

25 June 2004

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INFLUENZA VACCINE

PHARMAC invites proposals for the supply of Influenza Vaccine in New Zealand.

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

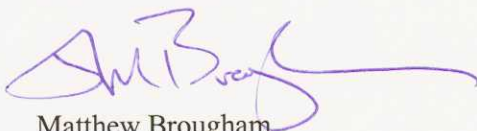
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceutical; and
- Schedule 4 contains the RFP form on which we invite you to provide details of your proposal.

If you wish to submit a proposal, you must submit it to PHARMAC no later than 5.00 p.m. on 16 July 2004.

If you have any questions about this RFP, please contact Andrea Dick (Hospital Pharmaceuticals Contracts Manager DDI 0064 4 916 7556) or Sarah Schmitt (Manger, Hospital Pharmaceuticals, DDI 0064 4 916 7517) at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely



Matthew Brougham
Acting Chief Executive

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

1. Pharmaceutical

PHARMAC is interested in considering any proposal from suppliers of Influenza Vaccine for supply to the eligible population for the annual national influenza vaccination campaign starting 1 March and concluding 30 June of each year. Proposals should be in relation to the supply of Influenza Vaccine alone and should not include any other vaccines or pharmaceuticals either related or not to influenza vaccination.

2. Background to RFP

Since 1997 the New Zealand Government has subsidised Influenza Vaccine for an eligible population.

Eligibility for Subsidised Vaccine

It is anticipated that the current groups that are eligible for subsidised vaccination would remain unchanged, these groups are:

- all people **65 years of age and over**
- people **under 65 years of age with** one or more of the following conditions:
 - cardiovascular disease; ischaemic heart disease
 - congestive heart disease
 - rheumatic heart disease
 - congenital heart disease
 - cerebro-vascular disease
 - chronic respiratory disease; asthma, if on regular preventative therapy
 - other chronic respiratory diseases with impaired lung function
 - diabetes
 - chronic renal disease
 - any cancer, excluding basal and squamous skin cancers if not invasive
 - other conditions; autoimmune diseases
 - immune suppression
 - HIV
 - transplant recipients
 - neuromuscular and CNS diseases
 - haemoglobinopathies
 - children on long-term aspirin

Eligibility and Funding

The resulting contract(s) from this process would be for a maximum exclusive period of three campaign years until 30 June 2007. During this period the eligibility criteria may change and any contract(s) resulting from this process would provide for this. Funding for Influenza Vaccine is provided to District Health Boards (**DHBs**) on an annual basis, the resulting contract(s) from this process would reflect that ongoing funding for Influenza Vaccine is not confirmed.

Delivery and Claiming

Currently the supplier is responsible for timely and appropriate delivery (including maintenance of cold chain) of the vaccines to the vaccinators (whether that be general practice or other eligible vaccinators). The vaccinator pays the cost of the vaccine and is reimbursed through the DHBs' payment agent, HealthPac, for the cost of the vaccine and the immunisation benefit. It is proposed that this mechanism would remain unchanged.

Cold Chain / IMAC Standards

Suppliers should demonstrate their ability to comply with the New Zealand Immunisation Advisory Centre (IMAC) Vaccine Storage and Distribution National Standards 2nd Edition (available from www.imac.auckland.ac.nz). The resulting contract(s) for supply will include a provision requiring the supplier to comply with any changes to these standards that occur during the tenure of the supply agreement.

Private (patient funded) Vaccinations

For those patients that do not meet the eligibility criteria, influenza vaccination is available at a cost to the patient (the private market). In some cases these are funded by an employer.

There is no requirement for the private market vaccine to be purchased from the same supplier as the subsidised vaccine.

However the same supplier has supplied a large proportion of the private market in the past as this enables vaccinators to carry only one brand of vaccine for both the subsidised and private market and avoids confusion.

We therefore estimate that the winning supplier(s) of this contract/these contracts would need to consider the impact this may have on the volumes of vaccines required and ensure that this would not effect the ability to supply the subsidised market.

Promotion

The contract(s) resulting from this RFP will not include any requirements for promotion of the vaccine or of the influenza campaign. No consideration will be given to any proposed promotional activity submitted as part of this RFP.

Pandemic Supply

Any contract(s) resulting from this process would not include provisions that would restrict the use of other brands of Influenza Vaccine in the event of a pandemic. Information pertaining to a supplier's ability to manufacture and supply additional volumes of vaccine in the event of a pandemic will however be considered. The resulting contract(s) would also include provisions pertaining to compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

Expected Outcome

PHARMAC is seeking an outcome from this process which includes a contract for supply of the vaccine to be available in the New Zealand market by 1 March 2005. This contract may be a sole supply, preferred supply or multiple party contract. For example a supplier may wish to be the only subsidised supplier for the campaign, the preferred supplier (in which case it is likely that more than one contract with more than one supplier would be the result) or the result could be multiple contracts with multiple suppliers. A supplier must specify its preference when submitting proposals under this process.

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

- Sole subsidised supply for a maximum period of three winter campaigns until 30 June 2007.
- Preferred subsidised supply for a maximum period of three winter campaigns until June 2007, where another supplier may also be a listed supplier of subsidised Influenza Vaccine.
- Listed subsidised supply at a secured price for a period to be specified in the proposal. Note this type of proposal could not involve any restriction on any other supplier gaining a subsidised listing.

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

- Any proposal that involves any product other than Influenza Vaccine.
- Any proposal that involves changes to the current eligibility criteria or changes to the process of administration by general practitioners and vaccinators or claiming of the subsidy.

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

Schedule 2: RFP process

The following is indicative of the process that PHARMAC expects to follow in relation to the RFP. PHARMAC expects to follow the process in the sequence set out below.

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 16 July 2004. 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) All proposals must be submitted to PHARMAC at Level 14, Cigna House, 40 Mercer Street, PO Box 10-254, Wellington, to the attention of Andrea Dick, Hospital Pharmaceuticals Contracts Manager, either by hand delivery, by courier or by post (and not by facsimile or email).
- (e) Please include a sample of vaccine presentation and packaging with your proposal.

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). The Evaluation Committee will seek any regulatory, legal, medical or other advice as it considers appropriate in assessing the proposals. The Evaluation Committee may request any further information from a supplier in relation to their proposal, any request for further information does not indicate acceptance of that proposal.
- (b) The matters to be taken into account by the Evaluation Committee will 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 Ministry of Health, PTAC or its relevant sub-committee;
 - (iii) the supplier's ability to meet the requirements specified in Schedule 1 of this document;
 - (iv) any other matters that the Evaluation Committee considers to be relevant,provided that 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 ultimately at the discretion of the Evaluation Committee.

- (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. **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 one supplier's proposal would exclude acceptance of the other proposal(s).
- (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. Influenza immunisation specific clauses as indicated in Schedule One would also be included in any resulting agreement.
- (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).

4. **Consultation and approval**

- (a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, and on Board approval (or approval by PHARMAC's Chief Executive 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 PHARMAC's Chief Executive under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.
- (d) If the Board or the Chief Executive 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 Chief Executive's decision to accept a negotiated agreement; or
 - (ii) the termination of the RFP process.

5. 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) not to provide reasons for the acceptance or non-acceptance of any proposal;
 - (iv) to enter into an agreement or arrangement that differs in a material respect from that envisaged in this RFP letter;
 - (v) 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;
 - (vi) to readvertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from the Ministry of Health, 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 Chief Executive.
- (d) You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, IMAC, the National Influenza Immunisation Strategy Group (NIISG), the Minister of Health or District Health Boards, with a view to influencing the outcome of this RFP process.
- (e) PHARMAC is not liable for any direct or indirect costs incurred in submitting a 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) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated. Further, PHARMAC is in no way contractually bound to follow the process outlined in this RFP, which is simply indicative.
- (h) As noted above, proposals are to be limited to the supply of Influenza Vaccine only.
- (i) Any sole subsidised supply or preferred supply proposal could be for a maximum period of 3 winter campaigns until 30 June 2007.

6. Anticipated timetable

- (a) Following receipt of proposals, PHARMAC anticipates:
 - (i) the Evaluation Committee evaluating proposals in July 2004;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in August 2004;
 - (iii) consulting on the provisional agreement(s) in August 2004;
 - (iv) PHARMAC's Board or Chief Executive considering the provisional agreement(s) in or after August 2004.

- (b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is October 2004 for the March 2005 campaign.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of Influenza Vaccine in recent years based on various sources. The information is approximate and indicative only and indicates differences each year. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of Influenza Vaccine 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.

Estimated Annual Units	Source and Notes
430,000 to 530,000 doses per annum for subsidised patients only.	HealthPAC – vaccinator payment agency based on subsidised claims in 2000 - 2001
166 vaccines distributed per 1000 population for 2000, estimated 160 doses per 1000 population in 2001.	Ministry of Health – Immunisation Handbook 2002
174 doses per 1000 population, with annual growth of approximately 7%.	ESR – Environment Sciences Research Influenza Report 2002
139 per 1000 population vaccine sales in 1999, 58% of which were administered under the free vaccination programme	Ministry of Health – An evaluation of the Free Influenza Vaccination Programme