

15 October 2008

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF PEGYLATED INTERFERON AND RIBAVIRIN**

PHARMAC invites proposals for the supply of pegylated interferon and ribavirin 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 7 November 2008.

If you have any questions about this RFP, please contact **Greg Williams** at PHARMAC by telephone (04) 916-7524 or email [greg.williams@pharmac.govt.nz](mailto:greg.williams@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 proposals from suppliers of pegylated interferon alpha and pegylated interferon alpha with ribavirin (hereinafter collectively referred to as 'Pegylated Interferon') for the treatment of chronic Hepatitis C.

### 2. Background to RFP

The background to this RFP is as follows:

- The following presentations of Pegylated Interferon alpha-2a are currently listed on the Pharmaceutical Schedule, under Special Authority restriction in respect of community supply, for the treatment of chronic Hepatitis C, in the "Immune modulators" category of Section B of the Pharmaceutical Schedule.

<b>Pegylated interferon alpha-2a</b>	
<b>Strength and presentation</b>	<b>Price and subsidy</b>
Inj 135 mcg prefilled syringe	\$362.00
Inj 180 mcg prefilled syringe	\$450.00
Inj 135 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 112	\$1799.68
Inj 135 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168	\$1975.00
Inj 180 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 112	\$2059.84
Inj 180 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168	\$2190.00

- The Special Authority restriction applying to pegylated interferon alpha-2a (with and without ribavirin) is as follows:

#### **Special Authority for Subsidy - Form SA0802**

**Initial application - (genotype 1, 4, 5 or 6 infection or co-infection with HIV)** from any specialist. Approvals valid for 11 months for applications meeting the following criteria:

- 1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
- 2 Patient has chronic hepatitis C and is co-infected with HIV.

Note: consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.

**Initial application - (genotype 2 or 3 infection without co-infection with HIV)** from any specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has chronic hepatitis C, genotype 2 or 3 infection; and
- 2 Either:
  - 2.1 Patient has bridging fibrosis or cirrhosis (Metavir stage 3 or 4 or equivalent); or
  - 2.2 is unsuitable for liver biopsy due to coagulopathy.

- The following presentations of Pegylated Interferon alpha-2b with ribavirin are currently listed on the Pharmaceutical Schedule, under Special Authority restriction in respect of community supply, for the treatment of chronic Hepatitis C, in the “Immune modulators” category of Section B of the Pharmaceutical Schedule.

<b>Pegylated interferon alpha-2b with ribavirin</b>	
<b>Strength and presentation</b>	<b>Price and subsidy</b>
Inj 50 mcg x 4 with ribavirin cap 200 mg x 112	\$1080.40
Inj 50 mcg x 4 with ribavirin cap 200 mg x 84	\$976.80
Inj 80 mcg x 4 with ribavirin cap 200 mg x 140	\$1583.60
Inj 80 mcg x 4 with ribavirin cap 200 mg x 168	\$1687.20
Inj 80 mcg x 4 with ribavirin cap 200 mg x 84	\$1376.40
Inj 100 mcg x 4 with ribavirin cap 200 mg x 112	\$1746.40
Inj 100 mcg x 4 with ribavirin cap 200 mg x 84	\$1642.80
Inj 120 mcg x 4 with ribavirin cap 200 mg x 140	\$2116.40
Inj 120 mcg x 4 with ribavirin cap 200 mg x 84	\$1909.20
Inj 150 mcg x 4 with ribavirin cap 200 mg x 140	\$2516.00
Inj 150 mcg x 4 with ribavirin cap 200 mg x 168	\$2619.60
Inj 150 mcg x 4 with ribavirin cap 200 mg x 84	\$2308.80

- The Special Authority restriction for pegylated interferon alpha-2b (with ribavirin) is as follows:

**Special Authority for Subsidy - Form: SA0846**

**Initial application** from any specialist. Approvals valid for 11 months for applications meeting the following criteria:

Either:

- 1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
- 2 Both:
  - 2.1 Patient has chronic hepatitis C, genotype 2 or 3 infection; and
  - 2.2 Either:
    - 2.2.1 has bridging fibrosis or cirrhosis (Metavir stage 3 or 4, or equivalent);
    - or
    - 2.2.2 is unsuitable for liver biopsy due to coagulopathy.

Note: Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.

PHARMAC has taken clinical advice regarding Pegylated Interferon supply and this advice is found in schedule 3 of this RFP.

PHARMAC now seeks proposals for Sole Indication Supply in the community until 31 December 2012, of Pegylated Interferon for the treatment of chronic Hepatitis C.

The term “Sole Indication Supply” refers to the sole subsidised supply listing of Pegylated interferon for the treatment of patients with the indication of chronic Hepatitis C only.

### 3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

- 3.1 Suppliers wishing to submit proposals must submit a proposal for community supply of Pegylated Interferon, with a period of Sole Indication Supply, until 31 December 2012.

Please note:

- If Sole Indication Supply is awarded, the Special Authority criteria applying to the Sole Indication Supply brand of Pegylated Interferon would be redrafted to allow subsidised access for all patients with chronic hepatitis C who have not previously been treated with pegylated interferon, however new patients would only receive a subsidy for the Sole Indication Supply brand of Pegylated Interferon.
- If a proposal for Sole Indication Supply of Pegylated Interferon is accepted, patients that are currently receiving subsidised Pegylated Interferon of another brand for chronic Hepatitis C would continue to receive a subsidy for that other brand of Pegylated Interferon, until the Special Authority approval expires (i.e. for the remaining duration of their course of treatment). Upon expiry of all Special Authorities the other brands of Pegylated Interferon would be delisted, or restricted such that they are no longer subsidised for chronic Hepatitis C.
- Proposals for Pegylated Interferon must include the supply of both pegylated interferon and ribavirin, either supplied individually or as a combination pack. Proposals do not need to include supply of packs containing pegylated interferon without ribavirin, although this is encouraged.
- If a proposal for Sole Indication Supply of Pegylated interferon is accepted PHARMAC would retain the option of subsidising (an)other brand(s) of Pegylated Interferon for indications other than chronic Hepatitis C.

- 3.2 In addition, PHARMAC is willing to consider the following types of proposals:

- proposals that involve wider access to Pegylated Interferon; and
- proposals that include a single price per pack of Pegylated Interferon, regardless of strength.
- proposals that include rebate arrangements.

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

- proposals that include pharmaceuticals other than Pegylated Interferon (and ribavirin);
- two part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of Pegylated Interferon on specific terms; and

- parity pricing, whereby PHARMAC may reduce the subsidy payable for Pegylated Interferon in a particular therapeutic sub-group to the level of the subsidy payable for Pegylated Interferon in any other sub-group.

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.

### 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 7 November 2008. 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 **Greg Williams, Therapeutic Group Manager** either by hand delivery or by courier to Level 9, Cigna House, 40 Mercer Street, Wellington, or by post to PO Box 10-254, Wellington 6143 (and not by facsimile or email). In addition to, but not instead of, providing PHARMAC with a hard copy of all proposals by hand deliver, courier or post, submitters must also provide a copy of all proposals by facsimilie (+64 4 460 4995) or email ([greg.williams@pharmac.govt.nz](mailto:greg.williams@pharmac.govt.nz)).

### 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 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](http://www.pharmac.govt.nz)), to the extent applicable;
  - (ii) any clinical advice from PTAC or its relevant sub-committee; and
  - (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. **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).

### 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 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) 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;
  - (viii) to readvertise for proposals.
- (b) 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.
  - (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 Pegylated Interferon and Ribavirin 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 November 2008;
  - (ii) PHARMAC seeking such additional advice as it considers necessary from PTAC or its relevant subcommittees;
  - (iii) negotiating with submitter(s) of one or more preferred proposals in November/December 2008;
  - (iv) consulting on a provisional agreement in December 2008;
  - (v) PHARMAC's Board or Chief Executive considering this provisional agreement in or after January 2009,

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 March 2009.

### Schedule 3: Current listing, market information and clinical advice

The following information relates to the estimated subsidised market size of pegylated interferon and pegylated interferon with ribavirin. 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 Pegylated Interferon 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, form and strength	Units subsidised		
	Year ending 30 June 2006	Year ending 30 June 2007	Year ending 30 June 2008
<b>Pegylated interferon alpha-2a</b>			
Inj 135 µg prefilled syringe	396	77	56
Inj 180 µg prefilled syringe	4380	556	281
<b>Pegylated inteferon alpha-2a with ribavirin</b>			
Inj 135 µg prefilled syringe x 4 with ribavirin tab 200 mg x 112	80	55	22
Inj 135 µg prefilled syringe x 4 with ribavirin tab 200 mg x 168	123	84	43
Inj 180 µg prefilled syringe x 4 with ribavirin tab 200 mg x 112	534	538	400
Inj 180 µg prefilled syringe x 4 with ribavirin tab 200 mg x 168	2176	2622	2584
<b>Pegylated interferon alpha-2b</b>			
Inj 150 µg	7	0	0
<b>Pegylated interferon alpha-2b with ribavirin</b>			
Inj 80 µg x 4 with ribavirin cap 200 mg x 84	0	3	0
Inj 100 µg x 4 with ribavirin cap 200 mg x 84	0	0	4
Inj 100 µg x 4 with ribavirin cap 200 mg x 112	32	44	56
Inj 120 µg x 4 with ribavirin cap 200 mg x 84	3	1	3
Inj 120 µg x 4 with ribavirin cap 200 mg x 140	63	68	82
Inj 150 µg x 4 with ribavirin cap 200 mg x 84	3	3	2
Inj 150 µg x 4 with ribavirin cap 200 mg x 140	41	16	24
Inj 150 µg x 4 with ribavirin cap 200 mg x 168	86	52	116

The following is the anti-infective subcommittee's advice on pegylated interferon from their meeting on 18<sup>th</sup> September 2007.

- The Subcommittee reviewed current access criteria and previous Anti-infective Subcommittee and PTAC minutes regarding pegylated interferons for viral hepatitis treatment.
- The Subcommittee noted that long-acting (pegylated) preparations of interferon alpha have been developed by the manufacturers of the two standard interferon alpha products: pegylated interferon alpha-2a (Pegasys, Roche) and Pegylated interferon alpha-2b (PEG-Intron/Pegatron, Schering-Plough). Members considered that these pegylated interferons increased cure rates when compared to standard interferon

products, probably as a result of the increased duration of suppression of viral replication. Members also considered that of these products in combination with ribavirin provided a further improvement in the cure rate.

- The Subcommittee noted that pegylated interferon alpha-2a with or without ribavirin (Pegasys, Pegasys RBV Combination Pack) and pegylated interferon alpha-2b with ribavirin (Pegatron Combination Therapy) are currently fully funded on the pharmaceutical schedule for the treatment of patients infected with hepatitis C virus (HCV) genotypes 1,4,5 or 6 and in patients with HCV genotype 2 or 3 virus where there is evidence of progressive liver damage. The Subcommittee noted that pegylated interferon alpha-2a with or without ribavirin was also funded for HCV-HIV co-infected patients whereas pegylated interferon alpha-2b with ribavirin was not currently funded for these patients.
- The Subcommittee noted that there were two current funding applications for pegylated interferon under consideration by PHARMAC, one for the treatment of patients with chronic Hepatitis C genotype 2 and 3 without cirrhosis and another for the treatment of patients with chronic Hepatitis B infection.
- The Subcommittee noted that both pegylated interferon alpha-2a and pegylated interferon alpha-2b were indicated for the treatment of chronic hepatitis C in combination with ribavirin. However, the Subcommittee noted that pegylated interferon alpha-2a was also indicated for the treatment of hepatitis B.
- The Subcommittee noted that pegylated interferon alpha-2a was given as a fixed dose injection once weekly, whereas pegylated interferon alpha-2b required weight based dosing.
- The Subcommittee considered that both pegylated interferon alpha-2a and pegylated interferon alpha-2b gave the same or similar therapeutic benefits and risks in hepatitis C patients. However, the subcommittee noted that although it was likely that the benefits and risks of the two would be similar in hepatitis B patients, only pegylated interferon alpha-2a was indicated for the treatment of hepatitis B, and therefore, they could not recommend that pegylated interferon alpha-2b be used in these patients at this time.
- The Subcommittee considered that it would be reasonable to have only one brand of pegylated interferon (either pegylated interferon alpha-2a or pegylated interferon alpha-2b) and one brand ribavirin (tablets or capsules) fully funded on the pharmaceutical schedule for the treatment of patients with Hepatitis C. The Subcommittee further considered that although more convenient, the provision of combination packs containing both pegylated interferon injections and ribavirin tablets/capsules was not essential.
- The Subcommittee considered that given the different dosing regimens for the two interferons, patients taking either pegylated interferon alpha-2a or pegylated interferon alpha-2b should not be switched part-way through treatment.

#### Schedule 4: 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  
C/- Greg Williams  
PHARMAC  
PO Box 10-254  
(or for courier delivery:  
Level 9, Cigna House  
40 Mercer Street)  
Wellington  
New Zealand

Dear Sir/Madam

#### Proposal for the supply of Pegylated Interferon

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

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. 30s)	
Packaging type (e.g. blister)	

(c) Key features of our proposal:

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(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.):

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

Date of market approval (please attach copy of Medsafe Gazette notice)	
<b>OR</b> Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
<b>OR</b> Expected date of dossier submission to Medsafe	
<b><i>Insert any other consents required for pharmaceutical</i></b>	

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

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

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- (h) 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:

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

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