

3 December 2015

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF VOLATILE ANAESTHETICS

PHARMAC invites proposals for the supply of volatile anaesthetics 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.
- Appendix 1 contains further market information on anaesthetic machines used by DHB Hospitals

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tenders Service (GETS) no later than 4.00 p.m. on 15 January 2016.

If you have any questions about this RFP, please submit them via GETS.

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

PHARMAC is interested in considering proposals for the supply of one or more of three volatile anaesthetics – sevoflurane, desflurane and isoflurane, via a listing in Part II of Section H of the Pharmaceutical Schedule for use in DHB hospitals, referred to individually and collectively as the Pharmaceutical(s).

2. Background to RFP

The background to this RFP is as follows:

In 2012, PHARMAC entered into an agreement with Baxter Healthcare Limited for the supply of sevoflurane, isoflurane and desflurane to DHB Hospitals, which included a period of sole supply (Hospital Supply Status; HSS). Hospital Supply Status under that agreement ended on 30 June 2015 and we are now looking to re-offer the opportunity for supply of these Pharmaceuticals to the market.

Volatile anaesthetics require vaporiser devices (referred to hereafter as “**Vaporisers**”) which may also require bottle adaptors or bottle keys for filling (referred to hereafter as “**Bottle Adaptors**”). Vaporisers are currently either owned by DHBs or loaned to the DHB by the relevant supplier and information on the anaesthetic machine models being used by DHB Hospitals, including a breakdown of current Vaporiser loans versus DHB ownership, can be found in Appendix 1. PHARMAC is seeking proposals for national contracts for supply of the Pharmaceuticals and proposals should consider and address the compatibility of each Pharmaceutical with the relevant Vaporisers and Bottle Adaptors (where applicable) used in New Zealand.

Several DHBs have already upgraded, or are in the process of upgrading, their anaesthetic machines due to a combination of technological advancement and existing machine age. New generation anaesthetic machines also require new models of vaporisers. PHARMAC is aware that some DHBs have purchased their own vaporisers when upgrading anaesthetic machines.

The Pharmaceuticals are currently listed in Part II of Section H of the Pharmaceutical Schedule as follows (prices are expressed ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Price and subsidy
sevoflurane solution for inhalation 100%, 250 ml bottle	Baxter	\$1230.00* per 6
desflurane solution for inhalation 100%, 240 ml bottle	Suprane	\$1230.00 per 6
isoflurane solution for inhalation 100%, 250 ml bottle	Aerrane	\$1020.00 per 6

*a confidential rebate applies to sevoflurane (Baxter).

Please note, in the event that a proposal for HSS is accepted and the successful supplier’s brand is not currently listed in Part II 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 alongside 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) proposals involving only one of the Pharmaceuticals;
- (b) aggregated proposals involving more than one of the Pharmaceuticals, provided that a separate proposal for each individual Pharmaceutical in the aggregated proposal is also provided;
- (c) proposals involving market exclusivity (in the form of HSS) for one or more Pharmaceutical provided that any exclusivity ends on 30 June 2019 (**Initial HSS period**) but may be extended for a maximum of two further years until 30 June 2021 if given notice by PHARMAC at PHARMAC's sole discretion as outlined in Schedule 2, clause 6 (c);
- (d) proposals that include a provision for the associated loan of Vaporisers and/or Bottle Adaptors (as relevant/applicable), provided that the loan of Vaporisers/Bottle Adaptors is specific to each Pharmaceutical offered in your proposal. For the avoidance of doubt, aggregated proposals involving more than one of the Pharmaceuticals which include provision for the associated loan of Vaporisers/Bottle Adaptors are permitted, provided that a separate proposal for each individual Pharmaceutical including provision for the associated loan of Vaporisers/Bottle Adaptors in the aggregate proposal is provided;
- (e) proposals involving discount on invoice, expenditure caps, non-confidential rebates, or other expenditure risk sharing mechanisms (PHARMAC notes a DHB preference for effective prices being the list prices, however risk sharing mechanisms will be considered);
- (f) All proposals must include the following:
 - (i) information regarding the presentations and packaging of the Pharmaceutical(s);
 - (ii) information regarding the type of, and proposed mechanism of supply to DHB hospitals of, Vaporiser(s) and Bottle Adaptors (as applicable) required for the Pharmaceutical(s);
 - (iii) loan of a sufficient and reasonable number of Bottle Adaptors to DHB Hospitals to meet their needs should a Pharmaceutical in your proposal require these;
 - (iv) the proposed price for the Pharmaceutical(s);
 - (v) a description of any product support offered as part of the proposal;
 - (vi) information on the registration status of the Pharmaceutical(s) in New Zealand and/or other international jurisdictions. If not currently registered in New Zealand, please provide the expected date of submission to Medsafe;
 - (vii) information about your ability to ensure the continuity of supply, including any specific measures you would have in place to secure stock for the New Zealand market. This should include a description of proposed manufacturing arrangements and supply chain;
 - (viii) the supplier's own rationale for PHARMAC's acceptance of the proposal;

- (ix) a sample of the Pharmaceutical(s) and, if applicable, a sample of each Bottle Adaptor required to fill all Vaporiser models in use in DHB hospitals;
- (g) Any proposals including the provision for the associated loan of Vaporisers must also include:
- (i) a list of Vaporiser makes and models you agree/are able to supply on loan to DHBs;
 - (ii) a detailed proposal for the provision, implementation and support of new Vaporiser models available on loan to align with planned and currently unplanned future DHB upgrades of anaesthetic machines throughout the contract/HSS period, given that DHB requirements are subject to change;
 - (iii) proposed maintenance and support arrangements for loan Vaporisers and who will meet the costs of each;
 - (iv) detailed plans to support DHBs during any product transition if required;
 - (v) prices for each Pharmaceutical accessible to DHBs that require loan Vaporisers for between 50% and 25% and less than 25%, of their anaesthetic machines (as per the pricing table in Schedule 4 (d)). PHARMAC's preferred mechanism for enabling these two additional prices to exist for a single Pharmaceutical is via a non-confidential rebate or discount on invoice accessible to DHBs who qualify for this alternate pricing. This pricing mechanism is intended to provide those DHBs who have significant ownership of Vaporisers with a financial benefit from this ownership; and
 - (vi) any other terms relating to the loan Vaporisers.

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

- (h) proposals involving pharmaceuticals or related products not specified in clause 1, Schedule 1; and
- (i) proposals involving confidential rebates.

Please note: PHARMAC has a preference for proposals which include provision for the associated Vaporiser loan where DHBs require this.

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 proposals must be submitted to PHARMAC via GETS (www.gets.govt.nz) no later than **4.00 pm (New Zealand time) on 15 January 2016**. 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 through 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) (if any).
- (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 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. The information to be taken into account in applying the decision criteria by the Evaluation Committee will include, in particular:
 - (i) The commercial attributes of your proposal, as these relate to PHARMAC's decision criteria; and
 - (ii) any clinical advice from PTAC or its relevant Subcommittee, or any other clinician or group of clinicians or other groups or individuals where appropriate, as these relate to PHARMAC's decision criteria.
- (c) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, compatibility with and provision of delivery systems 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, including (but not limited to):
 - (i) additional information on any customer support, training and educational resources that may be available to DHBs during any major switchover to your Pharmaceutical and throughout the life of the contract; and
 - (ii) 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 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, 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 or its relevant Subcommittee or any other clinician or group of clinicians 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) PHARMAC intends to provide, in any agreements that include HSS arising from this RFP, that PHARMAC may elect at its sole discretion to extend the HSS period beyond the Initial HSS Period for any Pharmaceutical or Pharmaceuticals resulting from this RFP process, subject to the following:
 - (i) should PHARMAC elect to extend the Initial HSS Period for a Pharmaceutical or Pharmaceuticals it shall do so by providing written notice to the supplier of the Pharmaceutical or Pharmaceuticals at least six months prior to the end date of the Initial HSS Period;
 - (ii) should no written notice be provided by PHARMAC before the date being six months prior to the date of expiration of the Initial HSS Period, no such extension shall occur;

- (iii) any extension of the HSS period shall be for a maximum period of 24 months inclusive and take effect immediately following the end of the Initial HSS period.
- (d) PHARMAC intends to include in any contractual agreements arising as a result of this RFP, a provision for supplier(s) to provide PHARMAC with 6-monthly reports detailing the numbers of each Vaporiser make, model and compatible Pharmaceutical provided on loan to each DHB during that 6-monthly period.
- (e) 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 agreement is accepted by PHARMAC's Board or the Board's delegate.
- (f) You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, the Minister of Health or District Health Boards, with a view to influencing the outcome of this RFP process.
- (g) You must pay your own costs for preparing and submitting your proposal.
- (h) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (i) 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.
- (j) 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 sevoflurane, isoflurane or desflurane by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.
- (k) 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.
- (l) 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 January 2016;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in February 2016;
 - (iii) consulting on a provisional agreement in February/March 2016;
 - (iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after March 2016,

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 1 April 2016.
- (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 market size for the Pharmaceuticals in DHB Hospitals. 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 volatile anaesthetics 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.

Pharmaceutical	Number of bottles 1 July 2014 to 30 June 2015
Sevoflurane, 250 ml bottle	13,054
Isoflurane, 250 ml bottle	267
Desflurane, 240 ml bottle	7161

Further information on the anaesthetic machine models being used by DHB Hospitals, including information on proposed upgrades and a breakdown of current Vaporiser loans versus DHB ownership, can be found in Appendix 1.

Schedule 4: Proposal form

An electronic version of this form is available on the Government Electronic Tenders Service (GETS). You should expand the boxes as necessary.

[Supplier to insert date]

Chief Executive
C/- Andrew Park
PHARMAC
Dear Sir/Madam

Proposal for the supply of volatile anaesthetics

In response to your request for proposals (**RFP**) dated 3 December 2015, we put forward the following proposal in respect of volatile anaesthetics.

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:

Chemical name	
Brand name	
Presentation (e.g. 250 ml)	
Pack size	
Packaging type (e.g. Bottle, glass)	

- (c) Key features of our proposal:

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- (d) Information relating to pricing for each Pharmaceutical with provision for associated Vaporiser loan and Bottle Adaptor supply (if applicable) **AND** a price for DHBs who only require Vaporiser loans for less than 25%, or between 25% and 50%, of their anaesthetic machines, accessible to those DHBs by means of a non-confidential rebate or discount on invoice (\$NZ, GST exclusive).

The following table is provided as an example of the tiered pricing structure PHARMAC is seeking for each of the Pharmaceuticals. This table may be duplicated for aggregated proposals.

	Sevoflurane	Desflurane	Isoflurane
Price per bottle to DHBs requiring loan for greater than 50% of their Vaporisers for that Pharmaceutical, based on the number of anaesthetic machines that DHB requires loan Vaporisers for.			
Price per bottle to DHBs requiring loan for between 50% and 25% and (inclusive) of their Vaporisers for that Pharmaceutical, based upon the number of anaesthetic machines that DHB requires loan Vaporisers for.			
Price per bottle to DHBs requiring loan for less than 25% of their Vaporisers for that Pharmaceutical, based upon the number of anaesthetic machines that DHB requires loan Vaporisers for.			

- (e) 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	

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

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- (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) An outline of the process we intend to follow to ensure DHB Hospitals who elect to utilise this service have access loan Vaporisers and/or other Vaporisers and/or Bottle Adaptors that may be needed to use our product:

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