

24 August 2023

Tēnā koe

REQUEST FOR PROPOSALS – SUPPLY OF LENALIDOMIDE AND POMALIDOMIDE

[Te Pātaka Whaioranga - Pharmac](#) invites proposals for the supply of lenalidomide and/or pomalidomide in the Aotearoa New Zealand subsidised market.

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

- **Schedule 1** specifies:
 - the pharmaceuticals we are seeking proposals for
 - the background to the RFP
 - our role within the Pae Ora (Healthy Futures) Act 2022
 - the types of proposals sought;
- **Schedule 2** describes the process that Pharmac expects to follow for 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 for you to provide your proposal.

If you wish to submit a proposal, you must submit it to Pharmac through the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **2.00 p.m. NZST on 4 October 2023**.

If you have any questions about this RFP, please post these on GETS, or if necessary, contact Pharmac by email, procurement@pharmac.govt.nz .

Responses to all questions will be anonymised and published on GETS.

We look forward to receiving your proposal(s).

Nāku noa, nā



Geraldine MacGibbon
Director, Pharmaceuticals

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

1. Pharmaceutical

Te Pātaka Whaioranga - Pharmac is interested in considering proposals from suppliers of lenalidomide and pomalidomide. Suppliers do not have to include both lenalidomide and pomalidomide in their proposal.

2. Background to RFP

Aotearoa New Zealand context

In Aotearoa, around 400 new cases of multiple myeloma are reported each year. Multiple myeloma is the second most common blood cancer in Aotearoa. Māori and Pacific peoples experience a higher age-standardised incidence of multiple myeloma, are diagnosed at younger age, are less likely to receive first-line treatment or autologous stem cell transplant, and have poorer outcomes than non-Māori and non-Pacific populations ([Moore et al. Clin Lymphoma Myeloma Leuk. 2022; 22:e762-e769](#); [The Burden of Multiple Myeloma: A study of the human and economic costs of myeloma in New Zealand](#)).

Multiple myeloma, also known as myeloma, forms in plasma cells, a type of white blood cell normally found in the bone marrow. When plasma cells become cancerous and grow out of control, they crowd out the healthy blood cells. This can make people with myeloma anaemic, more susceptible to infections and bleeding, and bruise more easily.

When people present with multiple myeloma, most people receive a bortezomib containing regimen, usually in combination with cyclophosphamide and dexamethasone.

For those eligible, autologous stem cell transplant (ASCT) is commonplace, followed by lenalidomide maintenance therapy. For those who do not access ASCT, first line treatment does not currently include lenalidomide.

Following first relapse, people would currently receive retreatment with a bortezomib containing regimen, which may include thalidomide. Lenalidomide is currently funded upon second relapse. Lenalidomide can be used after relapse if the person has experienced severe peripheral neuropathy with thalidomide or bortezomib.

Lenalidomide

Lenalidomide is currently funded:

- as maintenance treatment after autologous stem cell transplant
- for people with relapsed or refractory multiple myeloma.

In those with relapsed or refractory multiple myeloma:

- about 70-75% receive lenalidomide after two prior lines of treatment,
- the remaining 25-30% receive lenalidomide after one prior line of treatment – if peripheral neuropathy has been experienced with thalidomide.

This RFP process considers two possible funding outcomes for lenalidomide:

1. current access for the above indications, and
2. widened access to first-line treatment for all people with multiple myeloma regardless of transplant eligibility.

This is in line with the funding recommendations from Pharmac's clinical advisors, which are outlined in this document.

Pomalidomide

Pomalidomide is not currently funded. [Pomalidomide is Medsafe approved](#) for the treatment of individuals with relapsed and refractory multiple myeloma.

We have received and assessed a funding application for pomalidomide. This has been recommended for funding by our clinical advisors, as outlined later in this document.

Pharmac will use the RFP process to consider funding pomalidomide for relapsed or refractory multiple myeloma after one or more prior lines of therapy.

Risk management

Lenalidomide and pomalidomide are immunomodulatory pharmaceuticals. They are similar to thalidomide. These pharmaceuticals can cause abnormalities in fetuses, which is known as teratogenicity.

Pharmac considers it important to ensure the management of teratogenicity of immunomodulatory pharmaceuticals such as lenalidomide and pomalidomide is robust and well implemented. As a result, the consideration of proposed risk management programmes will be a key aspect of this RFP activity.

A risk management programme is a system or register that confirms that people understand the risks these medicines pose to fetuses. Such a system would be accessible to prescribers, dispensers (pharmacists), and people using lenalidomide or pomalidomide.

Having an acceptable risk management programme of teratogenicity of immunomodulatory medicines in place is a regulatory requirement from Medsafe.

Pae Ora (Healthy Futures) Act 2022

Pharmac's role within the sector and supporting New Zealanders achieve Pae ora

The Pae Ora (Healthy Futures) Act 2022 (the Act) took effect on 1 July 2022. It shapes the reform of the health sector in Aotearoa New Zealand. Its vision is that all New Zealanders achieve pae ora (healthy futures). Achieving pae ora means that people and their whānau will live longer in good health, have improved health and quality of life, are part of healthy, inclusive and resilient communities, and live in environments that sustain their wellbeing.

As a government health entity, Pharmac is to give effect to the principles of te Tiriti o Waitangi (as set out in [section 6](#) of the Act) and be guided by the health sector principles (as set out in [section 7](#) of the Act), including equity, engagement, and the promotion of health and wellbeing.

This RFP includes sections for suppliers to outline how they can support Pharmac and the broader health system to give effect to the principles of te Tiriti, that is, tino rangatiratanga (self-determination), ōritetanga (equity), whakamaru (active protection), kōwhiringa (options), and pātuitanga (partnership).

Current funding of lenalidomide

Lenalidomide has been funded since August 2014. It is listed in the Oncology Agents sub-group of the Oncology Agents and Immunosuppressants Section B and Part II of Section H of the Pharmaceutical Schedule. It is currently funded subject to Special Authority eligibility criteria (see: [SA2047](#))

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
LENALIDOMIDE				
Cap 5 mg	5,122.76	28		Revlimid
Cap 10 mg	4,655.25	21		Revlimid
	6,207.00	28		Revlimid
Cap 15 mg	5,429.39	21		Revlimid
	7,239.18	28		Revlimid
Cap 25 mg	7,627.00	21		Revlimid

The currently funded brand of lenalidomide (Revlimid, supplied by Bristol Myers Squibb) is subject to a listing agreement with Pharmac. This resulted from a widening of access in [March 2020](#), which included subsidy and delisting protection until 1 April 2023. Note that a confidential rebate applies which reduces the net expenditure on this product.

Patents

Pharmac is aware of the following New Zealand patents owned by Celgene/Bristol Myers Squibb relating to lenalidomide and pomalidomide:

Patent Number	Expiry	Brief description
NZ546054	03 Sep 2024	Disclosed are eight different polymorphs of 3-(4-amino-1-oxo-1,3 dihydroisoindol-2-yl)-piperidine-2,6-dione, and their use in treating cancer, a myelodysplastic syndrome, or a myeloproliferative disease.
NZ565309	29 June 2026	Claims to a process for preparing pomalidomide.
NZ594557	19 May 2030	Oral dosage of pomalidomide in capsule form together with starch or mannitol or a mixture thereof.

Pharmac makes no representation as to the patent status and descriptions outlined above. Pharmac accepts no liability for any patent infringement that might occur as a result of this RFP process or Pharmac's acceptance of any proposals.

Specialist Advisory Committee advice

Funding applications and recommendations

Pharmac has received funding applications for widening of access to lenalidomide and the funding of pomalidomide as follows:

Lenalidomide:

- First line treatment for people with [multiple myeloma who are eligible for a bone marrow transplant](#). The Cancer Treatments Advisory Committee (CTAC) recommended funding with a low priority. Full records of the clinical advice we have received are available [here](#)
- First line treatment for people with [multiple myeloma who are ineligible for a bone marrow transplant](#). CTAC recommended funding with a low priority (when used in combination with bortezomib and dexamethasone) and a medium priority (when used in combination with dexamethasone only). Full records of the clinical advice we have received are available [here](#)

Pomalidomide:

- for the treatment of people with [relapsed or refractory multiple myeloma](#), after one or more prior lines of therapy. CTAC recommended funding with a high priority. Full records of the clinical advice we have received are available [here](#).

The above applications have been fully assessed and ranked as [options for investment](#). This means they are treatments we would like to fund, subject to available budget. You can view the history of each application from the [application tracker](#).

Options for a competitive process

At its [October 2022](#) meeting the CTAC was supportive of a competitive commercial process for securing supply of funded lenalidomide and pomalidomide. The key points relevant to this RFP are summarised below.

Lenalidomide

- The greatest inequity regarding early access to lenalidomide is a person's age at diagnosis and uptake of autologous stem cell transplant.
- There are many generic lenalidomide pharmaceuticals that have received, or are in the process of seeking, approval from Medsafe. Medsafe assesses bioequivalence and safety of generic lenalidomide products.
- Medsafe requires arrangements to manage the teratogenicity of immunomodulatory pharmaceuticals. Suppliers must propose a risk management programme to consider as part of the proposal.

- Any brand change would require clear communications to people receiving lenalidomide and healthcare professionals. This must include clarity on
 - when the brand change would take place, and
 - that the new brand is equivalent to the old brand.
- Clear communications on any change to a new risk management programme are vital. Anyone receiving lenalidomide would need to be reconsented onto the new risk management programme. This may be time intensive for clinicians, pharmacists, and people taking lenalidomide.
- Even if there were a brand change, it is likely that the innovator lenalidomide risk management programme would have to be retained, because some people may need to change back to the innovator lenalidomide.
- If people needed to return to the innovator brand, Pharmac's Exceptional Circumstances Framework would be an appropriate system to manage this.
- Keeping the strengths and pack sizes of the currently funded brand would be very beneficial, if there was a brand change.
- People with multiple myeloma could get substantial benefits from an oral regimen in the first line setting, including Māori and Pacific peoples.

Pomalidomide

- Assessment and implementation considerations for pomalidomide would be similar to lenalidomide, including the implementation of a new risk management programme.
- It would be beneficial to fund all strengths as a result of this RFP. However Australia only funds the 3 mg and 4 mg strengths. Clinicians considered this to be the minimum requirement.

Reasons for running the RFP

Pharmac is aware of multiple lenalidomide and pomalidomide products (including the original brands and generics) currently approved by Medsafe or available overseas. In light of this competition, the purpose of this RFP is to:

- reduce the total expenditure in the lenalidomide market
- secure ongoing supply of funded lenalidomide
- determine if widened access for lenalidomide for the relevant indications, would be possible from within the available budget based on the bids received
- determine if funding of pomalidomide for the relevant indications, would be possible from within the available budget based on the bids received.

Any proposals progressed for consideration for funding would be assessed using Pharmac's decision-making framework as outlined in its [OPPs](#) with reference to the [Factors for Consideration](#) and in line with [Te Pātaka Whaioranga Te Tiriti policy](#).

Intended outcome of the RFP

Principal Supply Status

Through this RFP, Pharmac intends to award the successful supplier(s) Principal Supply Status (PSS) for:

- (a) lenalidomide (current access, or current plus widened access depending on available budget)
- (b) pomalidomide (depending on available budget).

The awarding of PSS means that the successful supplier's brand would be the principal funded brand of lenalidomide or pomalidomide in New Zealand. The supplier would be guaranteed at least 95% of the funded lenalidomide market and/or 95% of the funded pomalidomide market.

Brands of lenalidomide and pomalidomide other than the PSS brand could be funded for use in up to 5% of the funded market(s), using the alternative brand allowance outlined below. PSS includes both the community and hospital markets.

Bids for lenalidomide and pomalidomide will not be awarded by strength. Each bid is an 'aggregate' bid for all strengths proposed for each of lenalidomide and pomalidomide. See *Strengths* below for which strengths must be included in any bid. There is an option to propose additional strengths.

Pharmac may award one supplier PSS for lenalidomide and another PSS for pomalidomide, or we may award PSS to the same supplier for both medicines. See the Funding Scenarios below for details of the specific combinations of bids allowed in this RFP. Bid options are also in the response form.

The PSS period would be **3 years** with an optional PSS extension period of **1 year**. Exercising the extension period will be at Pharmac's discretion. See *Term* below for more information.

Alternative Brand Allowance

Typically, the 5% alternative brand allowance (ABA) would be for individuals with unique clinical circumstances who need an alternative brand of treatment funded. Pharmac retains its discretion as to who could access funding for an alternative brand and how funded access to it would be enabled. Funded access to an ABA brand could be by a listing on the Pharmaceutical Schedule or by Pharmac's [Exceptional Circumstances framework](#).

Transition period

For lenalidomide, PSS would start after a transition period of at least 6 months (if the successful proposal resulted in a brand change).

If funded, pomalidomide would be a new listing. PSS would start immediately from the date of listing (ie PSS would not be subject to a transition period).

Other considerations

As a result of this RFP, if awarded PSS, Pharmac would retain the right at its sole discretion to widen funded access to either lenalidomide or pomalidomide at any time during the PSS period.

Any proposal to widen access or list pomalidomide that results from this RFP would be progressed subject to ranking on Pharmac's options for investment list. We would determine its priority for funding relative to other funding proposals.

Eligibility Criteria

Please note that the eligibility criteria below are in line with those currently in place or recommended to Pharmac by the Cancer Treatments Advisory Committee(CTAC). The criteria are intended to be indicative and may change following consideration of consultation feedback or further advice from CTAC and/or PTAC. Pharmac reserves the right to change the criteria as part of this RFP process.

Lenalidomide [current access](#)

Initial application – (Maintenance following first line autologous SCT) only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1. Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and
2. Patient has at least a stable disease response in the first 100 days after transplantation; and
3. Lenalidomide maintenance is to be commenced within 6 months of transplantation; and
4. Lenalidomide to be administered at a maximum dose of 15 mg/day.

Renewal — (Maintenance following first line autologous SCT) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. No evidence of disease progression; and
2. The treatment remains appropriate and patient is benefitting from treatment.

Initial application – (Relapsed/refractory disease) only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1. Patient has relapsed or refractory multiple myeloma with progressive disease; and
2. Patient has not previously been treated with lenalidomide; and
3. Either
 - 3.1. Lenalidomide to be used as third line* treatment for multiple myeloma; or;
 - 3.2. Both:
 - 3.2.1. Lenalidomide to be used as second line treatment for multiple myeloma; and
 - 3.2.2. The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
4. Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Renewal — (Relapsed/refractory disease) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. No evidence of disease progression; and
2. The treatment remains appropriate and patient is benefitting from treatment.

Lenalidomide widened access

Initial application – (Multiple myeloma) from any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting all of the following criteria:

1. Patient has multiple myeloma requiring treatment; and
2. Patient has not received prior funded lenalidomide.

Renewal application – (Multiple myeloma) from any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

1. No evidence of disease progression.

Pomalidomide

Initial application – (relapsed/refractory multiple myeloma) from any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting all of the following criteria:

All of the following:

1. Patient has relapsed or refractory multiple myeloma with progressive disease; and
2. Patient has not received prior funded pomalidomide.

Renewal - (relapsed/refractory multiple myeloma) from any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

1. No evidence of disease progression.

3. Types of proposals sought

Funding Scenarios

Pharmac would consider the following funding scenarios as potential outcomes of the RFP.

Scenario A: Funding of lenalidomide for current access [criteria](#)

Scenario B: Funding of lenalidomide for widened access (to include use in previously untreated multiple myeloma subject to criteria as indicated above)

Scenario C: Funding of lenalidomide for current access criteria AND funding of pomalidomide for relapsed/refractory multiple myeloma (subject to criteria as indicated above)

Scenario D: Funding of lenalidomide for current access AND widened access AND funding of pomalidomide in for relapsed/refractory multiple myeloma (subject to criteria as indicated above)

Pharmac is willing to consider the following types of proposals:

Bid Options

The table below outlines the permitted bid options. You may submit more than one bid for each bid option in the response form.

Please note the mandatory requirements in the table. When bidding for widened access to lenalidomide, you must provide bid(s) for current access criteria.

When bidding for both lenalidomide and pomalidomide, you must provide bid(s) for the pharmaceuticals individually.

Table 1: Summary of bid options

Bid option	Lenalidomide current access	Lenalidomide widened access	Pomalidomide
1	✓		
2 ^a		✓	
3			✓
4 ^b	✓		✓
5 ^c		✓	✓
✓ indications that would be funded under a given bid option. a. Any bid for bid option 2 must include an individual bid for bid option 1 b. Any bid for bid option 4 must include an individual bid for bid options 1 and 3 c. Any bid for bid option 5 must include an individual bid for bid options 1, 2 and 3			

Pharmac reserves the right to contract for any of the above bid options.

Pricing and Proposal Structure

- (a) Suppliers **MUST** submit a proposal for lenalidomide and/or pomalidomide in accordance with the bid options in the section above, and subject to the eligibility criteria described above.
- (b) Proposals for lenalidomide and/or pomalidomide **MAY** include the following arrangements (that may be confidential):
 - (i) flat or linear % rebates on the per unit (mg) gross price of the pharmaceutical.
- (c) Suppliers **MAY** submit multiple bids for any bid option.

Proposal Validity Period

- (d) All proposals **MUST** remain valid for 12 months from the submission deadline. Respondents must honour the terms and conditions stated in their proposals. Changes to pricing, terms or conditions post-submission may result in disqualification. Pharmac may seek clarifications or engage in limited negotiations during the validity period.

Pack Sizes

- (e) Suppliers wishing to submit proposals for **lenalidomide MUST** submit proposals with a pack size of 21 capsules per pack. Proposals **MAY** include other additional pack sizes (for example 14 or 28 capsules per pack)
- (f) Suppliers wishing to submit proposals for **pomalidomide MUST** submit proposals with a pack sizes of 14 and 21 capsules per pack. Proposals **MAY** include other additional pack sizes (for example 28 capsules per pack)

Strengths

- (g) Suppliers wishing to submit proposals for **lenalidomide MUST** submit proposals that include the currently funded strengths of 5 mg, 10 mg, 15 mg and 25 mg. Other strengths in a range of from 2.5 mg to 25 mg, **MAY** be included in addition to the mandatory strengths.
- (h) Suppliers wishing to submit proposals for **pomalidomide MUST** submit proposals for strengths of 3 mg and 4 mg. Other strengths such as 1 mg or 2 mg **MAY** be included in addition to mandatory strengths.
- (i) The listing of any additional strengths to those mandated will be at Pharmac's discretion.

Lead Time

- (j) For each line item proposed, proposals **MUST** include a lead time, defined as the time in months or weeks from:
 - (i) Notification from Pharmac that the proposal has been accepted without any further consultation or decisions pending to;

- (ii) Pharmaceutical being made available in the New Zealand supply chain

Term

- (k) Proposals **MUST** include a PSS period for each pharmaceutical included in the proposal, with an alternative brand allowance of 5%. The PSS period will be approximately 3 years following the end of any transition period with an optional 12-month extension provided that the PSS period, inclusive of any extension, does not extend beyond 30 June 2029. The PSS period is exclusive of any transition period.
- (l) All proposals that would require a change of brand for lenalidomide **MUST** include a transition period of at least **six** months between listing the new brand and commencement of any PSS period, noting that this period may be subject to negotiation following evaluation of proposals.
- (m) Proposals **MAY** include lenalidomide and/or pomalidomide brands 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 Medsafe approval)). In such circumstances:
 - (i) Suppliers may be required to demonstrate their ability to obtain those Consents within a time frame acceptable to Pharmac.
 - (ii) Pharmac would not list the proposed brand in the Pharmaceutical Schedule until all Consents are obtained.

Risk Management Programmes

Suppliers **MUST** include information regarding the additional support that would be provided in terms of risk management of teratogenicity of the immunomodulatory medicines (both lenalidomide and pomalidomide).

- (n) Specific information about the risk management programme and the implementation/accessibility within community pharmacies is required, including compatibility and consistency with any existing risk management programmes, where necessary. The usability of the risk management programme would be considered by Pharmac during evaluation.
- (o) Proposals **MUST** include information about how any data retained within a risk management programme is managed, including who is able to access the data, what this data is used for, how patient consent would be sought, where this data is stored, what the retention period of the data is and any relevant data security protocols.

Transition and ongoing support

- (p) Suppliers **MUST** include information outlining the support that would be provided to implement the proposal, particularly any initiatives that would contribute to equitable access and outcomes for Māori, Pacific peoples, tāngata whaikaha (disabled people) and other populations experiencing health inequities.
 - (i) Proposals that would result in a change to the listed brand of lenalidomide **MUST** provide information regarding the support that would be provided by

the supplier to support the change.

- (ii) Proposals that would result in widened access for lenalidomide or listing of pomalidomide **MUST** include information regarding the education and support that would be provided to support successful introduction and equitable uptake of these medicines.

Pharmac is **NOT** willing to consider the following types of proposals (out of scope)

- (a) Proposals involving pharmaceuticals or related products other than lenalidomide or pomalidomide.
- (b) Proposals that include a requirement to widen access to funded lenalidomide, beyond what is defined as widened access in this RFP.
- (c) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- (d) Proposals that involve an end date for rebates.
- (e) 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.
- (f) Proposals that include a 'hard or soft cap', where a rebate exists over a certain level of expenditure or volume used.

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

Widened access

Notwithstanding the outcome of this RFP, Pharmac would retain the right at its absolute sole discretion to widen access to lenalidomide and/or pomalidomide (if funded), at any time.

Labelling, images and samples

Suppliers **MUST** provide Pharmac with detailed labelling and images of the products and packaging as part of their proposal.

Physical samples of all pharmaceuticals included should be provided, **upon request**, within a specified timeframe communicated to a supplier from Pharmac (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about the differences must be supplied).

Samples delivered to Pharmac are at the respondent's cost.

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 to Pharmac via the Government Electronic Tenders Service (GETS) no later than **2.00 p.m.** (New Zealand time) on **4 October 2023**. 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. If you do need to get in touch via email, please contact us at procurement@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). Pharmac may engage relevant external advisors at the evaluation stage, who would be required to enter into a confidentiality agreement with Pharmac prior to any review of proposals. For the avoidance of doubt, confidential pricing would not be shared with external advisors.
- (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 Te Pātaka Whaioranga Te Tiriti policy and 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) information provided by you in accordance with Schedule 4 of this RFP; including information regarding the *Risk Management Programme* which is additional to the information provided under clause 3 below;
 - (ii) any advice from PTAC, or relevant Specialist Advisory Committee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of the pharmaceuticals following the closing of this RFP;
 - (iii) previous supply performance and relevant expertise;
 - (iv) Information regarding the support that would be provided to support implementation of a proposal that would contribute to equitable access and outcomes for Māori, Pacific peoples, disabled people but also for people living in areas of high socioeconomic deprivation, those living rurally, and people who've been refugees in line with the Pae Ora Act; and
 - (v) 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) For the purpose of fiscal evaluation for this RFP, Pharmac will assess any pricing offered as commencing from no earlier than 1 May 2024. Suppliers may offer proposals that include a listing or price change prior to this date; however, any fiscal impact from this earlier listing/price change will not be included in Pharmac's primary fiscal evaluation of proposals.
 - (g) If two or more proposals were determined by Pharmac to be similar, having considered all the Factors for Consideration, Pharmac may undertake a secondary fiscal evaluation where we may consider the impact of earlier list date/price changes.
 - (h) 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;
 - (ii) any other additional information about your pharmaceutical; and
 - (iii) any other information regarding the implementation support requested and described above.

- (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. Clinical advice and prioritisation

- (a) Following evaluation of proposals Pharmac may seek clinical advice from PTAC, a Specialist Advisory Committee or other advisors if required.
- (b) Pharmac may rank preferred proposal(s) on our Options for Investment list if required. If proposal(s) that include widening access to lenalidomide or listing pomalidomide do not rank high enough to be progressed from within the budget available, Pharmac reserves the right not to accept these proposals.

5. 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 are applied. These terms and conditions are available as an attachment to this RFP on GETS.
- (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 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).

6. 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](#) and in line with Te Pātaka Whaioranga Te Tiriti policy.

- (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.

7. Miscellaneous

- (a) Pharmac reserves the right, having regard to probity principles:
 - (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 a relevant Specialist Advisory 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 your proposal(s), until such time as a provisional agreement is accepted by Pharmac's Board or the Board's delegate.

- (d) You must not initiate or engage in any communication with Pharmac, Manatū Hauora (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), Te Whatu Ora, Te Aka Whai Ora, Whaikaha, Te Aho o Te Kahu or any of their officers or directors, or advisors to Pharmac with a view to influencing the outcome of this RFP process. Failure to comply with this clause will entitle Pharmac, in its sole discretion, to disqualify you from 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 lenalidomide and/or pomalidomide 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, external advisors, Manatū Hauora, Te Whatu Ora, Whaikaha and Te Aka Whai Ora (**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.

8. Anticipated timetable

- (a) Following receipt of proposals, Pharmac anticipates:
 - (i) the Evaluation Committee evaluating proposals in October or November 2023
 - (ii) negotiating with submitter(s) of one or more preferred proposals in November or December 2023;
 - (iii) consulting on a provisional agreement in December 2023 or January 2024;
 - (iv) Pharmac's Board, or the Board's delegate, considering this provisional agreement in or after March 2024,

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 May 2024.
- (c) Please note the date of implementation may be delayed at Pharmac's discretion to allow for an orderly transition to any principal supply arrangement.

9. 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: Current listing and market information

The following information relates to the estimated subsidised market size of the pharmaceuticals in scope of this procurement.

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 the pharmaceuticals 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 changes to our estimates of the market size.

All figures below include both community and hospital dispensing's.

Current Listings

Table 2: Dispensed lenalidomide units (capsules) by strength

Row Labels	F2019/20	F2020/21	F2021/22	F2022/23*
Lenalidomide Cap 5 mg	455	6,411	12,507	18,794
Lenalidomide Cap 10 mg	37,612	65,161	84,720	96,029
Lenalidomide Cap 15 mg	17,983	31,530	35,618	37,715
Lenalidomide Cap 25 mg	25,648	23,990	24,754	23,380

*Forecasted units

Estimated uptake for other funding scenarios:

Based on advice from our clinical experts, New Zealand data sources, a number of commercial assumptions and modelling, we consider that the total number of people who may access treatment under each of the scenarios below each year in Aotearoa New Zealand could be as shown in the table below. We have also included indicative units (all scenarios) and patients (wider access/new listing).

Table 3: Estimated units (all scenarios) and Patient uptake (wider access/new listing) for the potential funding scenarios⁵:

Scenario		Year 1	Year 2	Year 3	Year 4	Year 5
Scenario A: Lenalidomide (current access criteria)	Units ⁶	193,000	209,000	220,000	226,000	230,000
Scenario B: Lenalidomide (widened access)	Lenalidomide Patients ⁷	437	442	448	454	459
	Units	276,000	368,000	418,000	421,000	422,000
Scenario C: Lenalidomide (current access criteria) AND pomalidomide (relapsed/refractory multiple myeloma)	Lenalidomide Units	193,000	209,000	220,000	226,000	230,000
	Pomalidomide Patients ⁸	422	329	299	298	283
	Pomalidomide Units	65,000	82,000	105,000	126,000	123,000
Scenario D: Lenalidomide (widened access) AND pomalidomide (relapsed/refractory multiple myeloma)	Lenalidomide Patients ³	437	442	448	454	459
	Lenalidomide Units	276,000	368,000	418,000	421,000	422,000
	Pomalidomide Patients ⁴	430	337	307	306	291
	Pomalidomide Units	76,000	95,000	120,000	135,000	132,000

⁵ Note this table is indicative of patient numbers for the first 5 full years from the funding date. Note anticipated patient numbers for lenalidomide current access have not been included.

⁶ Note that multiple strengths would make up the estimated total units.

⁷ Note that all estimates relating to patient uptake and units for widened access to lenalidomide do not include the patient numbers for current access and reflect only new patients starting treatment.

⁸ Note that all estimates relating to patient uptake and units for pomalidomide reflect new patients starting treatment and are impacted by access to lenalidomide.

Schedule 4: Proposal form

An editable version of this form is available on the GETS listing for this RFP

<Respondent to Insert Date>

Director, Pharmaceuticals
C/- Sam Bright, Procurement
Te Pātaka Whaioranga | Pharmac

[By electronic transfer using GETS \(https://www.gets.govt.nz\)](https://www.gets.govt.nz)

Tēnā koe

Proposal for the supply of Lenalidomide and/or Pomalidomide

In response to your Request for Proposals (RFP) dated 24 August 2023, we put forward the following proposal in respect of **lenalidomide and/or pomalidomide**

You may expand the boxes below to suit the content of your response, please remove any guidance in *[square brackets]*.

1. Our Company Details	
Trading name:	<i>[insert the name that you do business under]</i>
Full legal name (if different):	<i>[if applicable]</i>
Physical address:	<i>[if more than one office – put the address of your head office]</i>
Business website:	<i>[URL address]</i>
Type of entity (legal status):	<i>[sole trader / partnership / limited liability company / other please specify]</i>
Registration number:	<i>[if your organisation has a registration number insert it here e.g. NZBN number]</i>
Does your organisation identify as being a Māori business?	<i>[Yes / No]</i>
Pharmac is committed to the Government's progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori	<i>As part of adopting a progressive procurement policy, Pharmac are committed to understand and support what roles Māori businesses play in our supply chain</i>

<p>businesses.</p> <p>As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through this procurement. One aspect is understanding what roles Māori businesses have in the pharmaceutical supply chain and how we can support Māori businesses in those roles.</p> <p>Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business.</p> <p>A Māori business for Government procurement reporting purposes is:</p> <ul style="list-style-type: none"> • one that has at least 50% Māori ownership, or • a Māori Authority as defined by Inland Revenue. <p>Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac’s supplier’s database and will be reported to New Zealand Government Procurement (NZGP), subject to any concerns you identify (see below).</p>	
<p>Pharmac is required to report to NZGP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements.</p> <p>Please indicate either ‘Yes’ or ‘No’ as to whether you agree to Pharmac reporting on your organisation’s status. If you indicate ‘No’, please provide reasons for our consideration.</p>	<p>[Yes / No]</p>

2. Our Points of Contact	
Contact person:	<i>[i.e., who communications relating to the response(s) should be made to]</i>
Position:	
Phone number:	
Mobile number:	
Email address:	
Secondary contact person:	
Position:	
Phone number:	
Email address	

3. Information About Our Organisation	
(a) Information about our Organisation structure:	<i>[you may embed organisational charts or similar]</i>
(b) Information about our management and technical skills:	
(c) Information about our financial resources:	
(d) Information about our, or our supplier's, previous supply performance, and ability to ensure continuity of supply of the proposed product(s)	
(e) Information about our quality assurance processes:	
(f) 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, please outline: <ul style="list-style-type: none"> • how your Organisation meets or exceeds the expectations set out in the Supplier Code of Conduct 	
(g) Please outline how your Organisation support social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). Please also outline how your organisation: <ul style="list-style-type: none"> • Supports New Zealand businesses, including Māori, Pacific, and regional businesses, as well as social enterprises (if relevant) • Supports improving conditions for New Zealand workers and support workforce diversity 	

4. Details of pharmaceutical presentation (duplicate this table for more than one pharmaceutical)	
(a) Chemical name	
(b) Brand name	
(c) Strength(s)	<i>[e.g. capsule, tablet]</i>
(d) Form	<i>[e.g. mg]</i>

(e) Pack size	<i>[see page 11 of RFP for requirements around multiple pack sizes]</i>
(f) Packaging type	
(g) Shelf life and storage	<i>[include months from date of manufacture and temperature to be stored at]</i>
(h) Labelling and images	<p><i>[please embed file(s) into your response form or upload to GETS as clearly named file(s) separate to the response form(s)]</i></p> <p><i>Minimum specification requirements for images:</i></p> <ul style="list-style-type: none"> • <i>On a plain background (preferably white)</i> • <i>Minimal shadows and good lighting</i> • <i>Ideally images should include, pack exterior, sheet of units or similar, close up of unit</i> • <i>Separate images for different strengths or pack sizes</i> • <i>The product should take up 80% of the photo</i>

5. Details of pharmaceutical manufacture (duplicate this table for more than one pharmaceutical)

(a) Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
(b) Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body	<i>[e.g. TGA, FDA, MHRA]</i>
(c) Batch size/s	
(d) Lead time (time from final notification of award to product being available to supply the New Zealand market)	
(e) Approximate manufacture time	
(f) Approximate time for shipping	

6. Evidence of market approval and any other required consents (duplicate this table for more than one pharmaceutical)

(a) Evidence for market approval and any other required consents, include date of market approval	<i>[please attach copy of Medsafe Gazette notice, either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i>
(b) For any proposed products without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:	<i>[N/A if product is approved by Medsafe]</i>

<p>(c) For any proposed products without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:</p>	<p><i>[N/A if product is approved by Medsafe]</i></p>
<p>(d) Insert the details of any other consents required for the proposed products and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:</p>	<p><i>[N/A if product is approved by Medsafe]</i></p>
<p>(e) Please confirm that you will supply physical sample of the proposed products, to be provided within 12 business days of Pharmac's request.</p>	<p><i>[whether or not Pharmac requires a sample will be determined upon initial evaluation of your proposal, please wait to hear from us]</i></p>

7. Risk management programme	
<p>(a) Risk management programme – link to application/programme</p> <p>(i) Please include a link to, and any instructions for accessing, your programme that Pharmac would be able to register for and access in a “test” environment, allowing for multiple logins representing a prescriber, dispenser and patient.</p> <p>(b) You may embed instruction documents or similar, or upload to GETS as a clearly named appendix to your response.</p>	
<p>(c) Risk management programme – data management and privacy</p> <p>(i) Please outline how any data held by the risk management programme will be used and stored. Include details on who has access to this data, who can request access and where the system and data is held (server location)</p> <p>(d) Please include details of any privacy impact assessments you have conducted regarding the security of user data.</p>	
<p>(e) Risk management programme – support and promotion</p> <p>(i) support successful introduction of this system into New Zealand pharmacies and hospitals. Please detail what technical support is offered in terms of troubleshooting access, any training and education initiatives that may be tailored to prescriber, dispenser and patient.</p>	

<p>(ii) Please detail the compatibility of your risk management programme with the existing programme as this would contribute to the implementation of this within the New Zealand health system.</p> <p>(iii) If you have launched your risk management programme in other markets please detail any learnings from this experience</p>	
---	--

8. Context surrounding proposed products and capability to support the product(s).	
(a) Key features of our proposal	
(b) 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:	
(c) Information about our ability to ensure the continuity of supply of the pharmaceutical(s), including other countries where the product is widely in use; any additional information about our, or our suppliers existing supply commitments.	
(d) Information relating to the education and support plan (if applicable) for the introduction of your product(s) with regards to Te Whatu Ora Hospitals, healthcare professionals, individuals and their whānau transitioning to the proposed product(s). And relevant information regarding the launch of your pharmaceutical in other jurisdictions.	<i>[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i>
(e) Information relating to training and education materials that would be provided to Te Whatu Ora Hospitals, healthcare professionals, individuals and their whānau and caregivers using the proposed products. Consider ability to make patient materials available in multiple languages.	<i>[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i>
(f) Include information about the location, experience and qualifications of any staff that would be involved in supporting the proposed products (including those providing training and education).	
(g) Please outline how your Organisation would support improving access and responsible use of these medicines (eg services and resources that would be offered).	

<p>(i) How would you support implementation of your proposal to ensure that access to treatment is equitable and contributes to equitable outcomes, specifically for Māori, Pacific and disabled peoples (but also for communities who have been underserved by the health system, including those living rurally or people who've been refugees).</p>	
<p>(iv) Pharmac is committed to embedding Te Tiriti o Waitangi within our work, achieving health equity as a starting point, and supporting communities to promote and improve wellbeing.</p> <p>We are therefore interested in learning about your organisation's:</p> <ul style="list-style-type: none"> (i) views on the barriers to achieving equitable outcomes for Māori and our other priority populations and what you consider your organisation's role within the wider health sector in overcoming these barriers (ii) current resourcing, capabilities, infrastructure and/or initiatives to support Māori, Pacific peoples, disabled people and other groups experiencing health inequities to achieve pae ora. (iii) current relationships with stakeholders and communities to help support the above (iv) future initiatives to support Māori, Pacific people, disabled people and other groups experiencing health inequities achieve pae ora 	
<p>(h) Any other reasons why Pharmac should accept our proposal</p>	
<p>(i) Any additional information Pharmac should consider under its Factors for Consideration Framework:</p>	

9. Labour and human rights	
<p>(a) Visibility over our supply chain</p> <p>Please select one of the below options and explain why you have selected this option:</p> <p>High: we have mapped the full supply chain for key products and services used by our organisation and have identified key suppliers at all levels of your supply chain.</p>	

<p>Moderate: we have identified major suppliers and have partially or fully mapped the supply chains for key products and services of our supply chain.</p> <p>Developing: we have identified major suppliers. We have very limited or no visibility of our supply chains for key products and services of our supply chain.</p> <p>Other: summary of the current status of our supply chain visibility</p>				
(b) Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation	Yes		No	
(c) Our organisation has systems to monitor compliance with these policies	Yes		No	
(d) If you said yes to either of the two above statements, please attach or link to the supporting information. If the answer is no, please provide information on what your organisation is doing, or plans to do, to manage modern slavery and worker exploitation risk.				
(e) Our organisation performs due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains	Yes		No	
(f) If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns. If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future?				
(g) Our organisation complies with recognised standards	Yes		No	
(h) If yes, please identify the standard and outline the degree to which your organisation complies.				

10. Environmental Sustainability				
(i) Does your organisation have an environmental/sustainability policy?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>

(j) Does your organisation have a sustainability report?				
(k) If yes to either of the two above questions, please attach or link:				
(l) How does your organisation contribute to environmental sustainability?	<i>[Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP]</i>			
(m) Has your organisation received any environmental/sustainability award(s)?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(n) If yes, provide details:				
(o) Has your organisation received any environmental fine/prosecution(s)?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(p) If yes, provide details:				
(q) Has your organisation received any environmental audit(s), or does it comply with a recognised standard?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(r) If yes, provide details:				

11. Pricing and Terms of Supply

- As outlined in the RFP, you are required to submit pricing for the bid options that make up a proposal.
- All prices must be in New Zealand dollars and exclusive of GST.
- Each row is for one strength and pack size of a pharmaceutical, add more rows and bid options as required, see page 11 for mandatory strengths and pack sizes.
- The pricing is per pack, in line with what could be listed on the Pharmaceutical Schedule, but any rebate would apply on a per unit basis, i.e. the price is divisible by the pack size to have a per unit price.
- Please refer to page 10 for information on when it is mandatory to include bid options for a smaller market, where you are bidding on a larger market, in summary:
 - if you have a bid for widened access to lenalidomide, you **MUST** provide a bid for current access.
 - If you are bidding for an award of both lenalidomide and pomalidomide you **MUST** bid on each pharmaceutical separately
- You may duplicate the tables below in order to submit more than one bid for a given bid option.
- **Lead time definition:** This is the time in months or weeks from the date of Pharmac notifying you that the response has been accepted without any further consultation or decisions pending to the date that you are able to make the product available in the NZ supply chain.

Bid Option 1: Award of lenalidomide for current access criteria

Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time
<i>[Any comments in relation to bid]</i>						

Bid Option 2: Award of lenalidomide for current and widened access (must also provide an individual bid for bid option 1)

Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time

<i>[Any comments in relation to bid]</i>						

Bid Option 3: Award of pomalidomide for relapsed/refractory multiple myeloma						
Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time
<i>[Any comments in relation to bid]</i>						

Bid Option 4: Award of lenalidomide for current access criteria AND funding of pomalidomide for relapsed/refractory multiple myeloma (must also provide individual bids for bid options 1 and 3)						
Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time
<i>[Any comments in relation to bid]</i>						

Bid Option 5: Award of lenalidomide for current access criteria AND widened access AND funding of pomalidomide for relapsed/refractory multiple myeloma (must also provide individual bids for bid option 1, 2 and 3)						
Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time

[Any comments in relation to bid]						

Having considered the *Pharmac standard terms and conditions for the supply of pharmaceuticals* and the *Pharmac Principal Supply Status template terms* are there any special terms you would like to note up front? Please refer to the Out of Scope and Negotiation sections of the RFP for areas Pharmac will not negotiate on.

--