supply of respiratory equipment and consumables (including respiratory suction) to DHB hospitals in New Zealand.

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 general information you need to include in your proposal; and
- Schedule 4 and attachments 1, 3 and 4 specify the format, product information and specification that you must include as part 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 Friday 16 June 2017**.

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

We look forward to receiving your proposal.

Yours sincerely



Sarah Fitt
Director of Operations

Schedule 1: Medical Devices, 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.

(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 decided to expand its medical devices scope to include 11 new categories, one of which is respiratory equipment and consumables (including respiratory suction) (**Respiratory Products**) as referenced in Schedule 1, paragraph 4 (a) below.

(c) Impact of RFP

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

2. Expected outcome of the RFP

(a) As a result of this RFP, PHARMAC expects to:

- (i) list a range of Respiratory Products available for use in DHB hospitals in Section H, Part III of the Pharmaceutical Schedule;
- (ii) secure on-going supply of Respiratory Products for DHB hospitals at competitive prices;
- (iii) ensure access to an appropriate level of clinical support, education and training for relevant health professionals;
- (iv) engage and establish relationships with new and current suppliers of Respiratory Products; and
- (v) move commercial arrangements for Respiratory Products into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available in DHB hospitals.

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

- (i) The listing shall be non-exclusive and will include pricing and details of the Respiratory Products.

- (ii) It will be discretionary for DHBs to purchase the Respiratory Products from the supplier, however where they do, DHB Hospitals will be expected to purchase these Respiratory Products under the National Contract.
- (iii) It is anticipated that multiple suppliers of Respiratory Products will be listed, where appropriate.
- (iv) Any resultant National Contract will be between the supplier and PHARMAC. DHBs will be able to purchase under the National Contract, effective from the listing date, and will not be required to individually approve the National Contract for it to come into effect.

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals for listing in Part III of Section H of the Pharmaceutical Schedule for use in DHB hospitals:

- (a) Proposals for Respiratory Products.
- (b) PHARMAC is not willing to consider proposals for cross category bundles of products.
- (c) PHARMAC is willing to consider proposals that include volume based discount arrangements (volume based tiered pricing) – a maximum of 3 tiers will be considered.
- (d) Proposals must meet all the mandatory requirements as set out in the responses column of product information requirements in Schedule 3.
- (e) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Respiratory Products during the term of a National Contract, and that if agreed between PHARMAC and the successful supplier, the changed or upgraded product would be made available to DHBs within a reasonable timeframe.
- (f) Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to comply with the Pharmaceutical Schedule as determined by PHARMAC.

4 Scope of 'Respiratory Products' category

- (a) PHARMAC is willing to consider proposals that involve Respiratory Products for listing in Part III of Section H of the Pharmaceutical Schedule for use in DHB hospitals; and the following products are considered '**in scope**' of this RFP:
 - (i) Oxygen delivery consumables and accessories, including flow meters.
 - (ii) Aerosol delivery devices and associated consumables.
 - (iii) Non-powered humidifiers (passive and bubble) and associated tubing and consumables.
 - (iv) Laryngectomy and tracheostomy consumables.

- (v) Spirometers and respiratory muscle trainers and associated consumables.
- (vi) Breathing filters.
- (vii) Powered and non-powered respiratory suction devices and associated consumables.
- (viii) Ventilator circuits and associated consumables and accessories.

For this RFP, consumable medical devices will include both single use items, single-patient use and defined-life multiple use items.

- (b) PHARMAC is not willing to consider proposals for any other products, including but not limited to the following products identified as **'out of scope'** for this RFP:
 - (i) Positive Airway Pressure equipment and consumables (CPAP/BiPAP/VPAP/APAP).
 - (ii) Ventilators.
 - (iii) Nitric oxide delivery systems and associated consumables.
 - (iv) Powered humidifiers.
 - (v) Oxygen concentrators.
 - (vi) Oxygen analysers.
 - (vii) Oxygen sensors.
 - (viii) Gas blenders.
 - (ix) Medical gases.
 - (x) Medical gas hardware e.g. tanks, pipework, connectors and regulators.
 - (xi) Peak flow meters.
 - (xii) Spacer devices.
 - (xiii) Patient monitoring devices e.g. pulse oximeters, capnography devices.

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 proposals 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 5pm (New Zealand time) on Friday 16 June 2017. 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 (OPPs), 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 Factors for Consideration which relate directly to these aspects will be given the 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 Schedules 3 and 4 of this RFP;
 - (ii) product information requirements as set out in Schedule 3 of this RFP;

- (iii) ability to provide the appropriate level of clinical support needed for these products, including but not limited to:
 - (A) training and education in the use, handling, cleaning and care of products;
 - (B) clinical support for respiratory care teams;
 - (C) technical support for clinical engineers (if applicable);
 - (D) audits of respiratory suction equipment (if applicable)
 - (E) supply chain to support sustainable provision of the goods;
 - (iv) provision of DHB usage data where applicable and reference sites;
 - (v) any advice received from relevant clinicians and/or DHB staff; and
 - (vi) 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 submitter 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 suppliers 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 National Contract 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 National Contract within what PHARMAC considers being a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

- (a) Any provisional National Contract will be conditional on consultation with suppliers 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 National Contract 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 factors for consideration in PHARMAC's then current OPPs.
- (d) If the Board or its delegate does not approve the provisional National Contract, then PHARMAC may initiate negotiations for a provisional National Contract 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 National Contract(s); 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 National Contract 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 your proposal(s), until such time as a provisional National Contract 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 operating 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 it does 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 Respiratory 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 National Contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into National Contracts with other suppliers in respect of Respiratory 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 National Contract entered into with a supplier; or
 - (iii) in publicly notifying any approval by the PHARMAC Board of that National Contract; or
 - (iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.
- (l) 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

Following receipt of proposals, PHARMAC anticipates:

- (a) the Evaluation Committee evaluating proposals from mid-July– August 2017;
- (b) negotiating with submitter(s) of one or more preferred proposals in August– September 2017;
- (c) consulting on provisional National Contract(s) from September 2017;
- (d) PHARMAC's Board, or the Board's delegate, considering provisional National Contracts for approval in or after September 2017; and
- (e) Respiratory Products being listed, as National Contracts are approved, with the first National Contracts anticipated to be listed on 1 November 2017,

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.

8. 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: Information to be included in your proposal

1. The following information should be included in or form part of your proposal:

- (a) details of all types and sizes of your Respiratory Products currently available as set out in Attachment 1;
- (b) information on current usage and expenditure of your Respiratory Products as specified in Attachment 1;
- (c) information on usage and expenditure by DHB Hospital as specified in Attachment 1;
- (d) indicative pricing (GST exclusive, free into store), including any related conditions or proposed terms as set out in Attachment 1;
- (e) information about management and technical skills of your staff;
- (f) describe your current supply arrangements, supply volumes and relevant supply terms in other major markets including recent tenders awarded (in New Zealand and/or other countries);
- (g) describe proposed distribution and supply arrangements for your Respiratory Products, including but not limited to:
 - (i) Your status as to whether you are a manufacturer or distributor of the Respiratory Products
 - (ii) The terms of any distribution agreement, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement
 - (iii) Information regarding freight or delivery costs to DHBs;
- (h) explain your current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods;
- (i) a copy of your current insurance cover certificate relating to:
 - (i) Product Liability Insurance Cover
 - (ii) Public Liability Insurance Cover
- (j) evidence of:
 - (i) how you envisage working with PHARMAC and other key stakeholders;
 - (ii) availability of a comprehensive training, ongoing education and product and customer support package, including clinical engineers (if applicable);
 - (iii) how you envisage working with DHBs to provide an audit service for respiratory suction systems (if applicable).

2. Product information requirements

Suppliers are requested to provide the following information as part of their 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 requirement	Response
All products must be WAND registered	WAND registration number must be provided as per the format in Attachment 1. Please do not provide copies of the WAND documents	Mandatory
International compliance	Evidence of international compliance certificates must be provided.	Mandatory
DHB current usage data	Provide usage and current pricing information by DHB, by product code, for the period 1 Jan 2016 – 31 Dec 2016 for all line items submitted, as per the format in Attachment 1.	Mandatory (where DHBs are currently using your products)
Current contract status (if applicable)	Provide information on active DHB hospital contracts with expiry date, as per the format in Attachment 1.	Mandatory
Financial analysis of your proposal	Provide details of how your proposed pricing compares to the contracted/non-contracted pricing currently offered to DHBs. If DHBs are currently purchasing the proposed products, please include a financial impact analysis of your proposal for each DHBs based on current usage patterns. To be attached in Excel format.	Mandatory
Supply chain arrangements you have or expect to have in place to support NZ market requirements	<p>Information relating to continuity of supply of products in New Zealand. This should include information on:</p> <ul style="list-style-type: none"> • distribution arrangements and stockholding in New Zealand; • minimum order size; • delivery frequency and lead times for: <ul style="list-style-type: none"> ○ a stable demand situation; ○ in the event of supply disruptions; and ○ when there is an unexpected surge in demand for your product <p>Please include any specific measures you will take to secure stock for New Zealand from international production.</p>	Mandatory
Describe proposed distribution and supply arrangements for your Respiratory Products.	<ul style="list-style-type: none"> • Your status as to whether you are a manufacturer or distributor of the Respiratory Products • The terms of any distribution agreement, if you are not the manufacturer, for example the duration and exclusivity of the distribution • Information regarding freight or delivery costs to DHBs 	Mandatory

Requirement	Evidence requirement	Response
Demonstration of supply chain experience and knowledge within the healthcare sector and specifically with New Zealand DHBs.	Provide evidence of your supply chain experience, in NZ in a DHB or equivalent environment. If supply chain experience is for countries other than NZ, supply chain referees must be provided.	Mandatory
Education and Clinical Support	Provide a statement of your understanding of DHB educational requirements, and your experience in providing training and product support for the Respiratory Products submitted. If training and clinical product support experience is for countries other than NZ, clinical referees must be supplied	Mandatory
Audit support for respiratory suction	DHBs have an expectation that suppliers of respiratory suction devices provide an audit support service. Provide full details of audit support services that would be offered by your company, including but not limited to: <ul style="list-style-type: none"> • Frequency • Scope • Reporting • Corrective actions • Cost 	Mandatory – respiratory suction only
Warranties, Servicing and Cleaning for respiratory equipment	Provide details as applicable: Service Agreements and costs Warranties Cleaning instructions Sterilisation instructions	Mandatory – respiratory equipment only
AS/NZ Electrical Standards (for all powered equipment included in proposal)	Documented evidence of compliance with AS/NZ 3551:2012 must be provided	Mandatory
Warranties, Cleaning and Sterilisation (for all defined-life multiple use consumable items)	Provide details as applicable: Warranties Cleaning instructions Sterilisation instructions	Mandatory
Latex status	Indicate if products contain latex or are latex free, as per the format in Attachment 1.	Mandatory
GS1 status	Provide GTIN codes for items, as per the format in Attachment 1.	Desirable
UNSPSC	Provide UNSPSC codes for items, as per the format in Attachment 1.	Desirable
Does the manufacturer operate a waste reduction policy? Is there a recycling process for their products in New Zealand?	Please give details.	Desirable

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 complete all sections and expand the boxes as necessary.

[Supplier to insert date]

Director of Operations
PHARMAC
C/- Jacquie Pillay
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of Respiratory Products

In response to your request for proposals (RFP) dated 26 April 2017 we put forward the following proposal in respect of Respiratory Products.

You must also include information as outlined in Schedule 3 and 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	
Facsimile	
Email address	

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

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

(d) Information about our ability to ensure the continuity of supply of the medical devices:

(e) Information about our previous supply performance and relevant expertise including our overseas market (NB: site references and referees are available to contact):

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

(g) Information about proposed volume based discount arrangements (if applicable) and reasons why they should be considered by PHARMAC. If currently selling Respiratory Products to DHBs please indicate which Tier each DHB would qualify for based on current purchasing volumes. (NB: if required additional documents detailing proposed volume based discount arrangements should be attached to your proposal in word or excel format – not pdf). If Tiered pricing has not been offered please write N/A.

(h) Reasons why PHARMAC should accept our proposal:

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

- (j) Does the manufacturer operate a waste reduction policy? Is there a recycling process for their products in New Zealand?