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1 September 2019

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF A CDK4/CDK6 INHIBITOR FOR THE TREATMENT OF HR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER

PHARMAC invites proposals for the supply of a CDK4/CDK6 inhibitor for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer 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 Service (**GETS**) (www.gets.govt.nz) no later than 5.00 p.m. on 14 October 2019.

If you have any questions about this RFP, please post these on GETS; responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Definitions

"**CDK4/CDK6 inhibitor**" means a pharmaceutical that is an inhibitor of the cyclic-dependent kinases (CDK) 4 and 6.

"**HR-positive, HER2-negative locally advanced or metastatic breast cancer**" means hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

"**First-Line**" in the context of this RFP means for use in combination with an Aromatase inhibitor as initial treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer.

"**Second-Line**" in the context of this RFP means for use in combination with an Endocrine agent for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer with disease progression following prior Endocrine agent therapy.

"**Aromatase inhibitor**" in the context of this RFP means the class of treatments including letrozole, anastrozole and exemestane.

"**Endocrine agent**" in the context of this RFP means an Aromatase inhibitor, tamoxifen or fulvestrant (noting that fulvestrant is not currently funded in New Zealand, although a proposal to fund it is currently being consulted on).

2. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers of a CDK4/CDK6 inhibitor for funding as a treatment for HR-positive, HER2-negative locally advanced or metastatic breast cancer that comply with the *Types of proposals sought* set out in paragraph 4 of this Schedule One (below).

3. Background to RFP

The background to this RFP is as follows:

Approximately 3000 people are diagnosed with breast cancer each year in New Zealand. An unknown proportion will progress from localised to advanced disease, and approximately 20% of patients will have locally advanced or metastatic disease at diagnosis. PHARMAC's Cancer Treatments Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) considered that approximately 55%–65% of patients with advanced disease will have HR-positive, HER2-negative disease.

Although difficult to estimate, based on expert advice from our Cancer Treatments Subcommittee of PTAC and data from funded usage of Aromatase inhibitors in New Zealand, we consider that the number of patients with HR-positive, HER2-negative disease who would be eligible for treatment with a CDK4/CDK6 inhibitor each year in New Zealand could be:

- up to 550 people in the First-Line setting per year; and
- up to 1600 people in the Second-Line setting in the first year post-funding, and up to 400 people in the Second-Line setting in subsequent years.

Recent data from the United States of America indicates that the median overall survival for patients with stage IV HR-positive, HER2-negative disease, in the absence of treatment with a CDK4/CDK6 inhibitor, is 36 months (Gong et al. Sci Rep. 2017;7:45411).

Māori and Pacific women in New Zealand are two and three times, respectively, more likely to be diagnosed with metastatic breast cancer compared with NZ European women (Māori 7.6%, Pacific 10.9%, NZ European 3.9%; Seneviratne et al. BMC Cancer. 2016;16:129).

Current funding

Currently funded First-Line treatments for HR-positive, HER2-negative locally advanced or metastatic breast cancer in New Zealand are an Aromatase inhibitor (letrozole, anastrozole, exemestane) or tamoxifen. Second-Line treatment is with the class of treatment (Aromatase inhibitor or tamoxifen) that was not use as First-Line treatment. Patients with rapidly progressive visceral disease, patients at risk of end-organ dysfunction, or patients with proven endocrine resistance are treated with chemotherapy.

PHARMAC is currently consulting on a proposal to fund fulvestrant as a Second-Line Endocrine agent for HR positive, HER2-negative locally advanced or metastatic breast cancer, subject to fulvestrant gaining Medsafe registration.

Clinical advice

Funding applications for two different CDK4/CDK6 inhibitors for the treatment of HR positive, HER2-negative locally advanced or metastatic breast cancer have been previously considered by PTAC and the Cancer Treatments Subcommittee of PTAC.

Clinical advice we have received from PTAC and the Cancer Treatments Subcommittee of PTAC is that, based on currently available evidence, treatment with CDK4/CDK6 inhibitors improves progression-free survival with maintained quality of life for patients with HR-positive HER2-negative locally advanced or metastatic breast cancer.

Both PTAC and the Subcommittee also considered that, based on currently available evidence, there is a class effect from use of CDK4/CDK6 inhibitors in the treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer; and that agents within this class can be considered to provide the same or similar therapeutic effect.

Listed below is a timeline of relevant clinical advice for each and web links to the minutes.

Palbociclib

a) **21 September 2018** – the Cancer Treatments Subcommittee of PTAC reviewed a funding application from Pfizer New Zealand Ltd for palbociclib to be used in combination with an Aromatase inhibitor in the First-Line setting for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer. The Subcommittee recommended funding with a medium priority subject to Special Authority criteria.

b) **21/22 February 2019** - PTAC considered the Subcommittee's advice and requested the full application for use in the First-Line setting be reviewed by PTAC at a future meeting.

c) **5 April 2019** - the Cancer Treatments Subcommittee of PTAC reviewed a funding application from a consumer advocacy group, Breast Cancer Aotearoa Coalition (BCAC), for palbociclib to be used in combination with fulvestrant in the Second-

Line setting for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer. The Subcommittee recommended funding with a medium priority subject to Special Authority criteria.

d) **23/24 May 2019** - PTAC reviewed both the First-Line and Second-Line setting funding applications and recommended funding palbociclib with low and medium priority respectively subject to Special Authority criteria.

For more information, see the First-Line and Second-Line palbociclib funding application assessment records here:

https://www.pharmac.govt.nz/wwwtrs/ApplicationTracker.php?ProposalId=1631
https://www.pharmac.govt.nz/wwwtrs/ApplicationTracker.php?ProposalId=1724

Ribociclib

e) **23/24 May 2019** – PTAC reviewed a funding application from Novartis New Zealand Ltd for ribociclib to be used in combination with an Aromatase inhibitor in the First-Line setting for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer. PTAC recommended funding with a medium priority subject to Special Authority criteria.

For more information, see the First-Line ribociclib funding application assessment record here:
https://www.pharmac.govt.nz/wwwtrs/ApplicationTracker.php?ProposalId=1754

Class effect with CDK4/CDK6 inhibitors

f) At its April 2019 meeting, the Cancer Treatments Subcommittee of PTAC considered that, based on evidence available at the time, there is a class effect with CDK4/CDK6 inhibitors for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer; and made the following recommendations:

- The Subcommittee recommended that a CDK4/6 inhibitor for use in combination with an endocrine partner for the First-Line treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer be funded with a high priority.
- The Subcommittee recommended that a CDK4/6 inhibitor for use in combination with an endocrine partner for the Second-Line treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer in patients with hormone-sensitive disease be funded with a high priority.
- The Subcommittee recommended that a CDK4/6 inhibitor for use in combination with an endocrine partner for the Second-Line treatment of all HR-positive, HER2-negative locally advanced or metastatic breast cancer be funded with a medium priority.

The Subcommittee also considered that there is likely to be no significant difference in outcomes based on the Endocrine agent that the CDK4/CDK6 inhibitors are combined with.

g) At its May 2019 meeting, PTAC considered that the evidence suggests there is a class effect associated with CDK4/CDK6 inhibitors for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer and that the agents within this class can be considered to provide the same or similar therapeutic effect. Further, PTAC noted the Cancer Treatment Subcommittee's

view that there is likely to be no significant difference in outcomes based on the Endocrine agent that the CDK4/CDK6 inhibitors are combined with. PTAC recommended that a CDK4/CDK6 inhibitor be funded subject to the Special Authority criteria recommended by the Subcommittee.

Reasons for issuing the RFP

There are two CDK4/CDK6 inhibitors, palbociclib and ribociclib, currently registered in New Zealand for use in the First-Line setting to treat HR-positive, HER2-negative locally advanced or metastatic breast cancer.

Palbociclib is also registered in New Zealand for use in the Second-Line setting to treat HR-positive, HER2-negative locally advanced or metastatic breast cancer. Ribociclib is not currently registered in New Zealand for use in the Second-Line setting treatment to treat HR-positive, HER2-negative locally advanced or metastatic breast cancer, but it is registered for this indication in other countries.

PHARMAC is aware of another CDK4/CDK6 inhibitor, abemaciclib – supplied in Australia by Eli Lilly – which is registered in other countries for use in both First-Line and Second-Line settings as a treatment for HR-positive, HER2-negative locally advanced or metastatic breast cancer, but it is not currently registered in New Zealand.

As noted above, our expert clinical advisors consider that agents within the CDK4/CDK6 class can be considered to provide the same or similar therapeutic effect. As such, the purpose of this RFP is to seek competitive bids that would allow PHARMAC to fund a CDK4/CDK6 inhibitor for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer in New Zealand.

Dependant on the responses received to this RFP, PHARMAC could decide:

- not to progress any commercial proposals to a funding decision; or
- to progress a proposal to fund a CDK4/CDK6 inhibitor for treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer in the First-Line and/or Second-Line settings.

PHARMAC wishes to fund a CDK4/CDK6 inhibitor for treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer in both First-Line and Second-Line setting if supplier responses to this RFP and budget availability allow.

Eligibility criteria

PHARMAC is interested in proposals that would enable the funding of a CDK4/CDK6 inhibitor for the treatment for HR-positive, HER2-negative locally advanced or metastatic breast cancer subject to eligibility criteria substantially similar to the following (for First-Line and Second-Line combined, or First-Line only, or Second-Line only, as applicable):

> Special Authority for Subsidy – Retail Pharmacy-Specialist
>
> Initial application (first line) only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
> All of the following:
> 1. Patient has unresectable locally advanced or metastatic breast cancer; and
> 2. There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
> 3. Patient has an ECOG performance score of 0-2; and

4. Patient has not received prior systemic treatment for metastatic disease; and
5. Patient has been amenorrhoeic for 12 months of greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state.
6. Treatment must be used in combination with an endocrine agent.

Initial application (second line) **-** only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient has unresectable locally advanced or metastatic breast cancer; and
2. There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3. Patient has an ECOG performance score of 0-2; and
4. Patient has relapsed or progressed during prior endocrine therapy; and
5. Treatment must be used in combination with an endocrine agent.

Renewal (first- or second-line) - only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Treatment must be used in combination with an endocrine agent; and
2. No evidence of progressive disease; and
3. The treatment remains appropriate and the patient is benefitting from treatment.

Please note that the eligibility criteria above accord with those recommended to PHARMAC by PTAC and the Cancer Treatments Subcommittee of PTAC. The criteria are intended to be indicative of the patient population and could be amended following consideration of responses to this RFP, feedback from public consultation or further advice from the Cancer Treatments Subcommittee of PTAC and/or PTAC, or otherwise.

4. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

- Participating suppliers **MUST** submit proposals for a CDK4/CDK6 inhibitor for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer, subject to the eligibility criteria described above. For the avoidance of doubt, proposals for a CDK4/CDK6 inhibitor for the treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer are expected to contain terms of supply relating only to the CDK4/CDK6 inhibitor itself (unless they are 'bundle proposals' as described below). Proposals must not contain terms of supply for any Aromatase inhibitor/Endocrine agent that may be used in combination with the CDK4/CDK6 inhibitor.
- Participating suppliers **MUST** submit a proposal for a CDK4/CDK6 inhibitor for use in the First-Line and Second-Line settings **AND** for use in the First-Line setting only **AND** for use in the Second-Line setting only.
- Proposals **MUST** include a period of sole supply ("Sole Supply"), provided that the Sole Supply period does not extend beyond 30 June 2023.
    - For the avoidance of doubt, Sole Supply would be only at the indication (HR-positive HER2-negative locally advanced or metastatic breast cancer) and line of treatment (First-Line or Second-Line) level for the class (CDK4/CDK6 inhibitors) and would mean that PHARMAC would not fund another CDK4/CDK6 inhibitor for that line of treatment of HR-positive, HER2-negative locally advanced or metastatic breast cancer prior to 30 June 2023.
    - For the avoidance of doubt and for example, if Sole Supply were awarded in the First-Line setting only, then PHARMAC could fund another

CDK4/CDK6 inhibitor in the Second-Line setting only, either through this RFP process or through a separate funding process prior to 30 June 2023.

- Proposals **MAY** include any of the following arrangements (that may be confidential), provided that a supplier submits at least one bid with a flat rebate structure of one price per unit regardless of expenditure:
    - rebates or other risk-sharing arrangements;
    - a 'hard' cap, where a 100% rebate exists over a certain level of expenditure; and
    - a 'soft' cap, where a rebate of less than 100% exists over a certain level of expenditure, or a tiered pricing structure, where the level of rebate is linked to certain levels of expenditure.

  AND PROVIDED that any proposed rebate gives PHARMAC an option, with 6 months' notice (not to be issued prior to the end of the Sole Supply period), in its sole discretion, to amend the rebate structure to reflect the average net price per pack from the most recent preceding 6 month period.

- Proposals **MAY** include CDK4/CDK6 inhibitors that are yet to obtain all necessary Consents (where 'Consents' means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval)). In such circumstances:
    - you may be required to demonstrate your ability to obtain those Consents within a time frame acceptable to PHARMAC. For example, you may be required to demonstrate that you have the dossier for your product/s ready to submit to Medsafe within one month of such a request being made by PHARMAC; and
    - PHARMAC would not fund your product until all Consents are obtained.

- Proposals **MAY** involve pharmaceuticals other than CDK4/CDK6 inhibitors ('bundle proposals') **PROVIDED** that these do not include any Aromatase inhibitor/Endocrine agent that may be used in combination with your proposed CDK4/CDK6 inhibitor **AND** that these involve **EITHER**:
    - currently listed pharmaceuticals that would remain subject to any existing funding criteria **OR**
    - a new pharmaceutical, or widened access to an existing funded pharmaceutical, for which a funding application has been assessed by PHARMAC, has a positive clinical advisory recommendation (including 'only if cost-neutral') and has been ranked by PHARMAC at the time of proposal submission (see Application Tracker)

  AND you also submit the mandatory individual proposals above ('unbundled proposals') for a CDK4/CDK6 inhibitor for the funding of a treatment for HR-positive, HER2-negative locally advanced or metastatic breast cancer for use in the First-Line and Second-Line settings; use in the First-Line setting only and use in the Second-Line setting only – all of which must be capable of being accepted individually.

PHARMAC is **NOT** willing to consider the following types of proposals:

- Proposals for the concurrent listing (dual supply) of two CDK4/CDK6 inhibitors for HR-positive, HER2-negative locally advanced or metastatic breast cancer.

- Proposals for supply of CDK4/CDK6 inhibitors for indications other than for HR-positive, HER2-negative locally advanced or metastatic breast cancer.
- Proposals for supply for any Aromatase inhibitor/Endocrine agent that may be used in combination with the CDK4/CDK6 inhibitor.
- Proposals that involve an end date for rebates or other risk-sharing arrangements including expenditure caps or tiered pricing described above.
- Proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- 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.

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

Samples

Suppliers **SHOULD** provide PHARMAC with labelling and images of their products with their proposal. Samples of the CDK4/CDK6 inhibitor included should be able to be provided upon request by PHARMAC (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within a reasonable timeframe of such a request.

Supplier Code of Conduct

The New Zealand Government is committed to sustainable and inclusive government procurement and the Supplier Code of Conduct outlines the Government's expectations of suppliers in this respect. PHARMAC expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.

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 14 October 2019. Late proposals will only be considered at PHARMAC's discretion, considering 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 submit them on GETS, responses to all enquires will be published on GETS.

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 Factors for Consideration (**Factors**) that form part of PHARMAC's then current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

(c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee, but all Factors are important.

(d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

(i) Price and net present value (NPV) costs and savings;

(ii) Market approval and any other required Consents and standards;

(iii) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below;

(iv) appropriate labelling, packaging and instructions for use;

(v) lead times to supply commencing;

(vi) any advice from PTAC, its relevant subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of any pharmaceuticals included in the proposal(s) following the closing of this RFP; and

(vii) education and training for use;

(viii) previous supply performance and relevant expertise;

(ix) financial resources of the company; and

(x) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(e) 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.

(f) 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, including (but not limited to):

(i) detailed information about your company structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant subcommittee, any relevant professional organisations or healthcare professionals with regard to your product including evaluation of any product samples.

(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 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 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 PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(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 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 the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC 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 a CDK4/CDK6 inhibitor 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 **October 2019**;

(ii) negotiating with submitter(s) of one or more preferred proposals in **October/November 2019**;

(iii) consulting on a provisional agreement in **November 2019**;

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after **January/February 2019**,

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 funding could be implemented is **1 April 2019**.

8. **Governing Law**

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Listing and market information

See *Background to RFP* above for an estimate of market size.

The information in this RFP 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 a CDK4/CDK6 inhibitor for use in both or either the First-Line or Second-Line settings, and while PHARMAC has taken all reasonable care in preparing the information in this RFP, 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 our estimates of market size.

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Procurement Manager

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of a CDK4/CDK6 inhibitor for treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer

In response to your request for proposals (**RFP**) dated 1 September 2019, we put forward the following proposal in respect of a CDK4/CDK6 inhibitor.

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(s) (e.g. 500 mg)	
Form(s) (e.g. tablet)	
Brand name	
Pack size (e.g. 30 tablets)	
Packaging type (e.g. bottle)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	

(c) Details of pharmaceutical manufacture:

Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
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	

(d) Key features of our proposal:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC:

First-Line setting only

Second-Line setting only

Both First-Line and Second-Line settings

(f) 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 or changed-medicine notification submission (please attach confirmation from Medsafe that it has been submitted)	
OR Expected date of dossier or changed-medicine notification submission to Medsafe (please provide details)	

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

(h) Information about our ability to ensure the continuity of supply of the pharmaceutical, including other countries where the product is provided:

(i) Information about our previous supply performance, existing supply commitments and relevant expertise:

(j) Proposals/suggestions (e.g. pricing, rebate arrangements, etc) regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(k) Reasons why PHARMAC should accept our proposal:

(l) Please include any additional information you consider relevant under PHARMAC's Factors for Consideration decision making framework: