PHARMAC
TE PĀTAKA WHAIORANGA

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29 July 2019

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF FLUTICASONE AND FLUTICASONE WITH SALMETEROL, METERED DOSE INHALERS

PHARMAC invites proposals for the supply of fluticasone and fluticasone with salmeterol, metered dose inhalers (**MDIs**) in New Zealand.

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

- Schedule 1 specifies the pharmaceutical 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 pharmaceutical; 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**) (www.gets.govt.nz) no later than 5:00 pm on 19 August 2019.

If you have any questions about this RFP, please post these on GETS. Responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of:

- Fluticasone MDI; and
- Fluticasone with salmeterol combination MDI.

2. Background to RFP

The background to this RFP is as follows:

Funding history of fluticasone MDI and fluticasone with salmeterol combination MDI

Fluticasone is an inhaled corticosteroid (ICS) used as a prophylactic treatment in the management of asthma and in some cases chronic obstructive pulmonary disease. Fluticasone in combination with salmeterol, is a long-acting beta agonist (LABA) that provides an additional symptom control benefit.

Fluticasone MDIs and fluticasone with salmeterol combination MDIs have been fully funded in New Zealand since 1996 and 2006 respectively.

Current funding arrangements

Currently two brands of fluticasone MDIs and fluticasone with salmeterol combination MDIs are listed in Section B and Section H of the Pharmaceutical Schedule without restrictions as follows:

Fluticasone MDI

- Floair supplied by Rex Medical
- Flixotide supplied by GSK

Fluticasone with salmeterol combination MDI

- RexAir supplied by Rex Medical
- Seretide supplied by GSK

Administration device aids (eg Haleraid) and placebo MDIs are currently supplied free of charge to prescribers.

The table below summarises the current listings of fluticasone MDI and fluticasone with salmeterol combination MDI in Section B and Part II of Section H of the Pharmaceutical Schedule for use in the community and DHB hospitals. Confidential pricing arrangements are currently in place for all of these brands:

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
FLUTICASONE					
Aerosol inhaler 50mcg per dose	……	4.68	120 dose OP	✓	**Floair**
Aerosol inhaler 50mcg per dose CFC-Free	……	7.50	120 dose OP	✓	**Flixotide**
Aerosol inhaler 125mcg per dose	……	7.22	120 dose OP	✓	**Floair**
Aerosol inhaler 125mcg per dose CFC-Free	……	13.60	120 dose OP	✓	**Flixotide**
Aerosol inhaler 250mcg per dose	……	10.18	120 dose OP	✓	**Floair**
Aerosol inhaler 250mcg per dose CFC-Free	……	27.20	120 dose OP	✓	**Flixotide**
FLUTICASONE WITH SALMETEROL					
Aerosol inhaler 50 mcg per dose with salmeterol 25 mcg		14.58	120 dose OP	✓	**RexAir**
		33.74		✓	**Seretide**
Aerosol inhaler 125 mcg per dose with salmeterol 25 mcg		16.83	120 dose OP	✓	**RexAir**
		44.08		✓	**Seretide**

Reason for running the RFP

Fluticasone and fluticasone with salmeterol represent a significant expenditure to the Combined Pharmaceutical Budget (**CPB**). For the 2018 financial year (1 July 2017–30 June 2018), the approximate gross expenditure on fluticasone and fluticasone with salmeterol was $29 million.

There are currently two brands of fluticasone and fluticasone with salmeterol listed in the Pharmaceutical Schedule and additional brands are registered with Medsafe or available overseas. In view of this competition, the purpose of this RFP is:

(a) to reduce the total expenditure in the fluticasone and fluticasone with salmeterol combination MDI market;

(b) to secure supply of fluticasone and fluticasone with salmeterol combination MDIs for a three-year sole supply period, with the possibility of extending the sole supply period for two additional periods of one year each; and

(c) to develop PHARMAC's understanding of the supply market for respiratory inhalers to help inform future procurement activities in this therapeutic area.

Clinical Advisory Committee Advice

To inform the development of this RFP and the activities and resources required to support the implementation of any preferred proposal(s), PHARMAC has established a Respiratory Inhalers Advisory Committee made up of health practitioners from across New Zealand involved in the education, management and treatment of respiratory diseases including asthma.

The Respiratory Inhalers Advisory Committee will not evaluate proposals received in response to this RFP, but it will provide advice to PHARMAC staff similar to that of the Pharmacology and Therapeutics Advisory Committee (PTAC) and its subcommittees.

3. Scope

PHARMAC is seeking proposals for the following:

- Fluticasone MDI; and
- Fluticasone with salmeterol combination MDI.

Out of scope products:

PHARMAC considers the following products to be out of scope of this RFP:

- Inhaled corticosteroids and ICS/LABA combination inhalers other than fluticasone and fluticasone with salmeterol combination MDIs;
- Devices other than MDIs used in the treatment of asthma or respiratory diseases;
- Pharmaceuticals for the treatment of asthma or other respiratory diseases other than those pharmaceuticals specified in Schedule 1, Section 1 of this RFP; and
- Proposals involving sole supply or other protections of products other than those specified in Schedule 1, Section 4 of this RFP.

4. Types of proposals sought

PHARMAC is willing to consider the following types of proposals (with the following mandatory requirements):

(a) Suppliers wishing to submit proposals for the supply of fluticasone MDI or fluticasone with salmeterol combination MDI **MUST** submit proposals for community and hospital supply;

(b) Proposals **MUST** be for a three-year sole supply period in the community and DHB hospitals, where PHARMAC has the sole option to extend the sole supply period for two additional consecutive one-year periods. Accordingly, any proposals submitted (including pricing) **MUST** be valid over a period of five years.

(c) Suppliers wishing to submit proposals for the supply of fluticasone MDI or fluticasone with salmeterol combination MDI **MUST** submit proposals that would cover the entire public funded market in New Zealand.

(d) Proposals that involve bundling arrangements, provided that a supplier who submits a proposal including bundling arrangements **MUST** also submit individual pricing for each individual strength included in the bundle capable of being accepted on its own.

(e) Proposals which include bundling arrangements **MUST** be limited to fluticasone MDI and fluticasone with salmeterol combination MDI.

(f) Proposals **MUST** include a similar range of strengths as the strengths for the pharmaceuticals stated in Schedule 1, Section 2 of this RFP.

(g) Proposals **MUST** include information related to education and training for use including information provided to improve access and support adherence for the products amongst groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples.

(h) All proposals that would require a brand change **MUST** include:

- an option that permits use of another product for patients who have a clinical reason that would prevent them changing (e.g. allergic reaction to the new product); and

- a six-month transition period between listing the new brand and commencement of sole-supply.

(i) Proposals that include the following:

- expenditure caps, rebates or other risk-sharing arrangements;

- Proposals that include pharmaceuticals that have not yet gained all necessary Consents. Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate their ability to obtain those consents within a time frame acceptable to PHARMAC.

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

- proposals that restrict patient access to fluticasone MDI or fluticasone with salmeterol combination MDI;

- proposals that include pharmaceuticals other than those identified in Schedule 1, Section 1 of this RFP;

- proposals that involve foreign currency exchange rate clauses or prices linked to any index; and

- 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.

- tiered pricing and rebate arrangements where rebates offered are dependent on expenditure levels being met.

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

(l) PHARMAC is interested in proposals that include accessories such as an administration device aid (for example Haleraid) and placebo MDI's, and notes the Respiratory Inhalers Advisory Committee has indicated that there is a clinical need for Haleraid devices to be made available for patients and for placebo MDI's to be made available for training purposes. Where accessories are proposed, PHARMAC anticipates these would be provided free of charge, which reflects current practice.

(m) Suppliers should provide PHARMAC with samples of all strengths of products and any accessories included in the proposal (and, if supply is intended to be in a different presentation, and/or strength from the provided samples, information about differences must be supplied) within 10 business days of a request from PHARMAC.

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **5.00 p.m.** (New Zealand time) on **19 August 2019**. 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.

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

(d) If you have any enquiries about this RFP you should submit them on GETS, responses to all enquires will be published on GETS.

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 (**Factors**) that form part of PHARMAC's then current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors 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 which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.

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

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

(ii) suitability features (colour or other differentiating features, dose counters, ease of use, pamphlet inserts and brochures);

(iii) supply of accessories, such as Haleraid devices and placebo MDIs;

(iv) any clinical advice from PTAC or its relevant Sub-committee;

(v) any advice from relevant clinician and patient groups including the Respiratory Inhalers Advisory Committee;

(vi) education and training for use including information provided to improve access and support adherence for the products amongst groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples;

(vii) previous supply performance and relevant expertise;

(viii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(f) 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):

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

(ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant Subcommittee, the Respiratory Inhalers Advisory Committee or any relevant professional organisations or healthcare professionals with regards to your product including evaluation of any product samples.

(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 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 PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(d) If the Board or its delegate does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement with any other supplier(s).

(e) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decision to 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;

(viii) to readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC, its relevant Sub-committee or the Respiratory Inhalers Advisory 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 DHBs or advisors to PHARMAC 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 fluticasone MDI and fluticasone with salmeterol combination MDI 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 August/September 2019;

(ii) negotiating with submitter(s) of one or more preferred proposals in September 2019;

(iii) consulting on a provisional agreement in October 2019;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after November/December 2019;

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 March 2020;

(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.

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: Current listing and market information

The following information relates to the estimated subsidised market size of fluticasone MDI and fluticasone with salmeterol combination MDI. 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 fluticasone MDI and fluticasone with salmeterol combination MDI 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.

Fluticasone MDI FYR (ending 30 June) 2016-2018			
Strength (per dose)	**Total doses dispensed**		
	2016	*2017*	*2018*
50 mcg	13,766,880	12,914,523	12,084,600
125 mcg	37,864,200	35,401,030	32,796,240
250 mcg	8,458,680	7,501,942	6,585,480

Fluticasone with salmeterol MDI FYR (ending 30 June) 2016-2018			
Strength (per dose)	**Total doses dispensed**		
	2016	*2017*	*2018*
125 mcg with salmeterol 25 mcg	67,256,160	64,952,680	60,349,560
50 mcg with salmeterol 25 mcg	3,531,960	3,530,042	3,425,160

Fluticasone MDI and fluticasone with salmeterol MDI usage FYR (ending 30 June) 2018				
Pharmaceutical	**Strength**	**Doses**	**Inhalers**	**Gross expenditure**
fluticasone	50 mcg	12,084,600	100,705	$746,020
	125 mcg	32,796,240	273,302	$3,655,602
	250 mcg	6,585,480	54,879	$1,462,978
fluticasone total				
fluticasone with salmeterol	125 mcg with salmeterol 25 mcg	60,349,560	502,913	$21,800,716
	50 mcg with salmeterol 25 mcg	3,425,160	28,543	$953,560
fluticasone with salmeterol total				
Total		**115,241,040**	**960,342**	**$28,618,876**

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz).

You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
C/- Josh Wiles
PHARMAC
PO Box 10-254
(or for courier delivery:
Level 9
40 Mercer Street)
Wellington 6011
New Zealand

Dear Sir/Madam

Proposal for the supply of fluticasone and fluticasone with salmeterol, metered dose inhalers

In response to your request for proposals (**RFP**) dated 29 July 2019, we put forward the following proposal in respect of fluticasone and fluticasone with salmeterol, metered dose inhalers.

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:

You should duplicate this box as necessary

Chemical name	
Strength (e.g. 50mcg)	
Form (e.g. aerosol inhaler)	
Brand name	
Pack size (e.g. 120 doses)	

(c) Details of pharmaceutical manufacture:

You should duplicate this box as necessary

[Chemical name]	
[Inhaled Corticosteroid Treatment eg fluticasone, fluticasone with salmeterol]	
[Strength eg 50 mcg, 125 mcg, 250 mcg]	
Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(d) Key features of our proposal:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. risk sharing mechanisms, rebates, separate pricing arrangements, subsidy and delisting protections etc. (if any) is to be provided below:

Please add strengths to the below tables as required

Sole supply status (individual pricing)		
Aerosol Inhaler	Strength	Proposal
fluticasone MDI	50 mcg	
	125 mcg	
	250 mcg	
fluticasone with salmeterol combination MDI	50 mcg with salmeterol 25 mcg	
	125 mcg with salmeterol 25 mcg	

Sole supply status (bundled pricing)		
Aerosol Inhaler	Strength	Proposal
fluticasone MDI	50 mcg	
	125 mcg	
	250 mcg	
fluticasone with salmeterol combination MDI	50 mcg with salmeterol 25 mcg	
	125 mcg with salmeterol 25 mcg	

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

Date of market approval (please attach copy of Medsafe Gazette notice)	
[**OR** Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)]	
[**OR** Expected date of dossier submission to Medsafe]	

(g) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product for the proposed indications in New Zealand, with additional information if required:

(h) Information about our ability to ensure the continuity of supply of the pharmaceutical:

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

(j) Information about our education and training to be provided for clinicians, patients and other groups as part of our proposal:

(k) Information about our education, training and implementation programmes, to improve access and support adherence for the products included in our proposal amongst groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples (adults and children)

Please include any additional attachments such as proposed training programmes and resources to support your response to this question

(l) Information about suitability features of the pharmaceutical and/or inhaler such as dose counters, ease of use, colour or other differentiating features,

(m) Information about accessories such as administration device aids (eg Haleraids) to be provided as part of your proposal.

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

(o) Additional information that PHARMAC should consider when evaluating our proposal (e.g. if applicable, an estimate of any savings to the patient and/or health system as a result of less-frequent injections). Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework: