PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
Information line 0800 66 00 50
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

3 February 2016

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 via the Government Electronic Tenders Service (GETS) no later than 5:00pm on **3 March 2016**.

If you have any questions about this RFP, please contact **Chris Chapman** at chris.chapman@pharmac.govt.nz or **Caroline de Luca** at caroline.deluca@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
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 seasonal influenza vaccine for supply to the eligible population for the annual national influenza vaccination campaign in New Zealand. Exact start and end dates for each campaign's season will be notified 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

The background to this RFP is as follows:

Eligibility criteria

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

The current eligibility criteria in Section I (community access) of the Pharmaceutical Schedule are set out below. The eligibility criteria may be subject to change before or during the term of any agreement that may result from this RFP:

INFLUENZA VACCINE – [Xpharm]

A) is available each year for patients who meet the following criteria, as set by PHARMAC:

- a) all people 65 years of age and over; or
- b) people under 65 years of age who:
  - i) have any of the following cardiovascular diseases:
    - a) ischaemic heart disease, or
    - b) congestive heart failure, or
    - c) rheumatic heart disease, or
    - d) congenital heart disease, or
    - e) cerebo-vascular disease; or
  - ii) have either of the following chronic respiratory diseases:
    - a) asthma, if on a regular preventative therapy, or
    - b) other chronic respiratory disease with impaired lung function; or
  - iii) have diabetes; or
  - iv) have chronic renal disease; or
  - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
  - vi) have any of the following other conditions:
    - a) autoimmune disease, or
    - b) immune suppression or immune deficiency, or
    - c) HIV, or
    - d) transplant recipients, or
    - e) neuromuscular and CNS diseases/disorders, or
    - f) haemoglobinopathies, or
    - g) are children on long term aspirin, or
    - h) have a cochlear implant, or
    - i) errors of metabolism at risk of major metabolic decompensation, or
    - j) pre and post splenectomy, or

k) down syndrome, or

vii) are pregnant; or

c) children aged four years and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, 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) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

Eligibility criteria in hospitals are the same as for Section I with the addition of patients who are compulsorily detained long-term in a forensic unit within a DHB hospital" and removal of clauses B-D.

PHARMAC currently subsidises/lists two influenza vaccines for eligible patients as follows:

		Subsidy/Price	Per	Fully Subsidised	Brand or Generic Manufacturer
INFLUENZA VACCINE – [Xpharm]					
Inj 45 mcg in 0.5 ml syringe	……..	90.00*	10	✓	**Fluarix** **Influvac**

*both currently listed brands are subject to a confidential rebate arrangement.

Under current arrangements 250,000 doses of Fluarix are distributed each season in preference to Influvac, after which supplies of Influvac would be expected to meet the remaining demand of the market.

Distribution

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 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.

The resulting contract(s) with the supplier(s) would require the distributor to comply with the most recent New Zealand Immunisation Advisory Centre (IMAC) Vaccine Storage and Distribution National Standards (available from http://www.immune.org.nz/health-professionals/cold-chain) and with any changes to these standards that might occur during the tenure of a supply agreement.

Stock should be available to order by 15 March each year. Suppliers should be aware of the high demand for the vaccine in the early stages of each season. Data shows that each year about half of all vaccines ordered are ordered within the first month of the

season, and suppliers should be prepared for this busier period. Supply and payment conditions will be included in any supply agreement as a result of this RFP to take into account the importance of delivery timeframes.

PHARMAC is aware that DHBs are investigating allowing pharmacists to claim for administration of funded vaccines. It is likely that this may occur prior to 2020 and so be relevant to this RFP. Suppliers should be aware of this possible change and consider its effect on uptake and on distribution costs.

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 period of three seasonal influenza vaccine campaign years until the end of the 2019 season. During this period the eligibility criteria may change and any contract(s) resulting from this process would provide for this.

Claiming

Currently, the vaccinator pays for the cost of the influenza vaccine to the distributor and is reimbursed through claims made to the DHBs' payment agent, Sector Services 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 through 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, PHARMAC is aware that many vaccinators only stock the subsidised brands and therefore the subsidised brands 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. They are expected to ensure that private market demand does not affect their ability to supply the subsidised market.

Promotion

The Immunisation Advisory Centre (IMAC) coordinates annual promotional resources, including the Influenza Kit. It is anticipated that 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 include provisions allowing exclusivity to be suspended in the event of an influenza pandemic. The provisions would reflect

compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

3. Types of proposals sought

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

- subsidised supply for a maximum period of three winter seasonal influenza vaccine campaigns until the end of 2019 season, where the supplier meets the demand for doses of seasonal influenza vaccine ("Routine Supplier"), other than up to 250,000 initial doses which would be supplied by an alternative supplier; and

- a proposal to be the supplier of a fixed volume of an initial 250,000 doses that are to be supplied by 15 March of the relevant influenza season, which will occur prior to the supply of the seasonal influenza vaccine by the Routine Supplier.

Suppliers may in addition to the above two proposals exercise an option to submit a proposal in relation to a sole subsidised supply arrangement for:

- sole subsidised supply for a maximum period of three winter seasonal influenza vaccine campaigns until the end of 2019 season, where the supplier meets the demand for all funded doses of seasonal influenza vaccine.

Suppliers may also exercise an option to submit other types of proposals, including but not limited to:

- 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 also being subsidised.

- 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 also being subsidised.

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.

Within any of the above proposals, suppliers may wish to offer to supply:

- Trivalent vaccines

- Quadrivalent vaccines

- An arrangement whereby trivalent vaccines are supplied for the first one or two seasonal campaigns, followed by the supply of quadrivalent vaccines.

Suppliers must submit proposals which do not include any change to the current Pharmaceutical Schedule list price of influenza vaccines ($9.00 per unit) for trivalent influenza vaccines. However, proposals for quadrivalent vaccines with a different list price may be submitted.

The distributor must provide a free phone, free fax and online ordering system that vaccinators could use to place orders. The ordering system would need to be in place by 1 January 2017 to allow vaccinators to order influenza vaccine prior to the influenza season.

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

- Proposals involving products other than the influenza vaccine;
- Proposals involving changes to the eligibility restrictions;
- Expenditure risk sharing mechanisms based on claims data or that would require any audit of claims data;
- Proposals relating to pandemic supply – the Ministry of Health recently ran its own procurement process for pandemic vaccine and this RFP is unconnected to that process; and
- Proposals where the supplier would not pay for distribution costs.

Schedule 2: RFP process

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

1. **Submission**

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

   (b) Proposals must be submitted no later than 5:00pm (New Zealand time) on **3 March 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) If you have any inquiries about this RFP you should submit them on GETS or alternatively contact Chris Chapman by email at chris.chapman@pharmac.govt.nz or Caroline de Luca at caroline.deluca@pharmac.govt.nz.

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

   (e) All proposals must be submitted to PHARMAC via the GETS website to the attention of **Christine Chapman,** Senior Therapeutic Group Manager.

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). This Committee may include staff from the Ministry of Health.

   (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 mechanism 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 mechanism by the Evaluation Committee will include, in particular:

      (i) any clinical advice from PTAC or its relevant subcommittee or other appropriate clinical advisors sought by PHARMAC; and

      (ii) information provided in the proposal form (Schedule 4 of this document).

   (c) Please note that from 1 July 2016 PHARMAC is changing the way in which it makes decisions, instead of the current Decision Criteria it will be using the Factors for Consideration (FFC). Whilst it is PHARMAC's expectation that decisions arising out of this RFP will occur prior to 1 July 2016, please be aware of the FFC. More information on the FFC can be found at www.pharmac.govt.nz/factors-for-consideration.

   (d) 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.

(e) 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 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. 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.

(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).

4. **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 mechanism 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.

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) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) 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;

(vi) 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; and

(vii) to re-advertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant subcommittee 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's directors or officers, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards 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. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP.

(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 influenza vaccine 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.

6. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in **March 2016**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **March/April 2016**;

(iii) consulting on a provisional agreement in **April/May 2016**;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in **June 2016**; and

(v) Public notification of any decisions in **June/July 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, PHARMAC expects to have changes made to the Pharmaceutical Schedule by January 2017 for the 2017 influenza season.

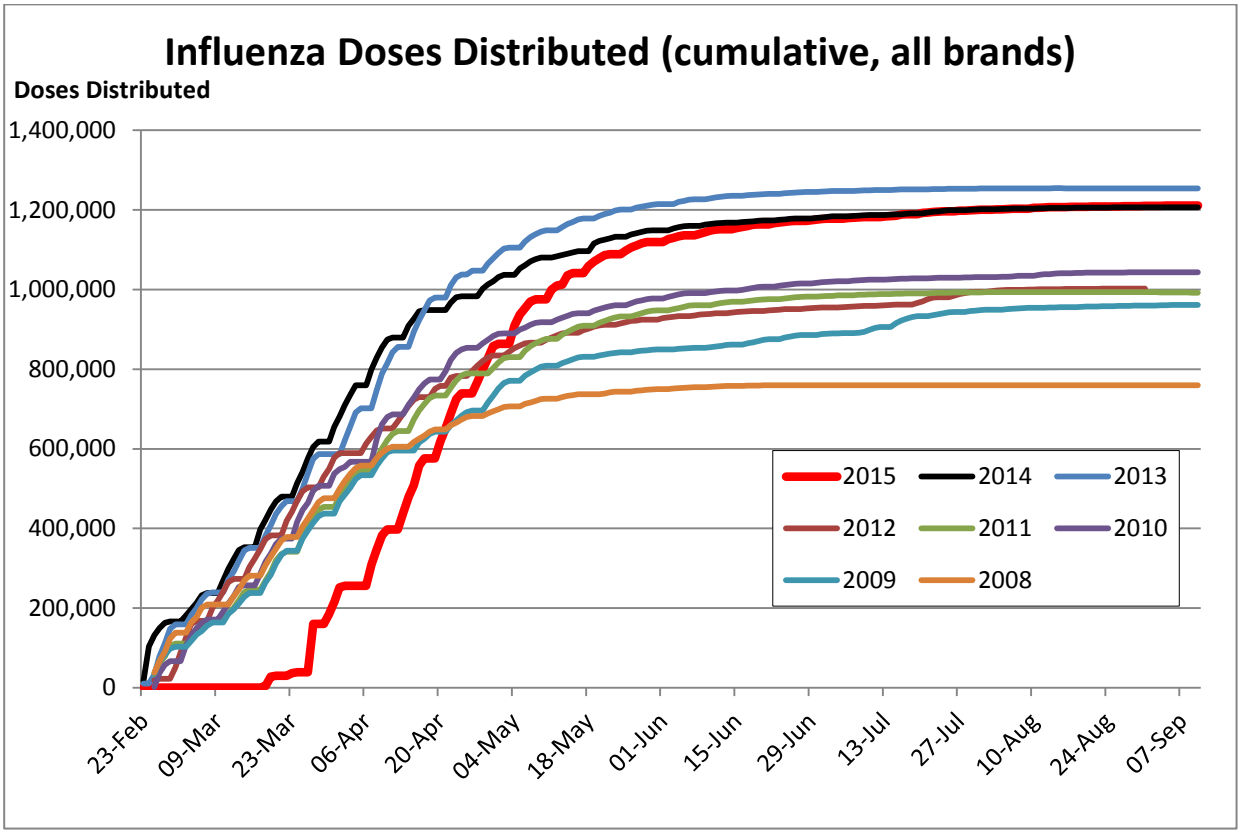
Schedule 3: Current listing and market information

The following information 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 seasonal 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 (private and funded)	Total vaccines subsidised in the community
2011	990,000	596,000
2012	1,000,000	612,000
2013	1,250,000	718,000
2014	1,210,000	687,000
2015	1,210,000	707,000

The total vaccine use each season is influenced by the Ministry of Health targets. Currently it aims to have 1.2 million vaccines distributed each year (private and funded). The Ministry could alter this target in the future.

In a typical season, half of all vaccines are ordered within the first month. After approximately two months, we typically see demand becoming much flatter, and orders in the latter half of the season are much lower. Demand patterns are also affected by weekends and holidays such as Easter.



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*]

Christine Chapman
Senior Therapeutic Group Manager
PHARMAC

By electronic transfer using GETS (https://www.gets.govt.nz)

Dear Madam

Proposal for the supply of influenza vaccine

In response to your request for proposals (**RFP**) dated 3 February 2016, we put forward the following proposal in respect of influenza vaccine.

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 vaccine presentation:

Brand name	
Full description of the vaccine including formulation, number of strains, which strains, potency (label claim), paediatric use	
Presentation	
Needle specification (including length), including if attached or available separately	
Route of administration (e.g. subcutaneous, intramuscular etc)	
Pack size (eg 1s, 10s)	
Packaging type (eg individual box)	
Known adverse events and details	

(c) Details of vaccine manufacture:

Name and address of manufacturer/s of the vaccine	
Lead time	
Details on vaccine manufacturing sites and their registration with Medsafe or other registrations	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

For a sole subsidised supply scenario PHARMAC may have a preference for suppliers who have multiple influenza vaccine manufacturing sites registered with Medsafe or have other mechanisms in place that would provide confidence around assurance of supply.

(d) Key features of our vaccine not mentioned above:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (for example but not limited to price in return for sole supply, reference price protection and risk sharing mechanisms). Note this price is to include distribution to vaccinators.

Proposals must be clear about which type of proposal the price relates to, Suppliers are welcome to submit more than one proposal, each will be considered separately.

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

(g) 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 vaccine	
If the vaccine is not registered in New Zealand, what countries is it registered in?	

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

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

(j) Proposals/suggestions (for example but not limited to pricing and risk sharing arrangements) regarding the vaccine not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(k) Reasons why PHARMAC should accept our proposal:

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