PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

17 October 2024

Tēnā koe

REQUEST FOR PROPOSALS – SUPPLY OF COVID-19 VACCINES

Pharmac | Te Pātaka Whaioranga invites proposals for the supply of COVID-19 vaccines in the Aotearoa New Zealand subsidised market.

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

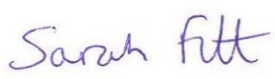
- **Schedule 1** specifies:
  - the vaccines we are seeking proposals for;
  - the background to the RFP;
  - the scope of the RFP;
  - our role within the Pae Ora (Healthy Futures) Act 2022; and
  - the types of proposals sought.
- **Schedule 2** describes the process that Pharmac expects to follow 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.
- **Schedule 5** which is available via GETS sets out Pharmac's proposed terms and conditions for the supply of COVID-19 vaccines that will apply if your proposal is awarded.

If you wish to submit a proposal, you must submit it to Pharmac via the Government Electronic Tenders Service (GETS) no later than **4.00 p.m**. **(New Zealand time) on 21 November 2024.**

If you have any questions about this RFP, you should submit them via GETS.

We look forward to receiving your proposal.

Yours sincerely



Sarah Fitt
Chief Executive

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

1. Vaccines

Pharmac | Te Pātaka Whaioranga invites proposals from suppliers of COVID-19 vaccines.

The intention of this RFP is to:

- secure ongoing supply of COVID-19 vaccine for:
  - (i) eligible children aged 6 months to 11 years, and
  - (ii) eligible people aged 12 years and older;
- align the supply agreements for COVID-19 vaccine with the standard supply agreements for other vaccines that Pharmac manages;
- achieve savings to the Combined Pharmaceutical Budget which could be reinvested into other pharmaceuticals.

As part of this process, Pharmac is considering possible changes to the eligibility criteria of COVID-19 vaccines in line with clinical advice we have received to ensure vaccines are funded in a cost-effective way. Pharmac intends to secure supply of the COVID-19 vaccine for the above groups of people who meet either the current or proposed amended eligibility criteria (see page 5 and 6 below).

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 our Te Tiriti o Waitangi policy and Equity Policy

2. Background to RFP

In 2020, the Government established a cross-agency COVID-19 Vaccine Strategy Taskforce. In late 2020/early 2021, advance purchase agreements were reached with four vaccine suppliers (Pfizer/BioNTech, Novavax, Janssen and University of Oxford/AstraZeneca), covering a range of different vaccine technologies. This helped supply start in early 2021.

The Ministry of Health released a summary of these agreements, including the circumstances they were negotiated in. This is available here:

https://www.health.govt.nz/information-releases/summary-statement-of-new-zealand-covid-19-vaccine-procurement-process-and-contracts-with-suppliers

On 1 July 2023, management of COVID-19 vaccines transferred to Pharmac from the Ministry of Health | Manatū Hauora. Pharmac is responsible for considering and deciding upon any changes to funded vaccines, including COVID-19 vaccines. Health New Zealand | Te Whatu Ora (Health NZ) manages the storage and distribution of COVID-19 vaccines to vaccinators. Health NZ is also responsible for implementing the vaccination programme.

The following COVID-19 vaccines are currently listed in Section I and Part II of Section H the Pharmaceutical Schedule:

Table 1: COVID-19 vaccine listed in Section I and Part II of Section H of the Pharmaceutical Schedule

Presentation	Brand
Inj 10 mcg raxtozinameran per 0.3 ml, 0.48 ml vial; paediatric vaccine, light blue cap	Comirnaty Omicron
Inj 3 mcg raxtozinameran per 0.2 ml, 0.4 ml vial; infant vaccine, maroon cap	Comirnaty Omicron

Inj 30 mcg raxtozinameran per 0.3 ml, 0.48 ml vial; adult vaccine, light grey cap	Comirnaty Omicron
Inj 30 mcg raxtozinameran per 0.3 ml, 2.25 ml vial; adult vaccine, dark grey cap	Comirnaty Omicron

This is the first RFP for the supply of COVID-19 vaccine in New Zealand. Pharmac is now seeking proposals for Principal Supply Status ("PSS")[1] for COVID-19 vaccine for:

- Children aged 6 months to 11 years, and
- Children and adults aged 12 years and older

We are also seeking proposals for the supply of COVID-19 vaccine for people who meet the current eligibility criteria and for people who meet a proposed amended eligibility criteria[2].

In preparation for this RFP, Pharmac released a call for applications from pharmaceutical suppliers who manufacture vaccines against COVID-19 in August 2023. In June 2024, a Future Procurement Opportunity (FPO) was also released on the Government Electronic Tender Service (GETS). In the FPO, Pharmac requested that suppliers submit applications to Pharmac for potential new vaccines that had not already been considered by the Immunisation Advisory Committee.

Clinical Advice

Pharmac sought clinical advice in November 2022, March 2023, March 2024 and September 2024 from the Immunisation Advisory Committee about:

- the procurement process for COVID-19 vaccines
- the suitability of COVID-19 vaccines that may be available in time for the supply period indicated in this RFP; and
- possible funding eligibility criteria changes.

The Immunisation Advisory Committee's meeting records are available on our website at:

https://pharmac.govt.nz/about/expert-advice/specialist-advisory-committees/ -:~:text=Immunisation%20Advisory%20Committee

Pharmac's role within the sector

The Pae Ora (Healthy Futures) Act 2022 (the Act) took effect on 1 July 2022 and 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.

[1] PSS is described on page 5 of this RFP document.
[2] The current and proposed amended eligibility criteria is outlined on page 5-6 of this document.

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

Pharmac will work closely with its health sector partners, including the Public Health Agency and Health New Zealand throughout this process to support Pae Ora.

3. Scope of RFP

We set out below some matters that you should consider in preparing a response to this RFP.

Supply Period

The contract(s) for COVID-19 vaccines as a result of this RFP process would be for supply in the community and hospital for a period of 20 months from 1 February 2026 until 30 September 2027, with two consecutive optional extension periods of twelve months each, at Pharmac's discretion. For the avoidance of doubt the extension periods available would be as follows:

(a) First possible extension period – from 1 October 2027 to 30 September 2028

(b) Second possible extension period – from 1 October 2028 to 30 September 2029

Transition Periods

Should a new brand of COVID-19 vaccine be awarded PSS as a result of this RFP, there would be dual brand listings in the Pharmaceutical Schedule for a finite period. This is intended to allow for an orderly transition between brands. The anticipated transition period is from 1 October 2025 to 31 January 2026.

We anticipate a transition period would occur at the end of the above PSS period should a different supplier gain PSS as a result of a future competitive procurement process.

Table 2: Anticipated Supply Period including Transition Period

Initial supply period	
Supplier to make best endeavours to submit for strain-update regulatory approval consistent with WHO strain recommendations as at 30 June 2025.	
Pharmac to raise Purchase Orders	Approximately June 2025
Supplier to supply stock of COVID-19 vaccine with up-to-date strain to relevant Health NZ vaccine store	Between 1 October 2025 – 1 February 2026, unless otherwise agreed
Transition period	1 October 2025 – 31 January 2026
PSS Period	1 February 2026 – 30 September 2027
First Extension Period (if required)	
Deadline for Pharmac to notify supplier if first extension period is to be utilised	By 1 July 2027
First extension period for PSS	1 October 2027 – 30 September 2028
Second Extension Period (if required)	
Deadline for Pharmac to notify supplier if second extension period is to be utilised	By 1 July 2028
PSS second extension period	1 October 2028 – 30 September 2029

Principal Supply Status (PSS) and Alternative Brand Allowance (ABA)

Through this RFP, Pharmac may award PSS to a supplier for each of the following markets:

(i) eligible children aged 6 months to 11 years, and
(ii) eligible people aged 12 years and older;

For the avoidance of doubt, Pharmac may award PSS to one supplier for both markets ((i) and ii)) noted above, or to one supplier for one market (i) and to a different supplier for the other market (ii).

The award of PSS means that the successful supplier's vaccine would be the principal funded brand in each of the specific New Zealand subsidised markets and would be guaranteed at least 95% of the specific vaccine market. This means that brands of the vaccine other than the PSS brand could be funded for use in up to 5% of the applicable funded vaccine market. 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 via a listing on the Pharmaceutical Schedule or via Pharmac's Exceptional Circumstances framework. Pharmac retains the right to negotiate the Alternative Brand Allowance with the preferred supplier, subject to clinical advice received during the evaluation of the bids.

If required, Pharmac would look to contract with a supplier to secure supply of an alternative brand of COVID-19 vaccine.

Eligibility Criteria

The current eligibility criteria for COVID-19 vaccine are available on our website:

https://schedule.pharmac.govt.nz/ScheduleOnline.php?edition=&osq=COVID-19+vaccine

As part of this RFP process, Pharmac may consider amending the eligibility criteria as follows (additions in **bold,** deletions in yellow-highlighted strikethrough):

Primary COVID-19 vaccination

1. Children aged 6 months to 4 years at high risk of severe illness
2. Anyone aged over 5 years

Additional dose / Booster

One additional dose (booster) every 6 months for previously vaccinated people meeting the following criteria:

Any of the following:

1. One dose for previously unvaccinated people aged 12-15 years old; or
2. Up to three doses for immunocompromised people aged 12-15 years old; or
3. Up to two doses for previously unvaccinated people aged 16-29 years old; or
4. Up to four doses for people aged 16-29 years at high risk of severe illness; or
5. One dose for previously unvaccinated people aged 30 years and older; or
6. One additional dose every 6 months for previously vaccinated people ~~aged 30 years and over~~ **meeting the following criteria:**
   - **6.1. all people aged 50 years and over; or**
   - **6.2. pregnant people; or**
   - **6.3. disabled people with significant or complex health needs, including those who receive Ministry of Disabled People | Whaikaha Disability Support Services; or**
   - **6.4. people with serious mental health conditions; or**
   - **6.5. people with obesity with a BMI of 35 kg/m2 or over; or**
   - **6.6. people aged 12 years and over with a medical condition that increases the risk of severe illness from COVID-19.**

The clinical advice we received in relation to the proposed eligibility criteria was for a slightly narrower group of people, specifically all people aged 65 years and over, and Māori and Pacific people from 50 years and over. We are proposing to widen this to include all people aged 50 years and over to allow targeted implementation to other groups who may be experiencing health disparities.

We would consult publicly on the above eligibility changes, or similar, before any decision is made by the Pharmac Board or its delegate.

Suppliers are required to submit proposals for both; people who meet the current eligibility criteria and for people who meet the proposed amended eligibility criteria described above.

Stock Purchase

Pharmac would place purchase orders for vaccine stock with the supplier with agreed lead times. Such purchase orders would be required to be delivered to a designated New Zealand delivery point and QA released by the supplier.

Private vaccine (ie not Pharmac subsidised)

We anticipate possible demand for a private market (ie not Pharmac subsidised) for COVID-19 vaccines, as this would provide choice for those who do not meet the eligibility criteria. There would be no requirement for the private market COVID-19 vaccine to be purchased from the same supplier as the subsidised COVID-19 vaccine.

However, for simplicity, Pharmac is aware that many immunisation providers only stock the subsidised brands of vaccines and therefore subsidised brands supply a large proportion of the vaccine market. Suppliers may also carry stock of and provide alternative brands for purchase through the private market. This currently occurs with the influenza vaccine market, and we anticipate this could be similar for the COVID-19 vaccine market. Suppliers would need to consider the impact this may have on the volumes of vaccines required on both the funded and private market. If suppliers supply the private market, they are expected to ensure that demand does not affect their ability to supply the subsidised market.

We would appreciate suppliers informing Pharmac during the RFP whether they intend to supply a private market for COVID-19 vaccines.

Donations to Pacific and Realm Countries

Donations of vaccine stock to Pacific and Realm Countries (Tokelau and the self-governing states of the Cook Islands and Niue) may be sought as part of New Zealand's commitment to supporting these countries. Agreement from Pharmac and suppliers would be required to support any offshore donation. Operational aspects of donations are managed by the Ministry of Health and Ministry of Foreign Affairs and Trade. Decision-making on donations now sits with Pharmac, noting that New Zealand has made commitments to purchase stock for Realm Countries and Pacific nations.

Distribution

Health NZ is currently responsible for the management of COVID-19 vaccine storage and distribution.

Suppliers would be required to ensure that vaccines are packed and transported to meet all storage and cold chain distribution requirements under their Licence to Sell by Wholesale.

Pharmac would place purchase orders for vaccines with the supplier. Such purchase orders would be required to be delivered to a designated delivery point.

4. Types of proposals sought

Bid Options

(a) Suppliers must submit proposals in response to the Bid Options outlined below which would be for both principal supply in the community via a listing in Section I of the Pharmaceutical Schedule (ie the National Immunisation Schedule) and hospital supply in Part II of Section H of the Pharmaceutical Schedule.

Scenario A:

(b) Scenario A outlines proposals being sought if the eligibility criteria were to remain as current.

(c) Suppliers **MUST** submit proposals for PSS of COVID-19 vaccine with a 5% Alternative Brand Allowance (ABA) for each of the populations as follows:

(i) Bid Option 1: all currently eligible children aged 6 months to 11 years, if their vaccine is indicated for use in this age range;

(ii) Bid Option 2: people aged 12 years and over who meet the current eligibility criteria;

For the avoidance of doubt, proposals received for Bid Option 2 will be considered alongside Bid Option 1 to ensure a COVID-19 vaccine is available for people of all ages.

(d) Suppliers **MAY** submit a combined proposal for PSS with a 5% ABA for:

(iii) Bid Option 3: all people who meet the current eligibility criteria (ie children aged 6 months to 11 years and all people aged 12 years and over who meet the current eligibility criteria).

Scenario B

(e) Scenario B is for bid options if the eligibility criteria were to be amended. The proposed amended eligibility criteria would be subject to consultation.

(f) Suppliers MUST submit a proposal for PSS of COVID-19 vaccine with a 5% Alternative Brand Allowance (ABA) as follows:

(iv) Bid Option 4: people aged 12 years and older who meet the proposed amended eligibility criteria as outlined on pages 5 and 6.

For the avoidance of doubt, there are no proposed changes to the eligibility criteria for children aged 5 months to 11 years. Therefore, proposals received for Bid Option 4 will be considered alongside proposals received for Bid Option 1 to ensure a COVID-19 vaccine is available for all age ranges.

(g) Suppliers **MAY** submit a combined proposal for PSS with a 5% ABA for:

(v) Bid Option 5: all people who meet the proposed amended eligibility criteria (as outlined on pages 5 and 6).

For the avoidance of doubt, the Bid Options are as follows:

	Bid Option	*Children under 12 years*	*People 12 years and over*
Scenario A (current eligibility criteria)	*1*	✓	
	2		✓
	3	✓	✓
Scenario B (proposed amended eligibility criteria) *The proposed amended eligibility criteria would be subject to consultation.*	*4*		✓
	5	✓	✓
If a supplier has a COVID-19 vaccine(s) indicated for use in all people from 6 months of age, it must submit bid options 1,2 and 4. It may also submit bid options 3 and 5 *If a supplier has a COVID-19 vaccine(s) indicated for use in people from 12 years of age, it must submit bid options 2, and 4.*			

Proposal Pricing

When submitting pricing please note the following:

(a) Suppliers **MUST** submit a *purchase price* from suppliers for COVID-19 vaccine. This is the price that Pharmac would be invoiced by a supplier, which may be confidential between the supplier and Pharmac.

(b) Any vaccine listed as a result of this RFP in Section I or Part II of Section H of the Pharmaceutical Schedule would have a publicly listed price of $0.00 NZD to reflect the fact that the vaccine is provided free to immunisation providers as no subsidy is claimed in respect of the cost of the vaccine.

(c) Suppliers **MUST** also provide a *manufacturer's price*, which is not confidential and can be used by Pharmac for public reporting and any funded vaccine distribution, which may occur where a price is required.

For the avoidance of doubt, the *manufacturer's price* may be the same or different to the *purchase pric*e; this would depend on individual supplier.

(d) Suppliers **MAY** submit pricing which includes confidential expenditure caps; however, a manufacturer's price for public reporting would still be required.

(e) Due to the distribution mechanism, any suppliers with one presentation of COVID-19 vaccine to cover the entire age range would need to submit one price for the whole market. Suppliers are able to submit proposals that include multiple presentations with different pricing to cover the required age groups.

Pandemic / Outbreak supply

(a) COVID-19 vaccine may also be used in the event of a disease outbreak. Suppliers of such vaccines would be required to deliver within a short timeframe, but Pharmac would be free to seek alternative supply in the event the contracted supplier could not meet the outbreak demand.

(b) Proposals should outline the supplier's or nominated distributor's capabilities in meeting any delivery timeframes, requirements (eg cold chain distribution or ultra-low temperature distribution) and its ability to comply with any national or international cold chain standards or guidelines.

(c) Any Agreement(s) resulting from this RFP process would include provisions allowing exclusivity to be suspended in the event of a pandemic and/or local outbreak. The proposed provisions reflect compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

Medsafe Approval

(a) Proposals **MUST** be for COVID-19 vaccines which have been approved, or have been under assessment, or are currently under assessment by Medsafe.

(b) Suppliers **MUST** provide information regarding the anticipated timelines and process for strain updates for COVID-19 vaccines.

Technological changes

(a) Pharmac is aware that there may be technological changes to the development of COVID-19 vaccines during the supply period. Suppliers MAY submit proposals which include technology changes throughout the supply period at no additional cost to Pharmac. For the avoidance of doubt, combination vaccines such as a combined COVID-19/influenza vaccine would not be considered to be a technology change and would be considered to be out of scope of this RFP.

Pharmac is not willing to consider the following types of proposals

(a) Any proposal that involves pharmaceuticals, vaccines or services other than COVID-19 vaccines. For the avoidance of doubt, bids for COVID-19/influenza or any other combination vaccines would be considered out of scope of this RFP.

(b) Proposals that include expenditure risk sharing mechanisms based on patient level data.

(c) Proposals involving changes to eligibility restrictions other than those changes set out in this RFP.

(d) Proposals for COVID-19 vaccines which have not been assessed by Medsafe at the time of the release of this RFP.

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

Schedule 2: RFP process

Pharmac expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted to Pharmac via the Government Electronic Tenders Service (GETS) no later than **4.00 p.m.** (New Zealand time) on **21 November 2024**. 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 Michael Chung at procurement@pharmac.govt.nz

2. **Evaluation**

(a) Following the deadline for submitting proposals, an Evaluation Committee comprising of 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:

(i) the Pae Ora health sector principles;

(ii) Pharmac's Te Tiriti o Waitangi policy;

(iii) Pharmac's Equity policy and

(iv) the Factors for Consideration (Factors) that form part of Pharmac's current OPPs 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 objectives 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 advice from Pharmac's Pharmacology and Therapeutics Advisory Committee (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 vaccines following the closing of this RFP; and

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

(e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(f) Pharmac is not bound to select the lowest priced proposal or any proposal.

3. **Pharmac may request further information**

(a) Pharmac may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to):

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

(ii) any other additional information about your pharmaceutical.

(b) Please note that Pharmac may seek advice from PTAC, or relevant advisory committee, any relevant professional organisations or healthcare professionals with regards to your product including evaluation of any product samples.

(c) 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 unfettered judgment this would not be unfair to any other party.

4. **Negotiation**

(a) Pharmac may negotiate with the submitter(s) of one or more preferred proposals. Where Pharmac is negotiating more than one preferred proposal, the acceptance of one supplier's proposal would not exclude acceptance of another proposal.

(b) Negotiations will proceed on the basis that the contractual terms and conditions set out in Schedule 5 shall apply.

(c) Given that Pharmac expects your proposal to be the best you can offer, Pharmac does not intend to initiate negotiation with you on price. However, Pharmac does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.

(d) Pharmac may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to Pharmac's terms and conditions, Pharmac considers appropriate.

(e) If Pharmac and the supplier(s) are unable to reach a provisional agreement within what Pharmac considers to be a reasonable time, Pharmac may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

(a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent Pharmac considers consultation to be necessary or appropriate, and on approval by the Pharmac Board (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 Pharmac's Te Tiriti o Waitangi policy and its Equity 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.

6. 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; and

(viii) to readvertise for proposals.

(b) Pharmac may consult or seek clinical advice from PTAC or relevant 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), the Minister of Health (or any Associate Ministers), Health New Zealand 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 vaccines 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 – Ministry of Health, Health New Zealand - Te Whatu Ora and Whaikaha – Ministry of Disabled People (Confidential Information). However, you acknowledge that it may be necessary or appropriate for Pharmac to release Confidential Information in accordance with:

(i) section 12 of the Official Information Act 1982; and

(ii) any other legal and administrative obligations,

and you consent to such disclosure.

Where Pharmac reaches a preliminary view that Confidential Information must be disclosed for the purposes stated in paragraph (j)(i) above, Pharmac will consult with you, and will act in good faith, before deciding whether to disclose the Confidential Information. To the extent permitted by law, Pharmac will inform you if Confidential Information is disclosed for the purposes stated in paragraph (j)(ii) above, including any disclosure to a court, inquiry or ombudsman.

7. Indicative timetable

(a) Following receipt of proposals, Pharmac anticipates:

(i) the Evaluation Committee evaluating proposals in December 2024;

(ii) negotiating terms of a provisional agreement with submitter(s) of one or more preferred proposals in January 2025;

(iii) consulting on any provisional agreement and eligibility criteria (if proposing to progress to an amended eligibility criteria) in February/March 2025;

(iv) Pharmac's Board, or the Board's delegate, making a decision in May 2025;

(v) Public notification of any decisions in June 2025,

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, Pharmac expects to have changes made to the Pharmaceutical Schedule between October 2025 and February 2026.

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

The following information relates to the estimated subsidised market size of COVID-19 vaccine under the current eligibility criteria and restrictions.

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 vaccines and, while Pharmac has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. Pharmac is not obliged to notify you in the event of any change to the figures below.

Total number of COVID-19 vaccines doses administered between 1 July 2023-30 June 2024

COVID-19 vaccine	**Administered doses***
Adult - total	737,000
ages 12 -49 years	*111,000*
ages 50 – 64 years	*172,000*
aged 65 +	*454,000*
Paediatric (5-12 years)	2,800
Infant (6 months – 4 years)	481

*Booster eligibility from age **30** years and over

Estimated doses administered based on proposed amended eligibility criteria for a 12 month period

COVID-19 vaccine	**Administered doses****
Adult (12 years+)	626,000
Paediatric (5-12 years)	2,800
Infant (6 months – 4 years)	481

Booster eligibility from age **50+ years and over

The eligibility criteria would not result in a change to the access of COVID-19 vaccine to children aged 12 years and under.

These estimates are based on current uptake/usage data for the number of doses (ie not the number of people, noting that each person would be eligible for two doses in a 12 month period). We don’t anticipate a change to the number of paediatric and infant doses with the proposed amended eligibility criteria, as there would be no change to eligibility for this group.

Schedule 4: Proposal form

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

<Respondent to Insert Date>

Chief Executive
C/- Michael Chung
Procurement Manager
Pharmac
By electronic transfer using GETS (https://www.gets.govt.nz)

Tēnā koe

Proposal for the supply of COVID-19 vaccine(s)

In response to your Request for Proposals (RFP) dated 17 October 2024 we put forward the following proposal in respect of **COVID-19 vaccine(s)**.

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:	*[insert the name that you do business under]*
Full legal name (if different):	*[if applicable]*
Physical address:	*[if more than one office – put the address of your head office]*
Business website:	*[URL address]*
Type of entity (legal status):	*[sole trader / partnership / limited liability company / other please specify]*
Registration number:	*[if your organisation has a registration number insert it here eg NZBN number]*
Does your organisation identify as being a Māori business?	*[Yes / No]*

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 businesses. 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. Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business. A Māori business for Government procurement reporting purposes is: • one that has at least 50% Māori ownership, or • a Māori Authority as defined by Inland Revenue. 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).	*As part of adopting a progressive procurement policy, Pharmac is committed to understanding and supporting what roles Māori businesses play in our supply chain*
Pharmac - is required to report to NZGP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements. 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.	*[Yes / No]*

2. Our Points of Contact	
Contact person:	*[i.e., who communications relating to the response(s) should be made to]*
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.	*[you may embed organisational charts or similar]*
(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: • how your Organisation meets or exceeds the expectations set out in the Supplier Code of Conduct.	
(g) Please outline how your Organisation supports social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). Please also outline how your organisation: • 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 vaccine presentation (please duplicate this table for multiple presentations)	
(a) Chemical name:	
(b) Brand name:	
(c) Full description of the vaccine formulation and potency (label claim):	
(d) Presentation:	*[eg prefilled syringe, individual vial, multi-dose vial]*
(e) Needle specification:	
(f) Needle included or available separately:	
(g) Route of administration:	*[eg subcutaneous, intramuscular]*
(h) Pack size:	*[eg 1's, 10's]*
(i) Packaging type:	
(j) Labelling and images:	*[please embed file(s) into your response form or upload to GETS as clearly named file(s) separate to the response form(s)]* *Minimum specification requirements for images:* • *On a plain background (preferably white)* • *Minimal shadows and good lighting* • *Ideally images should include, pack exterior, sheet of units or similar, close up of unit* • *Separate images for different strengths or pack sizes* • *The product should take up 80% of the photo*
(k) Shelf life/storage of the vaccine: Are there any specific handling and distribution requirements?	
(l) Information supporting the stability of offered vaccines when exposed to temperatures outside	

of the specified storage temperature and the specified distribution temperature range. We would anticipate that the specified distribution temperature range is cold chain (2-8C):	

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:	*[eg TGA, FDA, MHRA]*
(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 (Air):	
(g) Preferred order size:	

6. Regulatory approval Information	
(a) Date of market approval (please attach copy of Medsafe Gazette notice):	
(b) **OR** Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted):	
(c) Insert any other consents required for vaccine:	
(d) What countries is the vaccine registered in?	

(e) Information regarding the process and anticipated timeframe to achieve strain update regulatory approval:	

7. Pricing Information

Information relating to pricing for our COVID-19 vaccine ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for Pharmac:

- Each proposal will be considered separately. Proposals must be clear about what the price relates to, specifically:
  - Bid Option1: Children aged 6 months to 11 years, current eligibility criteria
  - Bid Option 2: People aged 12 years and over, current eligibility criteria
  - Bid Option 3: Combined proposal for children aged 6 months to 11 years and for people aged 12 years and over, current eligibility criteria
  - Bid Option 4: People aged 12 years and over, proposed amended eligibility criteria
  - Bid Option 5: Combined proposal for children aged 6 months to 11 years and for people aged 12 years and over, proposed amended eligibility criteria
- When submitting pricing please refer to the Proposal Pricing requirements outlined in Schedule 1. Please provide a Purchaser's Price and a Manufacturer's Price:

Bid Option 1: Children aged 6 months to 11 years, current eligibility criteria

Vaccine description (please distinguish between different presentations)	**Brand name**	**Manufacturer's price per unit (ie non-confidential price)**	**Purchase price per unit (price may be confidential between supplier and Pharmac)**

[Any comments in relation to bid eg expenditure cap]

Bid Option 2: People aged 12 years and over, current eligibility criteria

Vaccine description (please distinguish between different presentations)	Brand name	Manufacturer's price per unit (ie non-confidential price)	Purchase price per unit (price may be confidential between supplier and Pharmac)
[Any comments in relation to bid eg expenditure cap]			

Bid Option 3: Combined proposal for all children aged 6 months to 11 years and for people aged 12 years and over, current eligibility criteria			
Vaccine description (please distinguish between different presentations)	**Brand name**	**Manufacturer's price per unit (ie non-confidential price)**	**Purchase price per unit (price may be confidential between supplier and Pharmac)**
[Any comments in relation to bid eg expenditure cap]			

Bid Option 4: People aged 12 years and over, proposed amended eligibility criteria			
Vaccine description (please distinguish between different presentations)	**Brand name**	**Manufacturer's price per unit (ie non-confidential price)**	**Purchase price per unit (price may be confidential between supplier and Pharmac)**

[Any comments in relation to bid eg expenditure cap]			

Bid Option 5: Combined proposal for children aged 6 months to 11 years and for people aged 12 years and over, proposed amended eligibility criteria			
Vaccine description (please distinguish between different presentations)	**Brand name**	**Manufacturer's price per unit (ie non-confidential price)**	**Purchase price per unit (price may be confidential between supplier and Pharmac)**
[Any comments in relation to bid eg expenditure cap]			

8. Supply Information	
(a) Information about our ability to ensure the continuity of supply of the vaccine:	
(b) Information about our previous supply performance and relevant expertise:	
(c) Information about our intent to supply a private COVID-19 vaccine market if one were to develop:	

9. Other Information	
(a) Key features of our proposal not detailed elsewhere in our response:	
(b) Any feedback on the proposed terms and conditions for the supply of COVID-19 vaccine attached as Schedule 5 via GETS:	

10. Environmental Sustainability				
(a) Does your organisation have an environmental/sustainability policy?	Yes	*[delete one]*	No	*[delete one]*
(b) Does your organisation have a sustainability report?	Yes	*[delete one]*	No	*[delete one]*
(c) If yes to either of the two above questions, please attach or link:				
(d) How does your organisation contribute to environmental sustainability?	*[Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP]*			
(e) Has your organisation received any environmental/sustainability award(s)?	Yes	*[delete one]*	No	*[delete one]*
(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.				

Schedule 5: Proposed terms and conditions for supply of COVID-19 vaccines

The proposed terms and conditions for the supply of COVID-19 vaccines can be found in Attachment One.