

25 November 2009

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 Tuesday 22 December 2009**.

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



Matthew Brougham
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 25 µg per hour, 50 µg per hour, 75 µg per hour and 100 µg per hour are currently listed for community supply fully subsidised, subject to the application of Special Authority criteria, in the "Opioid Analgesics" section of Section B of the Pharmaceutical Schedule.
- Restrictions and Special Authority criteria applying to fentanyl transdermal patches in Section B of the Pharmaceutical Schedule are as follows:

Only on a controlled drug form
No patient co-payment payable

SA0935 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Both:

1 Patient is terminally ill and is opioid-responsive; and

2 Either:

2.1 is unable to take oral medication; or

2.2 is intolerant to morphine, or morphine is contraindicated.

Renewal from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

- The current price and subsidy for fentanyl transdermal patches is as follows:

Pharmaceutical	Form	Strength	Pack size	Price and subsidy
Fentanyl	Transdermal patch, matrix	25 µg per hour	5	\$55.23
Fentanyl	Transdermal patch, matrix	50 µg per hour	5	\$100.52
Fentanyl	Transdermal patch, matrix	75 µg per hour	5	\$139.18
Fentanyl	Transdermal patch, matrix	100 µg per hour	5	\$171.22

- Fentanyl transdermal patches are currently supplied under the brand name Durogesic by Janssen-Cilag Pty Limited. No delisting or subsidy protection currently applies to Durogesic.
- When Durogesic was first listed on the Pharmaceutical Schedule in October 2004 it was 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 Durogesic 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 matrix formulation of Durogesic is a

drug-in-adhesive matrix design that is bioequivalent to the Durogesic reservoir formulation.

- Following an RFP for the supply of fentanyl patches issued on 2 August 2007, PHARMAC entered into an agreement with Mylan New Zealand Ltd (formerly Pacific Pharmaceuticals) for the Fensic brand of fentanyl patches to replace Durogesic as the funded brand of fentanyl patches, subject to Fensic gaining Medsafe registration, at the following prices and subsidies:

Pharmaceutical	Form	Strength	Pack size	Price and subsidy
Fentanyl	Transdermal patch, reservoir	12.5 µg per hour	5	\$13.53
Fentanyl	Transdermal patch, reservoir	25 µg per hour	5	\$19.33
Fentanyl	Transdermal patch, reservoir	50 µg per hour	5	\$35.18
Fentanyl	Transdermal patch, reservoir	75 µg per hour	5	\$48.71
Fentanyl	Transdermal patch, reservoir	100 µg per hour	5	\$59.93

- The listing of Fensic was to be accompanied by widening of access via removal of the Special Authority.
- The agreement with Mylan for the supply of Fensic was recently terminated due to delays in Fensic gaining registration.
- PHARMAC now seeks proposals for community and hospital supply of fentanyl transdermal patches in matrix or reservoir form.
- Please note that we understand that there is a patent (NZ 528148) for fentanyl transdermal patches in matrix form that Janssen-Cilag owns (or has rights to).

3. Types of proposals sought

- (a) Suppliers wishing to submit proposals must submit proposals for community and hospital supply of the 25 µg per hour, 50 µg per hour, 75 µg per hour and 100 µg per hour strengths of fentanyl transdermal patches, which may be in the form of matrix or reservoir construction. Proposals for community and hospital supply of the 12.5 µg per hour strength of fentanyl transdermal patches are desirable but not obligatory.

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**”) from the date of listing until 30 June 2013. 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; and/or
- proposals for widening access.

Please note that PHARMAC would consider:

- widening access to include additional patient groups under a Special Authority (with the extent of access widening being dependent on the price reduction offered); and
- widening access by a general listing (i.e., with no Special Authority restriction) where proposals provide a 65% or greater reduction in marginal price from that of the current Durogesic price and subsidy.

Note that, in the event that a proposal is accepted as a result of this RFP, there may be a period of time where more than one brand of fentanyl transdermal patch is listed, potentially with different access criteria. Further, PHARMAC reserves the right to widen access to fentanyl transdermal patches at any point in time regardless of the price.

(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 25 µg per hour, 50 µg per hour, 75 µg per hour and 100 µg per hour strengths 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. Sample patches containing fentanyl (i.e. rather than placebo) 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 Tuesday 22 December 2009**. 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**, either by facsimile (+64 4 460 4995) or email (geraldine.macgibbon@pharmac.govt.nz). **Email is preferred.**

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;
 - (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 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 **January 2010**;
 - (ii) negotiating with submitter(s) of one or more preferred proposals in **January 2010**;
 - (iii) consulting on a provisional agreement in or after **February 2010**;
 - (iv) PHARMAC's Board or Chief Executive considering a provisional agreement in or after **February 2010**,

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 **April 2010**.

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 PHARMAC does not currently have a percentage of market share for fentanyl transdermal patches in relation to opioid analgesic sales to DHB hospitals).

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.

Chemical entity	Percentage market share (prescriptions) in the community in the period July 2008 to June 2009
Fentanyl transdermal patches	0.47% of opioid analgesics

The number of subsidised units (patches) for fentanyl transdermal patches in the community for the years ending 30 June 2007, 30 June 2008 and 30 June 2009 is shown below:

Pharmaceutical/form/strength	July 2006 to June 2007	July 2007 to June 2008	July 2008 to June 2009
Fentanyl transdermal patch 25 µg/hour	10,327	14,331	17,671
Fentanyl transdermal patch 50 µg/hour	7,304	9,151	10,407
Fentanyl transdermal patch 75 µg/hour	3,796	4,936	5,857
Fentanyl transdermal patch 100 µg/hour	9,700	11,584	14,515

The number of units (patches) for fentanyl transdermal patches purchased by DHB hospitals for the years ending 30 June 2007, 30 June 2008 and 30 June 2009 is shown below:

Pharmaceutical/form/strength	July 2006 to June 2007	July 2007 to June 2008	July 2008 to June 2009
Fentanyl transdermal patch 25 µg/hour	2,840	3,805	3,610
Fentanyl transdermal patch 50 µg/hour	1,980	2,095	1,730
Fentanyl transdermal patch 75 µg/hour	655	1,000	984
Fentanyl transdermal patch 100 µg/hour	1,120	1,355	1,334

Schedule 4: Proposal form

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

[Supplier to insert date]

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

By email geraldine.macgibbon@pharmac.govt.nz or facsimile (+64) 04 460 4995.

Dear Geraldine

Proposal for the supply of fentanyl transdermal patches

In response to your request for proposals (**RFP**) dated 25 November 2009 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 (eg reservoir)	
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	
<i>Insert any other consents required for pharmaceutical</i>	

(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: