PHARMAC
Pharmaceutical Management Agency

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16 March 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF BORTEZOMIB

PHARMAC invites proposals for the supply of bortezomib 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 via the Government Electronic Tenders Services (GETS) no later than **5.00 p.m.** on **13 April 2016**.

If you have any questions about this RFP, please post these on the Government Electronic Tenders Service (www.gets.govt.nz) or alternatively contact Chloë Dimock at PHARMAC by email procurement@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1) Pharmaceutical

PHARMAC is interested in considering any proposals from suppliers of bortezomib. Bortezomib is a Pharmaceutical Cancer Treatment (PCT) pharmaceutical.

2) Background to RFP

The background to this RFP is outlined below.

a) *Current listing arrangement*

i) Bortezomib inj 1 mg and inj 3.5 mg have been listed on the Pharmaceutical Schedule since 1 June 2011 and 1 May 2011 respectively and are subject to a listing agreement with Janssen-Cilag Pty Ltd.

ii) Two presentations of bortezomib are currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule, subject to restrictions with treatment naïve and relapsed/refractory multiple myeloma and systemic AL amyloidosis (i.e. first and second line treatment). There is also "Inj 1 mg for ECP" listed. The price and subsidy for the 1 mg for ECP presentation assumes 10% wastage based on the average dose, dosing schedule and number of patients treated.

iii) The current listing prices and restrictions are as follows:

		Subsidy/ Price	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BORTEZOMIB – PCT only – Specialist – Special Authority see **SA1576** below					
Inj 1 mg	.....	$540.70 *	1	✓	**Velcade**
Inj 3.5 mg	.....	$1,892.50 *	1	✓	**Velcade**
Inj 1 mg for ECP	.....	$594.77 *	1	✓	**Baxter**

*a confidential rebate currently exists

SA1576 Special Authority for Subsidy [Restricted in Part II of Section H]
Initial application — (Treatment naive multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:
Both:
1 Either:
1.1 The patient has treatment-naive symptomatic multiple myeloma; or
1.2 The patient has treatment-naive symptomatic systemic AL amyloidosis *; and
2 Maximum of 9 treatment cycles.
Note: Indications marked with * are Unapproved Indications.

Initial application—(Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:
All of the following:
1 Either:
1.1 The patient has relapsed or refractory multiple myeloma; or
1.2 The patient has relapsed or refractory systemic AL amyloidosis *; and
2 The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and
3 The patient has not had prior publicly funded treatment with bortezomib; and
4 Maximum of 4 treatment cycles.
Note: Indications marked with * are Unapproved Indications.

Renewal — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:
Both:
1 The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and

2 Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).

Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:
a) a known therapeutic chemotherapy regimen and supportive treatments; or
b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.
Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.

b) *Reasons for running the RFP*

i) Contractual restrictions on delisting and subsidy reduction for the Velcade brand of bortezomib ended on 1 December 2013.

ii) PHARMAC is aware of other brands of bortezomib which are currently in the process of seeking regulatory approval, meaning that competition in this market is now imminent.

iii) PHARMAC had included bortezomib inj 1 mg and inj 3.5 mg in its 2014/15 Invitation to Tender issued 6 November 2014. The tender for the inj 1 mg presentation was declined in February 2015 and the outstanding tender for bortezomib inj 3.5 mg was declined in February 2016 due to the length of time that had passed since the tender had been issued.

c) *Expected outcome of the RFP*

As a result of this RFP, we expect to secure future supply of bortezomib in the community and DHB hospitals at competitive prices.

d) *Relevant advisory committee advice:*

PHARMAC has previously received advice from the Cancer Treatments Subcommittee of PTAC (CaTSoP) regarding a competitive process for bortezomib. The Subcommittee had no strong opposition to a sole supply being awarded for bortezomib but noted that continuity of supply was very important to this product.

The Subcommittee considered that in the event of a brand switch to a generic product being implemented in this market it would be important to provide prescribers with pharmacokinetic/pharmacodynamic data for the generic product to provide reassurance of its bioequivalence with Velcade.

The Subcommittee noted that Velcade was currently supplied in a 3.5 mg and 1 mg vial and was approved for administration via intravenous (IV) or subcutaneous routes. Members considered it was essential that any generic could also be administered via IV or subcutaneous routes noting there was trend towards more patients receiving subcutaneous treatment. Members considered it was not necessary to also have both the 1 mg and 3.5 mg vial strengths funded subject to PHARMAC confirming this was acceptable with an Oncology Pharmacist.

The minute of the discussion can be found on PHARMAC's website: CaTSoP minute

3) **Types of proposals sought**

a) *PHARMAC is willing to consider the following types of proposals:*

i) proposals that include either the inj 3.5 mg presentation or both of the two currently listed presentations (inj 1 mg and inj 3.5 mg) of bortezomib on the Pharmaceutical Schedule;

ii) proposals that involve Hospital Supply Status (HSS) with a discretionary variance (DV) limit of 1% in DHB hospitals for a period of up to 3 years, provided that HSS does not extend beyond 30 June 2019. HSS means the status of being the brand of the relevant National Contract Pharmaceutical that DHBs are obliged to purchase, subject to any DV Limit, for the period of hospital supply, as awarded under an agreement between PHARMAC and the relevant Pharmaceutical supplier.

Note: bortezomib is a PCT-only pharmaceutical (defined in Section A of the Pharmaceutical Schedule) therefore should a supplier submit a proposal for HSS it does so on basis that, should PHARMAC enter into an agreement for HSS, the supplier's brand of bortezomib would also be listed in Section B as well as Part II of Section H of the Pharmaceutical Schedule at a price that is equal to (or subject to your agreement, less than) the price put forward in the proposal for claiming purposes only (unless otherwise advised in writing by PHARMAC).

iii) proposals that involve subsidy and delisting protection for a period of up to 3 years, provided that subsidy and delisting protection does not extend beyond 30 June 2019;

iv) proposals that include rebates (including volume-based rebates) or other expenditure risk-sharing mechanisms;

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

i) proposals that involve an end date for any proposed rebates (including volume-based rebates) or other expenditure risk-sharing mechanisms;

ii) cross-deal or bundling arrangements in respect of more than one chemical entity, therapeutic group or sub-group;

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

4) **Access by PHARMAC to price and volume data**

a) In submitting a proposal you acknowledge that PHARMAC and its agents may require access to price and volume data held by you and DHB Hospitals in respect of the Pharmaceutical and will assist with providing this information to assist PHARMAC to carry out its statutory function in relation to managing the purchasing of hospital pharmaceuticals on behalf of DHBs should PHARMAC enter into an agreement with you.

5) **Consents not yet held**

a) Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of your brand of bortezomib in New Zealand (including Ministry of Health market approval);

b) PHARMAC would consider proposals for a brand of bortezomib that is yet to obtain all necessary Consents. In those circumstances, you may be required to demonstrate your ability to obtain those Consents within a time frame acceptable to PHARMAC.

6) **Stability data**

a) Any supplier proposing HSS for its product would be expected to provide stability data for its product. PHARMAC has a preference for products where stability data is greater than 24 hours post compounding. PHARMAC requests product stability data is submitted with proposals or, if the data is unavailable at the time of submission, within 10 business days of any request from PHARMAC.

7) **Training, education and support**

a) Any supplier awarded HSS would be expected to provide initial associated services including training, education and product support where applicable

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) All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than 5.00 p.m. (New Zealand time) on **13 April 2016**. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

   (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

   (d) If you have any enquiries about this RFP you should contact Chloë Dimock (procurement@pharmac.govt.nz) or submit questions through GETS (www.gets.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 Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the decision mechanism 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. The information to be taken into account in applying the decision mechanism by the Evaluation Committee will be at its discretion, however it will include:

      (i) the information included in your proposal (Schedule 4: Proposal form);

      (ii) any clinical advice from PTAC or its relevant Subcommittee;

      (iii) any advice from any other relevant organisations and/or health professionals;

      (iv) any advice or feedback that PHARMAC receives regarding the post compounding stability of your brand of bortezomib;

      (v) any other matters that the Evaluation Committee considers to be relevant having regard to fairness and probity principles.

   (c) Please note that from 1 July 2016 PHARMAC is changing the way in which it makes decisions, instead of the current Decision Criteria it will be using the Factors for Consideration (FFC). Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

(d) 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.

(e) PHARMAC is not bound to select the lowest priced proposal or any proposal.

(f) Suppliers must provide PHARMAC with samples of the various presentations, forms and strengths of bortezomib included in the proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) no later than 10 business days following PHARMAC's request. For the avoidance of doubt suppliers must also provide the artwork of the product/s intended for the New Zealand market.

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, including (but not limited to):

(i) additional product samples, in which case you must supply the requested sample within 10 business days of PHARMAC's request;

(ii) additional information on any customer support, training and educational resources that may be available to health professionals during switchover to your brand of bortezomib and throughout the term of any contract (if applicable); and

(iii) detailed information about your company structure, credit status and any other relevant company information.

(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, provided that in PHARMAC's judgment this would not be unfair to 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 will be made available on GETS and on our website, 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 the Board's delegate acting 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 the Board's delegate acting under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.

(d) If the Board or its delegate 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 delegate'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;

(viii) to re-advertise 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 the Board's delegate.

(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 bortezomib 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 **April 2016;**

(ii) negotiating with submitter(s) of one or more preferred proposals could commence in **May 2016**;

(iii) consulting on a provisional agreement could occur as early as **May 2016;**

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement at the earliest in **June/July 2016;**

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 in or after **August/September 2016.**

(c) Please note that if a proposal for and hospital sole supply is accepted, the date of implementation may be later to allow for an orderly transition to any sole supply arrangement.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of bortezomib. 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 bortezomib 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.

Table One. Amount claimed per milligram for currently listed bortezomib presentations

		2013	2014	2015
Bortezomib	Inj 1 mg	41	59	9
Bortezomib	Inj 3.5 mg	9,595	8,109	5,657
Bortezomib	Inj 1 mg for ECP	15,136	16,289	16,609

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Chloë Dimock

Dear Sir/Madam

Proposal for the supply of bortezomib

In response to your request for proposals (**RFP**) dated **16 March 2016,** we put forward the following proposal in respect of bortezomib.

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. 1 mg)	
Form (e.g. injection)	
Route of administration (e.g intravenous and subcutaneous injection)	
Brand name	
Pack size (e.g. 10 vials)	
Packaging type (e.g. vial)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 25°C)	
Shelf-life post reconstitution (e.g. 24 hours reconstituted stored at 2° to 8°C (Refrigerate, do not freeze))	
Indications	

(c) Product stability data post compounding:

(d) Bioequivalence data (where applicable) including pharmacokinetics, pharmacodynamics and any other relevant data:

(e) Details of pharmaceutical manufacture:

Name and address of manufacturer/s of the pharmaceutical	
Lead time	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(f) Key features of our proposal:

(g) 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.):

(h) 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	

(i) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required:

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

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

(l) 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: