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

30 April 2013

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PEGYLATED INTERFERON, PEGYLATED INTERFERON WITH RIBAVIRIN, BOCEPREVIR AND TELAPREVIR

PHARMAC invites proposals for the supply of pegylated interferon, pegylated interferon with ribavirin, boceprevir and telaprevir in New Zealand.

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

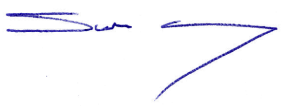
- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceuticals; 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 4:30 p.m. on 10 June 2013.

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**.

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 proposals from suppliers of:

- pegylated interferon alpha and pegylated interferon alpha with ribavirin (hereinafter collectively referred to as '**Pegylated Interferon'**) for the treatment of hepatitis B and hepatitis C, and

- boceprevir and telaprevir (hereinafter collectively referred to as **'HCV Protease Inhibitors')** for the treatment of chronic Hepatitis C;

The table below summarises the types of proposals being sought:

Pharmaceutical	Types of proposal*	End of Sole Supply or Dual Supply period
Pegylated Interferon	Sole Supply (community supply) **indicated for Hepatitis B**; or	30 June 2017
	Sole Supply (community supply) **indicated for Hepatitis C**; or	
	Sole Supply (community supply) **indicated for Hepatitis B and C**; or	
	Dual Supply (community supply) for **indications listed above**.	
HCV Protease Inhibitors	Sole Supply (community supply) for **indications described in 3.5.1 below**; or	30 June 2016
	Sole Supply (community supply) for **indications described in 3.5.2 below**; or	
	Sole Supply (community supply) for **indications described in 3.5.3 below**; or	
	Dual Supply (community supply) for **indications listed above**.	

*Further details about the type of proposals being sought is outlined under heading 3 below.

2. Background to RFP

The background to this RFP is as follows:

Pegylated Interferon

- The following presentations of pegylated Interferon alpha 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.

strength and presentation	Unit price and subsidy
Inj 135 mcg prefilled syringe	$362.00
Inj 180 mcg prefilled syringe	$450.00

strength and presentation	Unit price and subsidy
Inj 135 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 112	$1,799.68
Inj 135 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168	$1,975.00
Inj 180 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 112	$2,059.84
Inj 180 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168	$2,190.00

- The Special Authority restriction currently applying to pegylated interferon alpha-2a (with and without ribavirin) is as follows (note PHARMAC is currently consulting on amended these criteria see link: http://www.pharmac.health.nz/ckeditor_assets/attachments/310/consultation-2013-04-amending-various-anti-infective-group-listings.pdf):

  Special Authority for Subsidy - Form SA1134
  Initial application - (chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV) from any specialist. Approvals valid for 18 months for applications meeting the following criteria:
  Both:
  1 Either:
  1.1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
  1.2 Patient has chronic hepatitis C and is co-infected with HIV; and
  2. maximum of 48 weeks therapy

  Notes:
  o 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.
  o Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml

  Initial application - (chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV) from any specialist. Approvals valid for 12 months for applications meeting the following criteria:
  Both:
  1. Patient has chronic hepatitis C, genotype 2 or 3 infection; and
  2. maximum of 6 months therapy

  Initial application - (Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:
  All of the following:
  1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
  2 Patient is Hepatitis B treatment-naïve; and
  3 ALT > 2 times Upper Limit of Normal; and
  4 HBV DNA < 10 log10 IU/ml; and
  5 Either:
  5.1 HBeAg positive; or
  5.2 serum HBV DNA = 2,000 units/ml and significant fibrosis (= Metavir Stage F2); and
  6 Compensated liver disease; and
  7 No continuing alcohol abuse or intravenous drug use; and
  8 Not co-infected with HCV, HIV or HDV; and
  9 Neither ALT nor AST > 10 times upper limit of normal; and
  10 No history of hypersensitivity or contraindications to pegylated interferon; and
  11 maximum of 48 weeks therapy

Notes:
- Approved dose is 180 mcg once weekly.
- The recommended dose of Pegylated Interferon-alpha 2a is 180 mcg once weekly.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alpha 2a dose should be reduced to 135 mcg once weekly.
- In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.
- Pegylated Interferon-alpha 2a is not approved for use in children.

HCV Protease Inhibitors

- The Anti-Infective Subcommittee of PTAC recommended that PHARMAC fund boceprevir or telaprevir for the following indications with the following priorities:

1. treatment of naive hepatitis C genotype 1 patients with cirrhosis or advanced fibrosis who do not have the IL-28 genotype CC – high priority.
2. treatment-experienced hepatitis C genotype 1 patients regardless of fibrosis stage, who were responder relapsers or partial responders – high priority.
3. treatment of hepatitis C genotype 1 patients who were treated with standard or pegylated interferon and ribavirin prior to 2004 who did not achieve an SVR but for whom early on treatment responses are not available – low priority.
4. treatment naïve hepatitis C genotype 1 patients with either Il-28 TC or TT allele- low priority
5. treatment naïve hepatitis C genotype 1 patients – low priority (price dependent)

- The Special Authority restrictions that could apply to either boceprevir or telaprevir would be broadly as follows (note that the length of treatment funded would depend on the drug used):

Initial application – (chronic hepatitis C – genotype 1 with cirrhosis or advanced fibrosis) from Gastroenterologist, Infectious Disease Specialist or General Physician. Approvals valid for xx weeks for applications meeting the following criteria:

All of the following:

1 Patient has hepatitis C genotype 1; and
2 Patient has IL-28B genotype CT or TT; and
3 Patient has severe fibrosis (F3) or cirrhosis (F4) identified with Fibroscan or equivalent; and
4 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
5 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin.

Note: Boceprevir/telaprevir should not be used in patients with significant portal hypertension or varices or decompensated liver disease

Initial application – (Responder relapsers or partial responders) from Gastroenterologist, Infectious Disease Specialist or General Physician. Approvals valid for xx weeks for applications meeting the following criteria:

All of the following:

1 Patient has hepatitis C genotype 1; and
2 Patient has previously been treated with pegylated interferon and ribavirin; and has either

2.1 relapsed following a virological response on pegylated interferon and ribavirin; or
2.2 had a partial response to pegylated interferon and ribavirin; or
2.3 received pegylated interferon and ribavirin prior to 2004 and did not achieve a sustained virological response; and

3 Patient has not received previous treatment with a protease inhibitor; and
4 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
5 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin.

Note: Boceprevir/telaprevir should not be used in patients with significant portal hypertension or varices or decompensated liver disease

Initial application – (chronic hepatitis C – genotype 1 with Il-28 TC or TT allele) from a from Gastroenterologist, Infectious Disease Specialist or General Physician. Approvals valid for xx weeks for applications meeting the following criteria:

All of the following

1 Patient has hepatitis C genotype 1; and
2 Patient has either
2.1 Il-28 TC allele; or
2.2 Il-28 TT allele; and
3 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
4 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin.

Note: Boceprevir/telaprevir should not be used in patients with significant portal hypertension or varices or decompensated liver disease

Initial application – (chronic hepatitis C – genotype 1) from a Gastroenterologist, Infectious Disease Specialist or General Physician. Approvals valid for xx weeks for applications meeting the following criteria:

All of the following

1 Patient has hepatitis C genotype 1; and
2 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
3 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin.

Note: Boceprevir/telaprevir should not be used in patients with significant portal hypertension or varices or decompensated liver disease

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

Pegylated Interferon with/without ribavirin

3.1 Sole Supply for community supply of Pegylated Interferon until 30 June 2017 for Hepatitis B; or

3.2 Sole Supply for community supply of Pegylated Interferon until 30 June 2017 for Hepatitis C; or

3.3 Sole Supply for community supply of Pegylated Interferon until 30 June 2017 for Hepatitis B and C

3.4 Dual Supply for community supply of Pegylated Interferon with a period of Dual Supply until 30 June 2017.

Please note:

- If you wish to submit a proposal for Pegylated Interferon for both hepatitis B and hepatitis C, you must also submit individual proposals for both hepatitis B and hepatitis C.

- The Special Authority criteria applying to chronic hepatitis C may be widened to include those who have previously been treated with pegylated interferon and ribavirin when used in combination with a HCV protease inhibitor if HCV protease inhibitors are funded for this indication.

- If a proposal for Sole Indication Supply of Pegylated Interferon is awarded to a supplier other than the incumbent, patients that are currently receiving the subsidised Pegylated Interferon brand would continue to receive a subsidy for that brand of Pegylated Interferon until the Special Authority approval expires (i.e. for the remaining duration of their course of treatment), however no new patients would be able to access that brand of Pegylated Interferon during the transition.

- 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.

HCV protease Inhibitors

3.5 Sole Supply for community supply of HCV protease inhibitors until 30 June 2016 for the following indications:

3.5.1 treatment of naive hepatitis C genotype 1 patients with cirrhosis or advanced fibrosis who do not have the IL-28 genotype CC and treatment-experienced hepatitis C genotype 1 patients, regardless of fibrosis stage, who were responder relapsers or partial responders (including those prior to 2004); or

3.5.2 treatment naïve hepatitis C genotype 1 patients with either Il-28 TC or TT allele and those patients defined in 3.5.1 above; or

3.5.3 treatment naïve hepatitis C genotype 1 patients and those patients defined in 3.5.1 and 3.5.2 above.

3.6 Dual Supply for community supply of HCV Protease Inhibitors, with a period of Dual Supply until 30 June 2016

Please note:

- If you wish to submit a proposal for HCV protease inhibitors you must also submit separate proposals for all three indications defined in 3.5 above.

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

- proposals that involve wider access to Pegylated Interferon and/or HCV Protease Inhibitors.

- proposals that include a single price per pack of Pegylated Interferon regardless of strength.

- proposals that include bundling of Pegylated Interferon and HCV protease inhibitors, provided that individual proposals for Pegylated Interferon and HCV protease inhibitors are also submitted.

- proposals that include rebate arrangements.

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

- 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 and/or HCV Protease Inhibitors on specific terms; and

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

- proposals that include any pharmaceuticals other than Pegylated Interferon or HCV protease Inhibitors.

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 4:30 p.m. (New Zealand time) on 10 June 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 **Greg Williams, Senior Therapeutic Group Manager** by email to 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.health.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 HCV Protease Inhibitors 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 June 2013;

(ii) PHARMAC seeking such additional advice as it considers necessary from PTAC or its relevant subcommittees June/July 2013;

(iii) negotiating with submitter(s) of one or more preferred proposals in June/July 2013;

(iv) consulting on a provisional agreement in July 2013;

(v) PHARMAC's Board (or its delegate) considering this provisional agreement in or after August 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 September 2013.

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		
	2010	2011	2012
Pegylated interferon alpha-2a			
Inj 135 µg prefilled syringe	72	31	36
Inj 180 µg prefilled syringe	1,706	1,176	773
Pegylated inteferon alpha-2a with ribavirin			
Inj 135 µg prefilled syringe x 4 with ribavirin tab 200 mg x 112	32	7	8
Inj 135 µg prefilled syringe x 4 with ribavirin tab 200 mg x 168	43	22	9
Inj 180 µg prefilled syringe x 4 with ribavirin tab 200 mg x 112	1,642	1,152	1,049
Inj 180 µg prefilled syringe x 4 with ribavirin tab 200 mg x 168	3,268	2,729	2,301

The PTAC minutes relating to protease inhibitors for hepatitis C can be found at the following link:

http://www.pharmac.health.nz/ckeditor_assets/attachments/89/2012-08_ptac_minutes.pdf

The Anti-Infective Subcommittee's advice on protease inhibitors for hepatitis C (boceprevir and telaprevir) from their meeting on 13 December 2012 which was noted and accepted by PTAC at its February 2013 meeting can be found at the following link:

http://www.pharmac.health.nz/ckeditor_assets/attachments/303/anti-infective-subcommittee-minutes-2012-12-13.pdf

The relevant recommendations relating to the funding of HCV protease Inhibitors from the Anti-Infective Subcommittee are as follows:

- The Subcommittee **recommended** that either telaprevir or boceprevir would be an appropriate agent to fund as the products produced the same or similar efficacy.

- The Subcommittee **recommended,** with a high priority, funding either boceprevir or telaprevir for hepatitis C genotype 1 patients with cirrhosis or advanced fibrosis who are pegylated interferon and ribavirin treatment naïve, under the following Special Authority:

  Application from gastroenterologist, Infectious disease specialist or General physician. Approvals valid for 12 or 24 weeks (as appropriate) for applications meeting the following criteria:

  All of the following

1 Patient has hepatitis C genotype 1; and
2 Patient has IL-28B genotype CT or TT; and
3 Patient has severe fibrosis (F3) or cirrhosis (F4) or on fibroscan or equivalent; and both
  3.1 Patient does not have significant portal hypertension or varices; and
  3.2 Patient does not have decompensated liver disease
4 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
5 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin.

- The Subcommittee **recommended,** with a high priority, funding retreatment with pegylated interferon and ribavirin in combination with boceprevir or telaprevir for hepatitis C genotype 1 patients who were either responder relapsers or partial responders to prior treatment with pegylated interferon and ribavirin. Members noted that a Special Authority would be required and offered to develop this if required.

- The Subcommittee **recommended,** with a low priority, funding retreatment with pegylated interferon and ribavirin in combination with boceprevir or telaprevir for hepatitis C genotype 1 patients treated prior to 2004 with either standard interferon or pegylated interferon and ribavirin who did not achieve an SVR and in whom early on-treatment responses were not available.

- The Subcommittee **recommended** funding boceprevir or telaprevir for either responder relapsers or partial responders (high priority) or patients treated prior to 2004 who did not achieve an SVR (low priority), under the following Special Authority:

  Application from gastroenterologist, Infectious disease specialist or General physician. Approvals valid for 12 or 24 weeks (as appropriate) for applications meeting the following criteria:

  All of the following

  1 Patient has hepatitis C genotype 1; and
  2 Patient has an approved Special Authority for pegylated interferon and ribavirin; and
  3 Boceprevir/telaprevir is to be used in combination with pegylated interferon with ribavirin; and
  4 Patient has previously been treated with pegylated interferon and ribavirin; and
  either
    4.1 relapsed following a virological response on pegylated interferon and ribavirin; or
    4.2 had a partial response to pegylated interferon and ribavirin; or
    4.3 received pegylated interferon and ribavirin prior to 2004 and did not achieve a sustained virological response; and
  5 Patient has not received previous treatment with a protease inhibitor.

- The Subcommittee **recommended** funding for DAAs for treatment naïve patients or Il-28 TC or TT allele patient groups with a low priority, The Subcommittee noted that the budget impact of funding these groups should be considered.

Schedule 4: Proposal form

An electronic version of this form is available from PHARMAC. You should expand the boxes as necessary.

[*Supplier to insert date]*

Chief Executive
C/- Greg Williams

greg.williams@pharmac.govt.nz

Dear Sir/Madam

Proposal for the supply of Pegylated Interferon and HCV Protease Inhibitors

In response to your request for proposals (**RFP**) dated 26 April 2013, we put forward the following proposal in respect of Pegylated Interferon and HCV Protease Inhibitors.

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:

(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 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 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) 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:
