

28 April 2010

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INFLUENZA VACCINE

PHARMAC invites proposals for the supply of seasonal 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 in which you are 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 **2 June 2010**.

If you have any questions about this RFP, please contact Andrew Davies (+64 4 9167 531) at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Matthew Brougham', with a long, sweeping flourish extending to the right.

Matthew Brougham
Chief Executive

SCHEDULE 1: PHARMACEUTICAL, BACKGROUND TO RFP AND TYPES OF PROPOSALS SOUGHT

PHARMACEUTICAL

PHARMAC is interested in considering proposals from suppliers of seasonal Influenza Vaccine for supply to the eligible population for the annual national influenza vaccination campaign in New Zealand, which usually starts early March and concludes 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.

BACKGROUND TO RFP

Eligibility criteria

Since 1997 the New Zealand Government has subsidised Influenza Vaccine for eligible members of the population meeting set criteria.

Currently there are two suppliers contracted to supply influenza vaccine for eligible patients, although a third supplier has been used in 2010 as a result of production issues. Following the recent pandemic the eligibility criteria were amended in 2010 to include pregnant women, and children under 5 from high deprivation backgrounds. The eligibility criteria, may be subject to change during the term of any agreement that may result from this RFP.

The Eligibility criteria are currently as set out below, but are subject to change. In particular, no decision has been made to continue access for the groups added in 2010 as a response to the potential H1N1 'swine flu' second wave (being pregnant women, the morbidly obese, and young children from high deprivation background) beyond the 2010 season:

INFLUENZA VACCINE – Hospital pharmacy [Xpharm]

A) is available between 1 March and 30 June each year for patients who meet the following criteria, as set by the Ministry of Health:

- a) all people 65 years of age and over;
- b) people under 65 years of age with:
 - i) the following cardiovascular disease:
 - 1) ischaemic heart disease,
 - 2) congestive heart disease,
 - 3) rheumatic heart disease,
 - 4) congenital heart disease, or
 - 5) cerebo-vascular disease;
 - ii) the following chronic respiratory disease:
 - 1) asthma, if on a regular preventative therapy, or
 - 2) other chronic respiratory disease with impaired lung function;
 - iii) diabetes;
 - iv) chronic renal disease;
 - v) any cancer, excluding basal and squamous skin cancers if not invasive;
 - vi) the following other conditions:
 - a) autoimmune disease,
 - b) immune suppression,
 - c) HIV,
 - d) transplant recipients,
 - e) neuromuscular and CNS diseases,
 - f) haemoglobinopathies, or
 - g) children on long term aspirin.
- c) people under 65 years of age who are:
 - (i) pregnant; or
 - (ii) morbidly obese
- d) children aged over 6 months and under 5 years who are from high deprivation backgrounds.

The following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.

- B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor.
- D) Influenza Vaccine does not fall within the definition Community Pharmaceutical as it is not funded directly from the Pharmaceutical Budget. Pharmacists are unable to claim for the dispensing of influenza vaccine from the Funder.

Distribution

Up until 2005 the sole supplier of the influenza vaccine managed and met the cost for distribution of the vaccine in New Zealand. The distributor received stock from the supplier and managed orders from doctors and vaccinators. The distributor invoiced the doctors and vaccinators for the cost of the vaccine and accounted to the supplier for the amounts received from doctors and vaccinators. Doctors and vaccinators paid the cost of the vaccine and were reimbursed through the DHBs' payment agent, HealthPAC, for the cost of the vaccine and the immunisation service.

For 2005 – 2007, due to seeking alternative supplies in 2005 and then implementing dual supply in 2006 and 2007, PHARMAC managed the contracting for the distribution aspect of the seasonal influenza vaccine campaign.

For the 2008 – 2010 seasons the principal supplier resumed responsibility for the distribution arrangements for influenza vaccine.

It is our preference that supplier(s) continue to manage distribution under any proposals received as a result of this RFP. Proposals should therefore include distribution to doctors and vaccinators within the price of the vaccine.

Proposals should contain information on the nominated distributor's capabilities in managing the seasonal influenza vaccine campaign including delivery timeframes, returns policy and any minimum order requirements.

While we are seeking proposals for two vaccine suppliers, our preference is that both are supplied to clinics at the same price, as has been past practice. This does not mean the effective prices need to be the same.

The distributor must provide a free phone, free fax and online ordering system (where possible) that doctors and vaccinators could use to place orders. The ordering system would need to be in place by 1 January 2011 to allow doctors and vaccinators to pre-order influenza vaccine prior to the influenza season.

The resulting contract(s) with the supplier(s) would require the distributor 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) and with any changes to these standards that might occur during the tenure of a supply agreement.

Reporting

The supplier(s) would be required to provide comprehensive reports to PHARMAC throughout the influenza season including details of sales broken down by District Health Board (DHB) area not just the total sales for the country. The reports would be required to

be supplied to PHARMAC on a monthly basis in an electronic Excel spreadsheet format with sales volumes reported on a per week basis.

Contract duration

The resulting contract(s) from this RFP process would be for a maximum exclusive period of three seasonal influenza vaccine campaign years until 30 June 2013. During this period the eligibility criteria may change and any contract(s) resulting from this process would provide for this.

Funding

Funding for seasonal influenza vaccine is provided to DHBs on an annual basis; the resulting contract(s) from this process would reflect that ongoing funding for seasonal influenza vaccine is not confirmed.

Claiming

Currently, the vaccinator pays the cost of the influenza vaccine to the distributor and is reimbursed through claims made to the DHBs' payment agent, HealthPac, for the cost of the vaccine and the immunisation service. It is proposed that this claiming mechanism would remain unchanged.

Private (patient funded) Vaccinations

For those patients that do not meet the eligibility criteria, seasonal 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 seasonal influenza vaccine to be purchased from the same supplier as the subsidised seasonal influenza vaccine.

However for simplicity many vaccinators might only stock the subsidised brands and therefore these brands may supply a large proportion of the private market as well. Suppliers would need to consider the impact this may have on the volumes of vaccines required and ensure that private market demand would not affect their ability to supply the subsidised market.

Promotion

The National Influenza Strategy Group (NISG) co-ordinates the annual promotional resources, including the Influenza Kit. It is anticipated the supplier(s) would provide information and work with NISG when requested. Further information about NISG can be found at www.influenza.org.nz.

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 an influenza pandemic. The resulting contract(s) would however include provisions pertaining to compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

TYPES OF PROPOSALS SOUGHT

Suppliers must submit two proposals, being one for each of the following:

- Preferred subsidised supply for a maximum period of three winter seasonal influenza vaccine campaigns until June 2013, where the supplier meets the demand for all doses of seasonal influenza vaccine, other than up to 250,000 doses which would be supplied by the supplier of the initial stock; and
- A proposal to be the supplier of the initial stock of up to 250,000 doses that are to be supplied prior to the preferred supplier's stock.

Suppliers may also like to submit other types of proposals. Possibilities include:

- Supply of a fixed volume of doses per season. Note, it is possible agreement(s) would be necessary with other suppliers to ensure sufficient stock was supplied to cover the entire market and therefore if a proposal of this type is submitted there could be no restriction on any other supplier gaining a subsidised listing.
- 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 aware that, under a multiple supplier arrangement, it is possible PHARMAC would be required to have some co-ordination role in the distribution of the seasonal influenza vaccines; this would be negotiated with the applicable suppliers if necessary. However, please note that PHARMAC does not intend to contract with a distributor itself or to manage any payments for distribution services.

PHARMAC is also aware that there is now a dermal injection marketed in New Zealand. We would consider proposals for such a presentation, however these would either need to be price competitive with subcutaneous injections, or supported with evidence of additional health benefit. Even if additional benefit can be shown, additional funding may not be available, so we would recommend any proposal for dermal injections is accompanied by a separate proposal for subcutaneous or intramuscular injections or is competitive with such proposals.

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

- Sole subsidised supply.
- Any proposal that involves any product other than seasonal influenza vaccine.
- Any proposal that involves changes to the current eligibility criteria or changes to the process of administration by doctors and vaccinators or to the process of claiming of the subsidy and immunisation benefit.

- Expenditure risk sharing mechanisms based on claims data or that would require any audit of claims data.

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.

SUBMISSION

You may submit more than two proposals. Each proposal will be considered as a separate proposal.

Proposals must be submitted no later than 5.00 p.m. (New Zealand time) on Wednesday 2 June 2010. Late proposals will only be considered at PHARMAC's discretion.

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

All proposals must be submitted to PHARMAC by email to andrew.davies@pharmac.govt.nz

Please also send a sample of vaccine presentation and packaging to:

Andrew Davies
Procurement Initiatives Manager
PHARMAC
Level 9, Simpl House
40 Mercer St
Wellington 6143.

EVALUATION

Following the deadline for submitting proposals an Evaluation Committee will evaluate each proposal to select its preferred proposal(s). The Evaluation Committee will consist of PHARMAC staff, and may also include staff from the Ministry of Health.

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:

- 1) 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;
- 2) any clinical advice from PTAC or relevant PTAC sub-committees or other appropriate clinical advisors sought by PHARMAC; and
- 3) 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).

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.

PHARMAC is not bound to select the lowest priced proposal or any proposal.

NEGOTIATION

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.

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. In addition, a number of terms and conditions specific to the supply of influenza vaccine will be necessary. As an indication, some of these are outlined in Schedule 1 above, but this is without limitation to other clauses which may be necessary.

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.

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.

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).

CONSULTATION AND APPROVAL

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 PHARMAC's Chief Executive under delegated authority).

PHARMAC will not consider any counter-offers received during consultation.

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.

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).

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

- 1) the Board's or its Chief Executive's decision to accept a negotiated agreement; or
- 2) the termination of the RFP process.

MISCELLANEOUS

PHARMAC reserves the right:

- 1) 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;
- 2) not to accept any proposal;
- 3) to seek clarification of any proposal;
- 4) to meet with any supplier in relation to its proposal;

- 5) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;
- 6) 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;
- 7) to readvertise for proposals.

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.

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.

You must not at any time initiate any communication with PHARMAC's directors or officers, the Ministry of Health, the Minister of Health, NISG or District Health Boards, with a view to influencing the outcome of this RFP process.

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

Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

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.

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 influenza vaccine by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

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.

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:

- 1) pursuant to the Official Information Act 1982; or
- 2) in the course of consultation on a provisional agreement entered into with a supplier;
or
- 3) in publicly notifying any approval by the PHARMAC Board of that agreement; or
- 4) 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 (1) to (4) 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.

ANTICIPATED TIMETABLE

Following receipt of proposals, PHARMAC anticipates:

- 1) the Evaluation Committee evaluating proposals in **June 2010**;

- 2) negotiating with submitter(s) of two or more preferred proposals **June 2010**;
- 3) consulting on a provisional agreement in **June/July 2010**;
- 4) PHARMAC's Board or Chief Executive considering this provisional agreement in or after **July/August 2010**,
- 5) 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.

Under this indicative timetable, PHARMAC expects to have changes made to the Pharmaceutical Schedule by **January 2011** for the subsidised season beginning late February/early March 2011.

SCHEDULE 3: CURRENT LISTING AND MARKET INFORMATION

The information set out in the table below relates to the estimated subsidised market size for seasonal influenza vaccine. 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 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.

Year	Total vaccines distributed*	Total vaccines subsidised
2005	717,000	410,000
2006	761,000	440,000
2007	747,000	457,000
2008	756,000	472,000
2009**	961,000	569,000

* Until the end of the subsidised season which was 31 July in 2005 and 30 June in 2006, 2007 and 2008, and 30 September in 2009. In the absence of a decision otherwise, it is anticipated that the season for 2011-2013 would end 30 June. Further sales are possible after the end of the season however such sales would not be eligible for subsidy.

** An influenza pandemic was declared partway through the 2009 season, which had an impact on volume. It is not clear whether this increase will be enduring.

SCHEDULE 4: PROPOSAL FORM

An electronic version of this form is available on request from andrew.davies@pharmac.govt.nz. You should expand the boxes as necessary.

[Supplier to insert date]

Chief Executive
PHARMAC
C/- Andrew Davies
Procurement Initiative Manager

By email: andrew.davies@pharmac.govt.nz

Dear

Proposal for the supply of Influenza Vaccine

In response to your request for proposals (**RFP**) dated [*insert date*], we put forward the following proposal in respect of seasonal Influenza Vaccine.

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

Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

Details of pharmaceutical presentation (please include a sample of vaccine presentation and packaging with proposal):

Brand name	
Full description of the vaccine including formulation and potency (label claim)	
Presentation (e.g pre-filled syringe, individual vial, multi-dose vial)	
Needle specification, including if attached or available separately	
Route of administration (e.g. subcutaneous, intramuscular)	
Pack size (e.g. 1's, 10's)	
Packaging type (e.g. individual box)	
Name and address of manufacturer of the vaccine	
Shelf life of the vaccine	

Key features of our proposal:

Information relating to pricing (\$NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for preferred supplier, risk sharing mechanisms, etc). Note this price is to include distribution to vaccinators.

Proposals must be clear what the price relates to, for example preferred subsidised supply, or fixed volume, or general listing. Suppliers are welcome to submit more than one proposal, each will be considered separately.

Information about proposed distribution arrangements (including a returns policy for unused vaccines and any minimum order requirements) and ability to monitor cold chain requirements:

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	
Insert any other consents required for pharmaceutical	

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

Information about our previous supply performance and relevant expertise:

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:

Reasons why PHARMAC should accept our proposal:

Any additional information that PHARMAC should consider when evaluating our proposal: