PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street,
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

28 January 2013

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF FENTANYL TRANSDERMAL PATCHES

PHARMAC invites proposals for the supply of **fentanyl transdermal patches** in New Zealand.

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

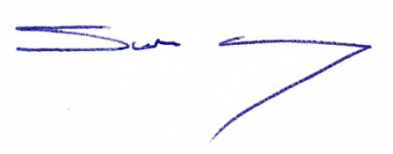
- Schedule 1 specifies the pharmaceutical(s) for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the subsidised market for the pharmaceutical(s); 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 pm on Friday 22 February 2013.**

If you have any questions about this RFP, please contact Geraldine MacGibbon at PHARMAC on (04) 916 7514 or geraldine.macgibbon@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely



Steffan Crausaz
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 **fentanyl transdermal patches**.

2. **Background to RFP**

The background to this RFP is as follows:

- Fentanyl transdermal patches at strengths of 12.5 μg per hour, 25 μg per hour, 50 μg per hour, 75 μg per hour and 100 μg per hour are currently listed, fully funded, in Section B of the Pharmaceutical Schedule. They are also listed in Part II of Section H of the Pharmaceutical Schedule.

- The current prices and subsidies for fentanyl transdermal patches are as follows:

Strength	Pack size	Price and subsidy
12.5 μg per hour	5	$8.90
25 μg per hour	5	$9.15
50 μg per hour	5	$11.50
75 μg per hour	5	$13.60
100 μg per hour	5	$14.50

- Fentanyl transdermal patches are currently supplied under the brand name Mylan Fentanyl Patch and are subject to a sole supply agreement with Mylan New Zealand Ltd. Sole supply ends on 1 July 2013.

- When fentanyl patches were first listed on the Pharmaceutical Schedule in October 2004 they were in the form known as a "reservoir" patch. The reservoir patch is a "form-fill-and-seal" system that contains fentanyl and alcohol gelled in a drug reservoir. From 1 January 2007 a new “matrix” form of fentanyl patches was listed on the Schedule and the reservoir form was delisted on 1 July 2007. In the matrix formulation, the fentanyl is embedded in the adhesive of the patch. The currently funded brand is a matrix patch.

- PHARMAC now seeks proposals for community and hospital supply of fentanyl transdermal patches in matrix form.

- Please note that we are aware that there is a patent (NZ 528148) owned by Alza Corporation USA (a Johnson and Johnson company that is related to Janssen) relating to fentanyl transdermal patches.

3. **Types of proposals sought**

(a) Suppliers wishing to submit proposals must submit proposals for community and hospital supply of the 12.5 μg per hour, 25 μg per hour, 50 μg per hour, 75 μg per

hour and 100 μg per hour strengths of fentanyl transdermal patches in the matrix form.

PHARMAC is willing to consider the following types of proposals:

- proposals that include a period of subsidy protection and/or protection from delisting; and/or
- proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms; and/or
- proposals that include a period of sole subsidised supply and hospital supply status (hereinafter referred to as "**sole supply**") for a period of time up to and including 30 June 2016. For the avoidance of doubt, if proposals include a period of sole supply, the proposed sole supply must be sole subsidised supply and hospital supply status for all strengths of fentanyl transdermal patches included in the proposal; and/or
- proposals with a flexible start date to allow for stock availability issues to be resolved; and/or
- proposals that are subject to registration approval by Medsafe.

Note that, in the event that a proposal for sole supply is accepted as a result of this RFP, there may be a transition period where more than one brand of fentanyl transdermal patch is listed.

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

- proposals that include pharmaceuticals other than fentanyl transdermal patches; or
- proposals that include presentations of fentanyl other than transdermal patches; or
- proposals that do not include the supply of all of the 12.5 μg per hour, 25 μg per hour, 50 μg per hour, 75 μg per hour and 100 μg per hour strengths of fentanyl transdermal patches; or
- proposals for a reservoir form of fentanyl transdermal patches; or
- two-part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

(c) Suppliers should provide PHARMAC with a sample pack of the various strengths of fentanyl transdermal patches included in the proposal (and, if supply is intended to be in a different form from that sample pack, information about the form in which they will be supplied) within 10 business days from the close of the RFP. Samples may contain placebo or fentanyl; sample patches containing fentanyl should be sent to PHARMAC care of the Medical Director.

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 **5.00 p.m. (New Zealand time) on Friday 22 February 2013**. 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 to the attention of **Geraldine MacGibbon** by email at geraldine.macgibbon@pharmac.govt.nz.

2. **Evaluation**

(a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff (including PHARMAC's Legal Counsel) will evaluate each proposal to select its preferred proposal(s).

(b) 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:

(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 Subcommittee or any other relevant clinical expert sought by PHARMAC;

(iii) 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).

(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. **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, in which case you must supply that information within 10 business days of PHARMAC requesting it.

(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.

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 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.

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; and

(viii) to readvertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant Subcommittee or any other relevant clinical expert 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, the Minister of Health or District Health Boards, 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 letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(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 fentanyl transdermal patches 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.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in **March 2013**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **March 2013**;

(iii) consulting on a provisional agreement in or after **March 2013 or April 2013**;

(iv) PHARMAC's Board or Chief Executive considering a provisional agreement in or after **April 2013**,

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 **July 2013**.

Schedule 3: Market information

The following information relates to the estimated subsidised market size of fentanyl transdermal patches in the community, and estimated market size of fentanyl transdermal patches being sold to DHB hospitals. Note that access was widened in the community from 1 February 2011 via removal of the Special Authority that previously restricted subsidies to terminally ill patients who were unable to take oral medication or couldn't take morphine.

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 fentanyl transdermal patches in the community and to DHB hospitals 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.

The number of subsidised units (patches, rounded to the nearest 100 units) for fentanyl transdermal patches in the community for the years ending 30 June 2010, 30 June 2011 and 30 June 2012 is shown below:

Pharmaceutical/form/ strength	1 July 2009 to 30 June 2010	1 July 2010 to 30 June 2011	1 July 2011 to June 2012
Fentanyl transdermal patch 12.5 μg/hour	Not funded	9,400 (funded from 1 February 2011)	52,600
Fentanyl transdermal patch 25 μg/hour	21,200	27,900	53,100
Fentanyl transdermal patch 50 μg/hour	12,600	15,400	28,000
Fentanyl transdermal patch 75 μg/hour	6,300	8,500	11,800
Fentanyl transdermal patch 100 μg/hour	14,300	15,900	23,400

The number of units (patches, rounded to the nearest 100 units) for fentanyl transdermal patches purchased by DHB hospitals for the years ending 30 June 2010, 30 June 2011 and 30 June 2012 is shown below:

Pharmaceutical/form/ strength	1 July 2009 to 30 June 2010	1 July 2010 to 30 June 2011	1 July 2011 to June 2012
Fentanyl transdermal patch 12.5 μg/hour	2,700	3,700	6,000
Fentanyl transdermal patch 25 μg/hour	3,700	4,200	5,300
Fentanyl transdermal patch 50 μg/hour	2,000	1,800	2,300
Fentanyl transdermal patch 75 μg/hour	1,100	1,100	1,200
Fentanyl transdermal patch 100 μg/hour	1,000	1,200	1,700

Schedule 4: Proposal form

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

[*Supplier to insert date*]

Chief Executive
C/- Geraldine MacGibbon
PHARMAC
Level 9, 40 Mercer Street
PO Box 10-254
Wellington 6143
NEW ZEALAND

By email geraldine.macgibbon@pharmac.govt.nz

Dear Geraldine

Proposal for the supply of fentanyl transdermal patches

In response to your request for proposals (**RFP**) dated 28 January 2013 we put forward the following proposal in respect of **fentanyl transdermal patches**.

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 (eg 50 μg/hour)	
Form	
Brand name	
Pack size (eg 10's)	
Packaging type (eg blister)	

(c) Key features of our proposal:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

(e) Evidence of market approval and any other required consents:

Date of Medsafe market approval	
OR Date of submission of dossier	
OR Expected date of dossier submission to Medsafe	
Insert any other consents required for pharmaceutical	

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

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

(h) Reasons why PHARMAC should accept our proposal:

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

e.g. our assessment of any potential intellectual property impediments to the supply of our proposed product