

12 December 2005

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ANTIBIOTICS FOR A POTENTIAL AVIAN INFLUENZA PANDEMIC

PHARMAC invites proposals for a guaranteed supply of antibiotics for a potential avian influenza pandemic in New Zealand.

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

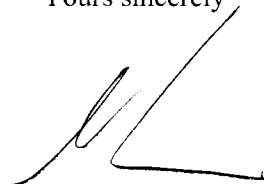
- Schedule 1 specifies the pharmaceuticals for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP; and
- Schedule 3 contains the RFP form in which you 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 10 January 2006.

If you have any questions or comments about this RFP, please contact Jackie Evans at PHARMAC on +64 (0) 4 916 7557.

We look forward to receiving your proposal.

Yours sincerely



Wayne McNee
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 antibiotics. A successful proposal must be justifiable under PHARMAC's Decision Criteria. PHARMAC reserves the right not to proceed if proposals do not meet the Decision Criteria.

2. Background to RFP

The background to this RFP is as follows:

In the event of an avian influenza pandemic it is likely that there would be an increase in the use of antibiotics for prophylaxis and treatment of secondary infections. During the 1918 influenza pandemic most of the deaths that occurred appear to have been due to secondary bacterial infection, if the next pandemic were to follow a similar course rapid access to sufficient supplies of antibiotics would be critical. The antibiotics required would need to be broad spectrum and effective against streptococci and staphylococci.

The Ministry of Health (MOH) has requested that PHARMAC secure guaranteed supplies of antibiotics for prophylaxis and treatment of secondary infections in the event of an avian influenza pandemic.

The MOH has requested that PHARMAC secure guaranteed supplies of 845,000 courses of oral antibiotics and 341,000 vials of injectable antibiotics. The MOH has also requested that 70% of the oral antibiotics be in tablet/capsule formulation with the remaining 30% as liquid formulation.

Based on the list of MOH requirements PHARMAC has calculated that the quantities and types of antibiotics required would be as follows (see next page):

| Chemical and preferred strength | Quantity | Total Units guaranteed for supply in the event of a pandemic |
|--|--------------------------------------|---|
| Amoxycillin Clavulanate 250 mg with potassium clavulanate 62.5 mg per 5 ml oral liquid | 152,100 courses @ 100ml per course | 152,100 x 100 ml bottles |
| Amoxycillin Clavulanate 500 mg with potassium clavulanate 125 mg tablet | 354,900 courses @ 20 Tabs per course | 7,098,000 Tabs |
| Amoxycillin Clavulanate 1g with potassium clavulanate 200 mg vial | 170,500 courses @ 1 vial per course | 170,500 vials |
| Cephazolin Sodium 1g vial | 85,250 courses @ 1 vial per course | 85,250 vials |
| Co-Trimoxazole trimethoprim 40 mg with sulphamethoxazole 200 mg per 5 ml oral liquid | 25,350 courses @ 100ml per course | 25,350 x 100 ml bottles |
| Co-Trimoxazole trimethoprim 80 mg with sulphamethoxazole 400 mg tablet | 59,150 courses @ 28 Tabs per course | 1,656,200 Tabs |
| Doxycycline Hydrochloride 100mg tablet | 84,500 courses @ 14 Tabs per course | 1,183,000 Tabs |
| Flucloxacillin Sodium 250 mg per 5 ml oral liquid | 50,700 courses @ 100ml per course | 50,700 x 100 ml bottles |
| Flucloxacillin Sodium 500mg capsule | 118,300 courses @ 20 Caps per course | 2,366,000 Caps |
| Flucloxacillin Sodium 1g vial | 85,250 courses @ 1 vial per course | 85,250 vials |

PHARMAC seeks proposals from suppliers for guaranteed supplies of the above antibiotics and quantities for use in the event of an avian influenza pandemic. It is intended that these supplies would be used over and above the normal Pharmaceutical Schedule Community Pharmacy or Hospital Pharmacy supply. PHARMAC welcomes proposals from existing Pharmaceutical Schedule suppliers as well as new suppliers.

A successful proposal must be justifiable under PHARMAC's Decision Criteria. PHARMAC reserves the right not to proceed if proposals do not meet the Decision Criteria. Any agreement reached would be subject to consultation and PHARMAC Board approval.

PHARMAC has identified some key aspects that need to be considered, PHARMAC welcomes suggestions or proposals from suppliers regarding other services or solutions that may be appropriate to address these key issues. They are:

- It is not possible at this time to predict when, or if, an avian influenza pandemic will affect New Zealand.

- There is a need to ensure that these guaranteed antibiotic supplies are readily available to distribute and administer to patients at short notice in the event of an avian influenza pandemic.
- It is anticipated that the distribution and administration of these antibiotics supplies would be subject to MOH defined emergency planning protocols outside the normal supplier – wholesaler - pharmacy - patient route. The MOH is yet to define these emergency distribution and administration plans. Suppliers would need to agree to adhere to any such emergency distribution systems in the event of an avian influenza pandemic.
- Although New Zealand has a defined five-stage pandemic planning strategy with corresponding proposed MOH/DHB alert codes i.e White (Information/Advisory), Yellow (Standby), Red (Activation) and Green (Stand Down) it is not possible to predict the timeframe for each stage or even if stages would be skipped altogether in the event of an avian influenza pandemic.
- Suppliers should consider the potential impact an avian influenza pandemic may have on their workforce and plan accordingly to ensure that guaranteed antibiotic supplies are readily available and accessible for distribution and administration to patients at short notice.
- Given the unknown timing of an avian influenza pandemic, or even if there will be one at all, suppliers should consider how best to manage these antibiotic supplies in order that guaranteed supplies are available within expiry date at all times, in readiness for use in the event of an avian influenza pandemic.
- It is likely that in the event of an avian influenza pandemic the general healthcare workforce would be constrained, therefore it may be advantageous to have these guaranteed antibiotic supplies packed in individual patient packs containing one course of antibiotics, thus reducing the reliance on the general healthcare workforce, e.g. pharmacists, to dispense or administer product to patients. Suppliers should consider how best to package these guaranteed antibiotic supplies and what supportive material to provide e.g. patient leaflets, to ensure that these antibiotic supplies can be administered to patients safely and effectively with minimal healthcare workforce involvement.

3. **Types of proposals sought**

Suppliers wishing to submit proposals must submit a minimum of four proposals as follows:

1. To guarantee supplies of one or more of the specified antibiotics at the quantities specified for use in the event of an avian influenza pandemic.
 - a. Including product packaging, storage and handling fees
 - b. Excluding product packaging, storage and handling fees
2. To guarantee patient-packed supplies of one or more of the specified antibiotics at the quantities specified for use in the event of an avian influenza pandemic.
 - a. Including product packaging, storage and handling fees
 - b. Excluding product packaging, storage and handling fees

Note: A supplier may submit further proposals as it sees fit.

Proposals must include information regarding the following;

- lead time if the supplier is awarded a contract for it to guarantee supplies; and,
- shelf life of the pharmaceuticals ;and,
- any stock recycling processes; and,
- packaging processes; and,
- storage arrangements; and,
- handling and distribution arrangements; and,
- any other related services or materials required administer the product to patients rapidly in the event of an avian influenza pandemic.

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 10 January 2006. 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, Wellington 6001, to the attention of Jackie Evans, either by hand delivery, by courier or by post (and not by facsimile or email).

2. Evaluation

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).
- (b) The 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 PTAC or its relevant sub-committee;
 - (iii) any advice from the Government, its Intersectoral Pandemic Groups or its workgroups, the Minister of Health, the MOH or its relevant committees and DHBs;
 - (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 either supplier's proposal would exclude acceptance of the other proposal.

- (b) 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.
- (c) 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.
- (d) 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 subject to consultation with suppliers and other interested parties as considered appropriate by PHARMAC, 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 advice from the Government, Intersectoral Pandemic Groups or its workgroups, the Minister of Health, the MOH or its relevant committees and DHBs, or, PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the 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 Government, its Intersectoral Pandemic Groups or its workgroups, the Ministry of Health, the Minister of Health or its relevant committees 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 no way contractually bound to follow the process outlined in this RFP, which is simply indicative.
- (h) 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 January 2005;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in February 2005;

- (iii) consulting on a provisional agreement in March 2005, if required;
 - (iv) PHARMAC's Board or Chief Executive considering this provisional agreement in or after April 2005.
- (b) Under this indicative timetable, the earliest that guaranteed supplies of antibiotics would be secured would be May 2005.

Schedule 3: Proposal form

An electronic version of this form is available on disc from PHARMAC or on PHARMAC's website at <www.pharmac.govt.nz>. You should expand the boxes as necessary.

[Supplier to insert date]

Chief Executive
PHARMAC C/- Jackie Evans
PO Box 10-254
(or for courier delivery:
Level 14, Cigna House
40 Mercer Street)
Wellington
New Zealand

Dear Sir/Madam

Proposal for the guaranteed supply of antibiotics for a potential avian influenza pandemic in New Zealand.

In response to your request for proposals (**RFP**) dated 12 December 2005, we put forward the following proposal(s) in respect of guaranteed supply of antibiotics for a potential avian influenza pandemic in New Zealand.

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 | |
| Strength [(e.g. 500mg)] | |
| Form [(e.g. capsule)] | |
| Brand name | |
| Pack size [(e.g. 30's)] | |
| Packaging type [(e.g. blister)] | |

(c) Key features of our proposal:

| |
|----------------|
| BULK |
| PATIENT PACKED |

(d) Information relating to pricing (\$NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC :

| |
|----------------|
| BULK |
| PATIENT PACKED |

(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] | |
| <i>Insert any other consents required for pharmaceutical</i> | |

- (f) Information about our ability to guarantee that supplies of the pharmaceutical(s) are available within expiry date at all times in readiness for use in the event of an avian influenza pandemic:

- (g) Information about our planning to ensure that we will have sufficient workforce to ensure that antibiotic supplies are readily available to distribute and administer to patients at short notice:

- (h) Information about our willingness and ability to work with Government, Intersectoral Pandemic Groups or its workgroups, PHARMAC, the Minister of Health, the MOH and DHBs in the event antibiotic supplies distributed through emergency protocols outside normal pharmaceutical distribution routes.

- (i) Information about our planning around how best to package these guaranteed antibiotic supplies and what supportive material to provide e.g. patient leaflets, to ensure that these antibiotic supplies can be administered to patients safely and effectively with minimal healthcare workforce involvement.

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

- (k) Proposals/suggestions regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

- (l) Reasons why PHARMAC should accept our proposal:

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

- (n) Additional information that PHARMAC, the Government, Intersectoral Pandemic Groups or its workgroups, the Minister of Health, the MOH and/or DHBs should consider when planning for an avian influenza pandemic: