PHARMAC
Pharmaceutical Management Agency

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23/03/2015

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF RESPIRATORY DEVICES

PHARMAC invites proposals for the supply of **peak flow meters, spacer devices and paediatric masks for use with spacer devices** in New Zealand.

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

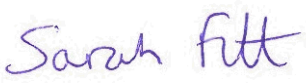
- Schedule 1 specifies the pharmaceuticals for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceuticals; and
- 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) no later than 5.00 p.m. on 20 April 2015

If you have any questions about this RFP, please contact Christine Chapman at PHARMAC on 04 916 7569 or christine.chapman@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely



Sarah Fitt

Director of Operations

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

1. Pharmaceutical

(a) PHARMAC is interested in considering any proposals from suppliers for sole supply in Section B of the Pharmaceutical Schedule for use in the community and listing in Part III of Section H of the Pharmaceutical Schedule (the hospital medicines list (HML)) for use in DHB hospitals of each of the following respiratory devices, referred to individually and collectively as the Pharmaceutical(s):

- Peak Flow Meter – low range
- Peak Flow Meter – normal range
- Spacer Device - small volume
- Spacer Device – medium volume
- Spacer Device – large volume
- Spacer Device - autoclavable
- Paediatric Mask for Spacer Device – for children aged six and under

(b) For the purposes of this RFP, the following definitions apply to the various presentations of peak flow meters and spacer devices:

Peak flow meter	Maximum measurement range
Low range	Up to 450 L per minute
Normal range	Up to 800 L per minute

Spacer device	Volume range
Small volume	100 - 200 mL
Medium volume	200 – 500 mL
Large volume	Greater than 500 mL

2. Background to RFP

The background to this RFP is as follows:

(a) Peak flow meters, medium volume spacer devices and a paediatric mask for use with the spacer devices are supplied under an agreement with Airflow Products. The agreement was the result of an RFP conducted in May 2011 and sole supply status expires on 30 June 2015.

(b) A large volume spacer device (Volumatic) is supplied under an agreement with GlaxoSmithKline. The agreement was the result of an RFP conducted in May 2011 and sole supply status expires on 30 June 2015.

(c) The Pharmaceuticals are listed in Section B and in Part II of Section H of the Pharmaceutical Schedule as follows:

Pharmaceutical	Brand	Price and subsidy
Peak flow meter - low range	Breath-Alert	$11.44
Peak flow meter - normal range	Breath-Alert	$11.44
Spacer device – 230 ml (autoclavable)	Space Chamber	$11.60
Spacer device – 230 ml (single patient)	Space Chamber Plus	$4.72
Spacer device – 800 ml	Volumatic	$8.50*
Mask for spacer device – Size 2	EZ-fit Paediatric Mask	$2.99

(prices are ex-manufacturer, exclusive of GST).

*a confidential rebate applies to Volumatic.

(d) The Pharmaceuticals are only available on a Practitioner's Supply Order (PSO). Up to 20 spacers and masks and 10 peak flow meters are able to be ordered. Up to 5 autoclavable spacers are subsidised by endorsement whereby the prescriber requires a spacer device that is capable of sterilisation in an autoclave and the PSO is endorsed accordingly.

(e) Given that the current sole supply period is to expire on 30 June 2015 PHARMAC now seeks proposals for sole supply in the community until 30 June 2018 and listing in the Hospital Medicines List for each of the Pharmaceuticals.

(f) Please note, in the event a proposal for sole supply in Section B and listing in Part III of the HML is accepted and the successful supplier's brand is not currently listed in Section B or Part III of Section H of the Pharmaceutical Schedule, there would be a transition period (the length of any transition period would be determined at PHARMAC's discretion) where the successful supplier's brand would be listed in the Pharmaceutical Schedule along-side the currently listed brand, prior to the currently listed brand being delisted.

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

(a) PHARMAC seeks proposals for sole supply in the community and listing in Part III of Section H of the Pharmaceutical Schedule for each of the Pharmaceuticals. In addition to individual proposals PHARMAC is also willing to accept proposals for two or more of the Pharmaceuticals (any supplier who submits a multiple Pharmaceutical proposal must also submit a proposal for each Pharmaceutical included in the multiple proposal).

For clarification:

(i) Currently only one size of paediatric masks is funded. PHARMAC considers that only one paediatric mask is required however PHARMAC would be willing to consider proposals that include a paediatric and an adult mask size.

(ii) Proposals for the supply of a spacer device should also include a proposal for the supply of a mask for use with the spacer device.

(iii) Currently two medium sized spacer devices are listed in the Pharmaceutical Schedule (a non-autoclavable spacer and an autoclavable spacer). PHARMAC considers that only a non-autoclavable spacer is required but is willing to consider proposals that include an autoclavable spacer.

(iv) Currently two spacer sizes are listed (230 mL and 800 mL). PHARMAC is open to proposals for the supply of a smaller spacer device.

(v) PHARMAC is not offering hospital sole supply status for the Pharmaceuticals.

(b) Proposals must include the following:

(i) the presentations and packaging;

(ii) the proposed prices;

(iii) information on the maintenance of the Pharmaceuticals;

(iv) information on how robust the Pharmaceuticals are;

(v) information on the registration status of the Pharmaceutical in New Zealand and/or other international jurisdictions;

(vi) the suppliers own rational for PHARMAC's acceptance of the proposal; and,

(vii) a sample of the various Pharmaceuticals.

(c) Proposals for spacer devices must include the following :

(i) information about the compatibility of the spacer device with currently available aerosol inhalers; and,

(ii) evidence that the particle size distribution of a spacer device meets international standards.

(d) Proposals may include expenditure caps, rebates, or other expenditure risk sharing mechanisms – if proposals contain an expenditure cap(s) and/or rebate(s) then these should continue past the sole supply expiry dates.

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

(e) two part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms; or

(f) any pharmaceuticals that are not included in this RFP.

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) Proposals must be submitted no later than **5.00 p.m. (New Zealand time) on 20 April 2015.** Late proposals will only be considered at PHARMAC's discretion.

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

(d) If you have any enquiries regarding this RFP you should contact **Christine Chapman**, (christine.chapman@pharmac.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 basis on which the Evaluation Committee will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are to be determined by the Evaluation Committee at its sole discretion. The matters to be taken into account by the Evaluation Committee will, however, include:

(i) the decision criteria set out in PHARMAC's then current Operating Policies and Procedures (**OPPs**), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable;

(ii) any clinical advice from PTAC or its relevant sub-committee;

(iii) 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).

(c) 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.

(d) 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, in which case you must supply that information within 10 business days of PHARMAC requesting it.

(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.

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 supplier's proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, which are available on request from PHARMAC, will apply.

(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, as a result 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).

5. **Consultation and approval**

(a) Any provisional agreement 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 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 decision criteria 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:

(i) to make such adjustments to the above RFP process as it considers appropriate, 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;

(viii) to readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) 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.

(d) 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 District Health Boards, including any of their officers or directors and Health Alliance with a view to influencing the outcome of this RFP process.

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

(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 letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(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 the Pharmaceuticals 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) 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, 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 Evaluation Committee evaluating proposals in **April/May 2015**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **April/May 2015**;

(iii) consulting on a provisional agreement in May 2015;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after May/June 2015,

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 **July 2015**.

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

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of the Pharmaceuticals. 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 these products and, 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 the figures below.

The number of subsidised units in the community in the years ending 31 December 2012, 31 December 2013 and 31 December 2014 are:

Device	**Jan – Dec 2012**	**Jan – Dec 2013**	**Jan – Dec 2014**
Mask for Spacer Size 2	63,811	62,395	66,691
Peak Flow Meter Low Range	7,593	7,689	7,717
Peak Flow Meter Normal range	30,110	31,697	36,842
Spacer Device 230 ml (autoclavable)	4,468	2,593	3,587
Spacer Device 230 ml (single patient)	189,969	196,651	220,072
Spacer Device 800 ml	12,706	9,498	7,818

Respiratory devices are only available on a PSO with an allowance of up to 5 for the autoclavable spacer, 10 for each of the peak flow meters and 20 for the single patient spacer and the mask. The autoclavable spacer is only subsidised where the prescriber requires a spacer device that is capable of sterilisation in an autoclave and the PSO is endorsed accordingly.

A PSO only applies in the community and, as defined in Section A of the Pharmaceutical Schedule, is a written order made by a Practitioner to ensure medical supplies are available for emergency use, teaching and demonstration purposes, and for provision to certain patient groups where individual prescription is not practicable. Supply under a PSO varies from other pharmaceuticals in the Community in that the Pharmaceutical is given to the patients by their doctor rather than being dispensed by the Pharmacist. From a suppliers point of view delivery for community supply is the same as for other pharmaceuticals namely through the wholesaler to pharmacy which in turn supplies the doctor.

Schedule 4: Proposal form

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

Chief Executive
C/- Christine Chapman
PHARMAC

By email: christine.chapman@pharmac.govt.nz

Dear Sir/Madam

Proposal for the supply of respiratory device(s) Pharmaceuticals

In response to your request for proposals (**RFP**) dated 23 March 2015 we put forward the following proposal in respect of respiratory devices.

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

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of pharmaceutical presentation:

Product	
Size/Range	
Brand name	
Pack size (# units per pack)	
Packaging type	

(c) Key features of our proposal:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

(e) Evidence of market approval and any other required consents:

WAND registration number/s	
Other international standards that the product meets and the registration numbers where applicable	
Insert any other consents obtained or required for the product	
Peak flow meters - evidence of product testing against New Zealand standards (NZS 4237:1994)	
In the event that the product does not have any of the above consents please indicate the date by which you anticipate you will obtain the relevant approval/s.	

(f) Information about our ability to ensure the continuity of supply of the Pharmaceutical:

(g) Information about our previous supply performance and relevant expertise:

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

(i) Reasons why PHARMAC should accept our proposal:

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