

6 July 2022

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF IMMUNE CHECKPOINT INHIBITORS FOR THE TREATMENT OF LOCALLY ADVANCED AND METASTATIC, NON-SMALL CELL LUNG CANCER

Pharmac invites proposals for the supply of immune checkpoint inhibitors for the treatment of, locally advanced or metastatic, non-small cell lung cancer for use in Health New Zealand hospitals.

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 response 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 **4.00 p.m. NZST on 31 August 2022**.

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

Definitions

The following definitions shall be used in this RFP and shall have the meanings set out below:

“1L or First-Line” means the initial treatment following diagnosis for Advanced NSCLC;

“2L or Second-Line” means the treatment that a patient receives for Advanced NSCLC once their disease has progressed following treatment with platinum-based chemotherapy;

“1L combination therapy” means an Immune Checkpoint Inhibitor is administered alongside platinum-based chemotherapy as the initial treatment following diagnosis for Advanced NSCLC;

“1L monotherapy” means an Immune Checkpoint Inhibitor is administered on its own as the initial treatment following diagnosis for Advanced NSCLC;

“2L monotherapy” means an Immune Checkpoint Inhibitor is administered once the patient’s disease has progressed following treatment with platinum-based chemotherapy;

“Advanced NSCLC” means locally advanced or metastatic, non-small cell lung cancer;

“Health NZ” means Health New Zealand, a Crown agent established under section 11 of the Pae Ora (Healthy Futures) Act 2022;

“Health NZ Hospital” are the sites for treatment of Advanced NSCLC;

“ICI or Immune Checkpoint Inhibitor” means a monoclonal antibody that inhibits programmed cell death protein 1 (PD1) or its ligand 1 (PD-L1);

“Indication” means a clinical context of treatment and includes 1L monotherapy, 1L combination therapy or 2L monotherapy

“PCT only” means Pharmaceutical Cancer Treatment only, which when applied to a specific Community Pharmaceutical, means a Pharmaceutical where only a Health NZ Hospital Pharmacy can claim the subsidy;

“PD-1 and PD-L1” means programmed cell death-1 and programmed cell death-ligand 1, proteins found on the surface of cells, that when present on tumour cells, help those cells evade the bodies immune system; and

“PD-1 and PD-L1 testing” means a biopsy taken from a patient, tested in a laboratory with in-vitro diagnostic technology, to measure the amount of PD-1 or PD-L1 on the cancer cells.

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

1. Pharmaceutical

Pharmac invites proposals for the supply of ICIs for the treatment of, locally advanced or metastatic, non-small cell lung cancer.

Pharmac is interested in proposals for ICIs that target PD-1 or PD-L1 with evidence of benefit in patients with Advanced NSCLC. Pharmac will seek clinical advice at its sole discretion on the evidence of benefit of any proposed ICI and its unfunded combination agent (if relevant).

2. Background to RFP

Lung cancer is the fifth most commonly diagnosed malignancy in New Zealand and is the leading cause of cancer-related death. More than 2,000 cases are diagnosed each year, and more than 1,600 individuals will die from the disease annually, with the median age at diagnosis for people with lung cancer being 70 years.

Lung cancer registration and mortality rates are consistently higher for Māori when compared with non-Māori with incidence and mortality 3-4 times higher for Māori, compared with non-Māori.

Survival rates for patients with Advanced NSCLC are poor with currently funded treatments.

ICIs are monoclonal antibodies that can be used to treat Advanced NSCLC, either alone or in combination with systematic anti-cancer therapy (chemotherapy).

ICIs used to treat Advanced NSCLC are administered via intravenous infusion, usually in a Health NZ Hospital outpatient clinic setting.

See Section 3 'Scope and types of proposals sought' for specifics on what treatment scenarios are in scope of this RFP.

Currently funded Advanced NSCLC treatments and ICIs

Pharmac currently funds several medicines for certain types of Advanced NSCLC, which are listed on the [Pharmaceutical Schedule](#). Pharmac also currently funds several chemotherapeutic agents that can be used for the treatment of NSCLC.

Pharmac currently funds some [ICIs](#) for the treatment of advanced melanoma.

From 1 August 2022, Pharmac will fund [durvalumab](#) (an ICI) as maintenance treatment for Advanced NSCLC after chemoradiation treatment.

Pharmac does not fund any ICI for Advanced NSCLC, which makes this procurement process a new investment for a treatment not currently available for this patient group.

Details of currently funded medicines specifically for the treatment of NSCLC are shown below, current as at 1 July 2022.

Protein-tyrosine Kinase Inhibitors

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
ALECTINIB – RETAIL PHARMACY – SPECIALIST - Special Authority see SA1870				
Cap 150 mg	7,935.00	224	✓	Alecensa
ERLOTINIB – RETAIL PHARMACY – SPECIALIST - Special Authority see SA2115				
Tab 100 mg	764.00	30	✓	Tarceva
Tab 150 mg	1,146.00	30	✓	Tarceva
GEFITINIB – RETAIL PHARMACY – SPECIALIST - Special Authority see SA2116				
Tab 250 mg	1,700.00	30	✓	Iressa

Antimetabolites

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
PEMETREXED – PCT ONLY – SPECIALIST - Special Authority see SA1679				
Inj 100 mg vial	60.89	1	✓	Juno Pemetrexed
Inj 500 mg vial	217.77	1	✓	Juno Pemetrexed
Inj 1 mg for ECP	0.55	1	✓	Baxter
		mg		

Details of currently funded immune checkpoint inhibitors for indications other than the treatment of NSCLC are shown below, current as at 1 July 2022: ^

Immune Checkpoint Inhibitors

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
NIVOLUMAB – PCT ONLY – SPECIALIST - Special Authority see SA2120				
Inj 10 mg per ml, 4 ml vial	1,051.98	1	✓	Opdivo
Inj 10 mg per ml, 10 ml vial	2,629.96	1	✓	Opdivo
Inj 1 mg for ECP*	27.62	1 mg	✓	Baxter
PEMBROLIZUMAB – PCT ONLY – SPECIALIST - Special Authority see SA2121				
Inj 25 mg per ml, 4 ml vial	4,680	1	✓	Keytruda
Inj 1 mg for ECP*	49.14	1 mg	✓	Baxter

* Health NZ Hospitals are able to procure ICIs from third-party compounders (a Contract Manufacturer) provided that Health NZ Hospitals ensure that all of the component pharmaceuticals used in its manufacture are listed on the Pharmaceutical Schedule and comply with any national contracting obligations. The “Inj 1mg for ECP” formulation listed in the Schedule allows Health NZ Hospitals to claim a subsidy for the correct number of mg provided by the compounder. This ECP price is determined by Pharmac.

Confidential rebates apply to all sales of Opdivo and Keytruda to Health NZ Hospitals, reducing the net funded expenditure on this medicine.

^ From 1 August 2022 durvalumab (an immune checkpoint inhibitor) will be funded for people with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.

Clinical Advisory Committee Advice

Pharmac has received several funding applications for ICIs for First-Line or Second-Line treatment of Advanced NSCLC. There are currently three agents (pembrolizumab, nivolumab and atezolizumab) with positive clinical advice recommendations for use in Advanced NSCLC.

In order to provide a fair opportunity for any ICI to achieve a listing on the Pharmaceutical Schedule, it has been determined that a competitive process be issued, via this RFP.

Pharmac has previously sought advice from the Cancer Treatments Advisory Committee (CTAC or The Committee) on both individual funding applications for ICI use in Advanced NSCLC, and on the general Advanced NSCLC funding landscape. The key points, relevant to this RFP, from the most recent advice from [April 2022](#), is summarised below. The full records of the other previous discussions regarding ICIs for locally advanced or metastatic lung cancer are available on our [website](#).

- (a) The Committee noted that ICIs for the treatment of Advanced NSCLC had been reviewed on several occasions by the Committee and emphasised that these prior reviews had detailed the unmet health need for Advanced NSCLC patients, equity issues relating to stage at diagnosis and disease specific survival for Māori and Pacific patients, the results of the clinical portfolios for the ICIs, and the uncertainty regarding PD-L1 testing platforms as well as interpretation of PD-L1 testing results.
- (b) The Committee noted that Stage IV disease typically included patients with disease that had spread to another area either within the lung, or to another organ outside the lung. In contrast the Committee noted that those with unresectable locally advanced disease could be considered in two groups; those that can be considered for radical treatment (intensive course of radiotherapy) and those that are being managed palliatively. The Committee noted that patients with locally advanced disease (Stage III) would be considered for radical treatment in the first line, but part of this patient cohort includes patients who, due to comorbidities or performance status, would not be fit for radical treatment and would therefore be managed palliatively.
- (c) The Committee noted the available evidence and considered that it remains appropriate to consider that atezolizumab and pembrolizumab provide the same or similar health benefit for 1L monotherapy, such that funding of either agent in this line of therapy would be clinically appropriate. The Committee noted updated progression-free survival and overall survival available across the other ICIs. The Committee considered it reasonable to assume equivalent treatment benefit could be achieved from ICIs (pembrolizumab, nivolumab and atezolizumab) when funded as 2L monotherapy.
- (d) The Committee considered the funding and availability of ICIs internationally and considered it would be reasonable to consider funding of any ICI that has received a positive recommendation from the Committee for Advanced NSCLC in the various treatment lines based on likelihood of clinical benefit. The Committee considered that it was appropriate to assess previously assessed ICIs as having a class effect for the purpose of enabling listing and noted whilst this may apply to new ICIs, there would still need to be an assessment undertaken of the adequate strength and quality of evidence for any new ICI or ICI without a positive funding recommendation.

- (e) The Committee considered that it would be clinically acceptable to have different ICIs funded in different lines of therapy for Advanced NSCLC e.g., 1L monotherapy, 1L combination therapy, and 2L monotherapy.
- (f) The Committee considered that the choice of ICI funded in each line was unlikely to change the proportion of which patients access monotherapy versus combination therapy and noted that this would be driven by performance status, prior treatments and PD-L1 testing. The Committee considered that having different agents available in different lines or combinations could easily be managed by clinicians.
- (g) The Committee noted that there are differences between Stage IV and locally advanced (Stage III) NSCLC that would impact which patients are considered for treatment with ICI's. The Committee noted that Stage IV disease typically included patients with disease that had spread to another area either within the lung, or to another organ outside the lung. In contrast the Committee noted that those with unresectable locally advanced disease could be considered in two groups; those that can be considered for radical treatment (an intensive course of radiotherapy) and those that are being managed palliatively. The Committee noted that patients with locally advanced disease (Stage III) would be considered for radical treatment in the first line, but part of this patient cohort includes patients who, due to comorbidities or performance status, would not be fit for radical treatment and would therefore be managed palliatively.
- (h) The Committee noted that assessment of patient numbers is dependent on the scenario of funding (i.e. lines of treatment funded, with testing considerations) but considered it reasonable to assume that if a 1L monotherapy were listed for Advanced NSCLC, (as well as providing access to patients needing second-line treatment), all new eligible patients would receive an ICI in the first line setting and the second-line market would be restricted to prevalent patients only, with this patient population diminishing over a relatively short period of time (within the first year of listing).
- (i) The Committee considered that access to PD-L1 testing ensures selection of the patient group for 1L monotherapy and would be important to enable avoidance of the morbidity of chemotherapy (in combination with immunotherapy). The Committee considered testing should be mandated in this line of therapy in order to access 1L monotherapy. The Committee considered access without confirmation of PD-L1 expression in this patient population may result in a proportion of patients receiving futile therapy with significant cost to the sector noting the patient group most likely to receive monotherapy are those who are unable to receive combination therapy with chemotherapy.
- (j) The Committee considered there is high variability in access to PD-L1 testing, which is partly impacted by the fiscal arrangement within DHB's and how this interacts with national laboratory programmes.
- (k) The Committee considered that in any scenario, there are likely to be patients where the amount of tissue obtained from biopsy is insufficient to enable testing, or cannot be undertaken, and considered that a route to ICI therapy should be considered for these patients to avoid the need of multiple biopsies. The Committee considered access to ICI's in 1L combination therapy and 2L monotherapy without PD-L1 testing would reasonably accommodate for this and reduce the impact on lab testing for PD-L1 testing upon listing of any ICI, giving time to develop the systems required to support reflex PD-L1 testing within New Zealand.

- (l) The Committee considered that funding of ICIs would have a significant impact on infusion service capacity and that the funding of an ICI would require an “all of sector,” multi-agency response.

Reasons for running the RFP

Pharmac considers that substantial health benefit could be gained through the funding of ICIs for the treatment of Advanced NSCLC. In addition to the funding applications received, Pharmac is aware of multiple ICIs for Advanced NSCLC currently approved by Medsafe or available overseas. In light of this competition, the purpose of this RFP is to:

- (a) Address a significant unmet health need, which particularly affects Māori and Pacific populations;
- (b) Determine whether funding of ICIs for Advanced NSCLC is possible from the available budget for the funding scenarios stated below.

Intended outcome of the RFP

The anticipated outcome is a scenario where one or more of the ICIs, which have a positive recommendation from our clinical advice Committees¹ would have principal supply status for a period of **3 years** from the date of listing on the Pharmaceutical Schedule. Please note any listing of the Pharmaceutical Schedule would be subject to Medsafe market approval being granted prior to listing.

Principal supply status would be applied at the indication level (1L monotherapy, 1L combination therapy or 2L monotherapy) rather than the chemical level, this means that ICIs currently listed on the Pharmaceutical Schedule for other indications would be excluded from the scope of principal supply status as a result of this RFP.

The award of Principal Supply status means that the successful supplier's ICI, would have principal supply status at an indication level and would be the principal funded brand, for that indication, available in Health NZ Hospitals and would be guaranteed at least 95% of the funded market included within the scope of that indication.

This means that other brands of ICIs other than the principal supply status brand could be listed in the Pharmaceutical Schedule for use in up to 5% of the funded market included within the scope of the indication(s) awarded as a result of this RFP.

Please note a number of suppliers could be awarded principal supply status as a result of this RFP.

As a result of this RFP, Pharmac would retain the right at its sole discretion to widen funded access to ICIs at any time during the principal supply status period.

Any recommended proposal as a result of this RFP will be subject to ranking on Pharmac's options for investment list to determine its priority in comparison to other investments.

Depending on the responses received as a result of this RFP, Pharmac reserves the right to:

¹ See section 3 (e) in 'Scope and types of proposals sought' for actions to take if proposed product does not currently have a positive funding recommendation

- (a) Not to progress any proposals submitted in response to the RFP; or
- (b) To evaluate proposals submitted in accordance with the terms of this RFP.

Funding Scenarios

Pharmac would consider proposals for use of ICI for treatment of Advanced NSCLC as per the below scenarios:

Scenario A

- As 1L monotherapy (for patients where the disease expresses PD-L1 at a level $\geq 50\%$ as determined by a validated test);
- 1L combination therapy with platinum chemotherapy irrespective of PD-L1 status; and
- 2L monotherapy irrespective of PD-L1 status.

Scenario B

- Only 2L monotherapy irrespective of PD-L1 status.

Table 1: Summary of funding scenarios that Pharmac anticipates could result from this RFP and the relevant bid options are as follows:

	Bid options	1L monotherapy	1L combination therapy	2L monotherapy
Scenario A	1 ^{a,b}	✓	✓	✓
	2 ^{a,c}	✓		✓
	3 ^{a,d}		✓	✓
	4 ^a			✓
	5 ^e	✓	✓	
	6	✓		
	7			✓
Scenario B	8			✓
All	Any bid that includes offsets from currently funded pharmaceuticals would require a separate bid for the investment component on its own.			
^a Any bid that includes options 1-4 must include a separate bid for option 8 (scenario B) ^b Any bid that includes option 1 must include bids for options 4,6,7 and 8 ^c Any bid that includes option 2 must include bids for options 4,6 and 8 ^d Any bid that includes option 3 must include bids for options 4,7 and 8 ^e Any bid that includes option 5 must include bids for options 6 and 7 ✓ indications that could be funded under the given scenario.				

Eligibility Criteria

Please note that the eligibility criteria above are in line with those currently recommended to Pharmac by CTAC. The criteria are intended to be indicative and may be amended following consideration of any consultation feedback or further advice from CTAC and/or PTAC. Pharmac reserves the right to amend the criteria as part of this RFP process.

Initial application - (NSCLC first-line) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2. The patient has not had chemotherapy for their disease in the palliative setting; and
3. Patient has not received prior treatment with an immune checkpoint inhibitor for NSCLC; and
4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase; and
5. Either
 - 5.1. [chemical] to be used in combination with platinum-based chemotherapy; or
 - 5.2. Both
 - 5.2.1. [chemical] to be used as monotherapy; and
 - 5.2.2. There is documentation confirming the disease expresses PD-L1 at a level $\geq 50\%$ as determined by a validated test; and
6. Patient has an ECOG 0-1; and
7. [chemical] to be used at a maximum dose of [dose] for a maximum of 12 weeks; and
8. Baseline measurement of overall tumour burden is documented as per RECIST criteria.

Initial application- (NSCLC second-line) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1. Patient has locally advanced or metastatic non-small cell lung cancer; and
2. Patient has not had prior treatment with immune checkpoint inhibitors for NSCLC; and
3. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase; and
4. Patient has an ECOG 0-1; and
5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
6. [chemical] is to be used as monotherapy at a dose of [dose] for a maximum of 12 weeks; and
7. Baseline measurement of overall tumour burden is documented as per RECIST criteria.

Renewal – (NSCLC first or second-line) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following

1. Any of the following:
 - 1.1. Patient's disease has had a complete response to treatment according to RECIST criteria; or
 - 1.2. Patient's disease has had a partial response to treatment according to RECIST criteria; or
 - 1.3. Patient has stable disease according to RECIST criteria; and
2. Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
3. No evidence of disease progression according to RECIST criteria; and
4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. [chemical] to be used at a maximum dose of [dose] (or equivalent); and
6. [chemical] to be discontinued at signs of disease progression; and
7. Treatment with [chemical] to cease after a total duration of 24 months from commencement.

3. Scope and types of proposals sought

Pharmac is willing to consider the following types of proposals:

- (a) Suppliers **MUST** submit a proposal for an ICI in accordance with the bid options in Table 1 above, and subject to the eligibility criteria described above.
- (b) Proposals **MUST** include ICIs for the treatment of Advanced NSCLC for either Scenario A or Scenario B; or both. If a proposal includes more than one indication (Scenario A options 1, 2, 3 and 5)), pricing must be submitted separately for each indication as indicated in Table 1 above.
- (c) Where a proposal is received that includes pricing and supply terms for Scenario A that includes 2L monotherapy, pricing and supply terms **MUST** also be submitted for Scenario B.
- (d) Proposals **MUST** include pricing and supply terms for any other non-ICI agents (not already listed under contract with Pharmac) that are required for use in combination ICI regimens for Advanced NSCLC.
- (e) Where a Supplier is submitting a proposal that includes cost savings on other currently funded agents and/or indications, a separate proposal **MUST** be submitted for the relevant indication(s) that does not include cost savings on other currently funded agents and/or ICI indications.
- (f) Where the ICI is not approved for use in an indication (or treatment line), Proposals **MUST** be able to obtain Ministry of Health market approval and any other relevant Consents in a timeframe acceptable to Pharmac. For clarity, Pharmac is not seeking an additional level of Regulatory approval based on the eligibility criteria, but the treatment **MUST** be approved for the indication in which a proposal has been submitted.
- (g) Where the ICI does not yet have a positive clinical recommendation from CTAC, the proposal **MUST** provide evidence that a funding application, with an appropriate amount of detail, has been submitted via [PharmConnect](#) prior to a response being submitted to this RFP.
- (h) Proposals that include 1L monotherapy (Scenario A options 1, 2, 5 and 6) **MUST** include information on the validated testing options available for the proposed ICIs, and implementation support that would be offered to ensure successful introduction of PD-L1 testing into the New Zealand health sector. This would need to specifically be centred on the provision of support to enable access to timely and consistent results across New Zealand.
- (i) Suppliers **MAY** submit multiple proposals for the supply of ICIs.
- (j) Suppliers **MUST** include information regarding the additional support that would be provided to support implementation of a proposal that would contribute to equitable access and outcomes for Māori and Pacific populations.
- (k) Suppliers **MUST** include information regarding the additional support that would be provided to support implementation of a proposal that would contribute to equitable access and outcomes for other populations experiencing health disparities, including those with disabilities.

- (l) Suppliers **MAY** include information relevant to the Factors for Consideration that would support more equitable access to, or benefit from its ICI.
- (m) Proposals **MAY** include any of the following arrangements, provided that a supplier has also submitted a response which has a flat % rebate on the net price.
 - (i) confidential rebates or other risk-sharing arrangements; and/or
 - (ii) a 'hard' cap, where a 100% rebate exists over a certain level of expenditure; and a 'soft' cap, where change in rebate percentage exists over a certain level of expenditure, or a tiered pricing structure, where the level of rebate percentage is linked to certain levels of expenditure.
- (n) Proposals **MAY** include cost savings on other currently funded agents and/or ICI indications, so long as these are fully funded and listed on the Pharmaceutical Schedule at the date of RFP release.
- (o) Proposals **MAY** include ICIs 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:
 - (i) Suppliers may be required to demonstrate their ability to obtain those Consents within a time frame acceptable to Pharmac; and
 - (ii) Pharmac would not list the proposed brand in the Pharmaceutical Schedule until all Consents are obtained.

Pharmac is not willing to consider the following types of proposals (out of scope):

- (a) Proposals for the concurrent listing (dual supply) of two ICIs in any one treatment line (i.e. two different products could not be listed for 1L monotherapy)
- (b) Proposals that include a requirement to widen access for a funded ICI.
- (c) Proposals for supply of other unfunded pharmaceuticals or indications, **EXCEPT** those that meet the above eligibility or where the agent is part of an ICI combination regimen for the treatment of Advanced NSCLC.
- (d) Proposals that include cost-offsets on additional pharmaceutical(s) or indication(s) that are not fully funded and listed on the Pharmaceutical Schedule at the date RFP release.
- (e) Proposals that include cost-offsets on pharmaceuticals that are indicated as a future procurement opportunity on GETS by Pharmac.
- (f) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- (g) Proposals that involve an end date for rebates or an end date for indication based rebates.
- (h) 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.

Widened access

Notwithstanding this RFP, Pharmac would retain the right at its absolute sole discretion to widen access to ICIs. This is expected to include enabling further assessment of funding applications that have not been previously considered for funding or have previously received a recommendation from PTAC (or similar Advisory Committee) to decline for funding.

Samples

Suppliers **SHOULD** provide Pharmac with detailed labelling and images of the products as part of their proposal. Physical samples of all ICI presentations included should be provided, upon request, within the 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).

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 **4.00 p.m.** (New Zealand time) on **31 August 2022**. Late proposals will only be considered at Pharmac's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.
- (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (d) If you have any enquiries about this RFP, you should 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 Sam Bright 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).
- (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) information provided by you in accordance with Schedule 4 of this RFP; including information provided under clause 3 below;
 - (ii) any updated or new advice from PTAC, or relevant Advisory Committee regarding the appropriateness of inclusion of the relevant ICI for the relevant indication;
 - (iii) any advice from PTAC, or relevant Advisory Committee, any relevant professional organisation or healthcare professionals. This may include

specific clinical advice regarding relative risks and benefits of ICIs following the closing of this RFP;

- (iv) previous supply performance and relevant expertise;
 - (v) information regarding the support that would be provided to, where relevant ensure successful introduction of PD-L1 testing into the New Zealand health sector;
 - (vi) 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, populations experiencing health disparities and populations with disabilities;
 - (vii) information regarding any aspects of the ICI and the support provided that would contribute to equitable access and/or outcomes; and
 - (viii) 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 would assess any pricing offered as commencing from 1 April 2023. 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 would not be included in Pharmac's primary fiscal evaluation of proposals. 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.
- (g) 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;
 - (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, Specialist Advisory Committee or other party if required.
- (b) Pharmac may rank preferred proposal(s) on our Options for Investment list if required. If proposal(s) are not fundable within the budget available, Pharmac reserves the right not to accept any proposals and terminate the RFP process.

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, which are available as an attachment to this RFP on GETS and the Pharmac website.
- (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](#).
- (d) If the Board or its delegate does not approve a provisional agreement, then Pharmac may initiate negotiations for a provisional agreement with any other relevant 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 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), Health NZ, the Minister of Health (or any Associate Ministers) 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 an ICI 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 Health NZ (**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) seeking clinical advice (if necessary) following receipt of responses in September and/or October 2022;
 - (ii) the Evaluation Committee evaluating proposals in September and/or October 2022;
 - (iii) negotiating with submitter(s) of one or more preferred proposals in November 2022 and/or December 2022;
 - (iv) consulting on a provisional agreement in December 2022 and/or January 2023;
 - (v) Pharmac's Board, or the Board's delegate, considering this provisional agreement in or after February 2023;

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 1 April 2023.
- (c) Please note that if a proposal for principal supply is accepted, the date of implementation may be later to allow for an orderly transition to any principal supply arrangement.

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: Current listing and market information

Current Listing

There are currently no ICIs currently funded in New Zealand for the treatment of Advanced NSCLC. From 1 August durvalumab will be funded for some patients with locally advanced NSCLC.

Anticipated patient uptake:

Based on advice from our clinical experts, New Zealand data sources, a number of commercial assumptions and modelling, we consider that the number of patients who may access treatment under each scenario each year in New Zealand could be as shown in the table below.

Table 2: Anticipated patient uptake for the proposed funding scenarios:

		Year 1	Year 2	Year 3	Year 4	Year 5
Scenario A:	First Line	413	523	634	628	634
	Second Line (WITH funding of 1L)	318	40	20	0	0
Scenario B:	Second Line: (WITHOUT funding of 1L)	528	340	391	380	384

Note this table is indicative of patient numbers for the first 5 full years from the funding date.

See eligibility criteria under the Funding Scenarios section of this RFP for information on Special Authority criteria. Note that any changes to the Special Authority criteria may impact on patient numbers.

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 ICIs and, while Pharmac has taken all reasonable care in preparing the information set out above, 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 the market size.

Schedule 4: Proposal form

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

<Respondent to Insert Date>

Lisa Williams, Director of Operations
C/- Sam Bright
Pharmac

By electronic transfer using GETS (<https://www.gets.govt.nz>)

Dear Lisa,

Proposal for the supply of Immune Checkpoint Inhibitors for the Treatment of, Locally Advanced AND Metastatic, Non-Small Cell Lung Cancer

In response to your Request for Proposals (RFP) dated 6 July 2022, we put forward the following proposal in respect of ICIs for Advanced NSCLC.

You may change the 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>
Postal address:	<i>[e.g. P.O Box address]</i>
Registered office:	<i>[if you have a registered office insert the address here]</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	<i>As part of adopting a progressive procurement policy, Pharmac are committed to understand</i>

<p>procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori 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> <p>One that has at least 50% Māori ownership, or A Māori Authority as defined by Inland Revenue.</p> <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><i>and support what roles Māori businesses play in our supply chain</i></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 Point 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:	

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, existing supply commitments for the products in scope, including other markets supplied:	
(e) Information about our, or our supplier's, previous supply performance, and ability to ensure continuity of supply of the proposed product(s)	
(f) Information about our quality assurance processes:	
(g) 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 	
(h) 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, Pasifika 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	
(a) Chemical name	
(b) Brand name	
(c) Strength(s)	<i>[e.g. mg per ml]</i>
(d) Form	<i>[e.g. solution for injection]</i>
(e) Pack size	<i>[e.g. 1 vial]</i>
(f) Packaging type	
(g) Shelf life	<i>[include months from date of manufacture and temperature to be stored at]</i>
(h) Stability	<i>[include information regarding stability duration at room temperature and if relevant, once diluted for infusion]</i>

5. Details of pharmaceutical manufacture	
(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 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	
(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>
(c) For any proposed products without market approval and where the dossier has not been submitted to Medsafe, please provide	<i>[N/A if product is approved by Medsafe]</i>

details of the planned submission date and timeframes to achieve registration:	
(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:	<i>[N/A if product is approved by Medsafe]</i>
(e) Please confirm that you will supply physical sample of the proposed products, to be provided within 10 business days of Pharmac's request.	<i>[whether or not Pharmac requires a sample will be determined upon initial evaluation of your proposal, please wait to hear from us]</i>
(f) Confirmation that your proposed products have either been submitted as funding application via PharmConnect, and review is in progress, or an outcome of your funding application has been previously received.	

7. 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, including other countries where the product is widely in use:	
(d) Information about our previous supply performance, existing supply commitments and relevant expertise:	
(e) Information relating to the education support plan for the introduction of your treatment(s), including information regarding compounding (if relevant) and stability data once compounded; training for clinicians regarding administration; 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>
(f) PD-L1 testing will be an important component of a patients journey to treatment with an ICI and would be a requirement for access to 1L monotherapy. Please outline how your organisation would:	

<p>(i) support successful introduction of this testing into New Zealand laboratory systems. Consider how you could support consistency across New Zealand and how you could support capacity.</p> <p>(ii) support equitable access to testing for Māori and Pacific populations, and other populations experiencing disparities (those living in high socioeconomic deprivation, those living rurally and those who've been refugees and those with disabilities).</p>	
<p>(g) Please outline how your Organisation would support improving access and responsible use of these medicines (e.g., services and resources that would be offered).</p> <p>a. In the context of a strained health system, for groups experiencing health disparities in New Zealand, specifically Māori and Pacific peoples (but also those living in high socioeconomic deprivation, those living rurally and those who've been refugees and those with disabilities), how would you support implementation of your proposal to ensure that access to treatment is equitable and contributes to equitable outcomes.</p>	
<p>(h) Reasons why Pharmac should accept our proposal</p>	
<p>(i) Any additional information Pharmac should consider under its Factors for Consideration Framework:</p>	

8. Environmental Sustainability				
(a) Does your Organisation have an environmental/sustainability policy?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(b) Does your Organisation have a sustainability report?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(c) If yes to either of the two above questions, please attach or link:				
(d) 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>			
(e) Has your Organisation received any	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>

environmental/sustainability award(s)?				
(f) If yes, provide details:				
(g) Has your Organisation received any environmental fine/prosecution(s)?	Yes	[delete one]	No	[delete one]
(h) If yes, provide details:				
(i) Has your Organisation received any environmental audit(s), or does it comply with a recognised standard?	Yes	[delete one]	No	[delete one]
(j) If yes, provide details:				

9. Pricing and Terms of Supply

As outlined in the RFP, you are required to submit prices for each scenario you are intending to supply for, if you are not making an ICI available for a particular line of treatment put N/A.

All prices must be in New Zealand dollars and exclusive of GST.

You may propose an alternative pricing methodology underneath.

Table 3. Individual bids capable of being awarded in isolation

Scenario A, ICIs for multiple lines of treatment, see 'Funding Scenarios' in the RFP for full details			
	1L monotherapy	1L combination therapy	2L monotherapy
Strength			
Presentation			
Pack size			
List price			
Net price			
% Rebate			

Other Pricing mechanism			
Scenario B, 2L monotherapy only*			
Strength			
Presentation			
Pack size			
List price			
Net price			
% Rebate			
Other Pricing mechanism			

* If a bid is submitted for 2L monotherapy in Scenario A, a bid must be submitted for 2L monotherapy in Scenario B

Table 4. Combined bids for multiple indications.

Scenario A, ICIs for multiple lines of treatment, see 'Funding Scenarios' in the RFP for full details			
	1L monotherapy	1L combination therapy	2L monotherapy
Strength			
Presentation			
Pack size			
List price			
Net price			
% Rebate			
Other Pricing mechanism			
Scenario B, 2L monotherapy only*			
Strength			
Presentation			

Pack size	
List price	
Net price	
% Rebate	
Other Pricing mechanism	

Note: If a pricing proposal is submitted for more than one indication, the pricing for each indication, capable of being awarded on its own must be provided in Table 3

* If a pricing proposal is submitted for 2L monotherapy in Scenario A, a bid must be submitted for 2L monotherapy in Scenario B

Unfunded, non-ICI agents required for combination therapy*	
Strength	
Presentation	
Pack size	
List price	
Net price	
% Rebate	
Other Pricing mechanism	

Note: May not be relevant for all suppliers

Proposals including cost-offsets on pharmaceuticals or indications not expressly identified in this RFP that we would like Pharmac to consider in addition to the above. Note that any cost-offsets on additional pharmaceuticals or indications detailed below must be fully funded and listed on the Pharmaceutical schedule at the date RFP release, and not have been indicated as a future procurement opportunity on GETS by Pharmac.

If submitting a proposal that includes cost savings on other currently funded agents and/or indications, a separate proposal **must** be submitted for the indication(s) that does not include cost savings on other currently funded agents and/or ICI indications

Having considered the *Pharmac standard terms and conditions for the supply of pharmaceuticals 2022* 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.