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11 November 2022

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF VARIOUS VACCINES AND A DIAGNOSTIC AGENT

Pharmac invites proposals for the supply of various vaccines (including influenza) and a diagnostic agent in New Zealand.

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

- Schedule 1 specifies the vaccines and a diagnostic agent 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 vaccines and diagnostic agent;
- Schedule 4 contains the RFP form in which you are to provide details of your proposal; and
- Schedule 5, which is available via GETS sets out Pharmac's proposed terms and conditions for the supply of 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 22 December 2022.**

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

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Vaccines

Pharmac is interested in considering proposals from suppliers of the non-influenza vaccines ("Various Vaccines"), influenza vaccines ("Influenza Vaccines") and a diagnostic agent as set out in Tables 1 and 2 below:

Table 1. Currently funded vaccines included in the RFP

Vaccine description	Currently funded brand(s)
Various Vaccines	
Bacillus Calmette-Guerin vaccine	BCG Vaccine
Diphtheria, tetanus and pertussis vaccine	Boostrix
Diphtheria, tetanus, pertussis and polio vaccine	Infanrix IPV
Diphtheria, tetanus, pertussis, polio, hepatitis B and *Haemophilus influenzae* type B vaccine	Infanrix-Hexa
Haemophilus influenzae type B vaccine	Hiberix
Hepatitis A vaccine	Havrix & Havrix Junior
Hepatitis B recombinant vaccine	Engerix-B & Engerix B - Paediatric
Human papillomavirus vaccine	Gardasil9
Measles, mumps and rubella vaccine	Priorix
Meningococcal ACWY vaccine	Menactra[1]
Meningococcal C conjugated vaccine	Neisvac-C
Pneumococcal (PCV13) vaccine	Prevenar 13
Pneumococcal (PPV23) polysaccharide vaccine	Pneumovax23
Poliomyelitis vaccine	IPOL
Rotavirus oral vaccine	Rotarix
Varicella vaccine [chicken pox vaccine]	Varivax
Influenza Vaccines	
Influenza vaccine (quadrivalent inactivated)	Afluria Quad Afluria Quad Junior
Diagnostic Agent	
Tuberculin PPD (Mantoux) test	Tubersol

Table 2. Currently unfunded vaccines included in this RFP

Vaccine description
Various Vaccines
Adult diphtheria and tetanus vaccine
Pneumococcal conjugate (PCV15) vaccine
Influenza Vaccines
Adjuvanted influenza vaccine
High dose quadrivalent influenza vaccine
Live attenuated influenza vaccine (intranasal)
Cell-based influenza vaccine

See clause 2 below for details of the applicable eligibility criteria and possible amendments following this RFP.

[1] Meningococcal ACWY vaccine will be changing from Menactra to MenQuadfi in early 2023

2. Background to RFP

Since 1997, the New Zealand Government has subsidised Influenza Vaccines for eligible people that meet set clinical criteria. Pharmac began managing the Influenza Vaccine in 2004 and the National Immunisation Schedule for Various Vaccines from 1 July 2012.

Pharmac is responsible for considering and deciding upon any changes to the vaccines listed in the National Immunisation Schedule, including the eligibility criteria, funding of new vaccines and managing the supply and distribution of vaccines. We also work closely with the Ministry of Health and Te Whatu Ora on determining the need for vaccines, and securing supplies, during localised and/or national outbreaks of vaccine preventable diseases. Since July 2022, Pharmac has also been responsible for the management and funding of the COVID-19 vaccine (which is not included in this RFP).

The National Immunisation Schedule sets out the vaccines that are fully funded for babies, children, adolescents and adults. It is set out in Section I of the Pharmaceutical Schedule available at the following link:

https://schedule.pharmac.govt.nz/ScheduleOnline.php?code=A45

Further information about the series of vaccines, sequence and timing of immunisations is available at the following link:

https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/new-zealand-immunisation-schedule

The last RFP for the supply of Various Vaccines, Influenza Vaccines and a diagnostic agent was released in November 2018.

This resulted in agreements with four suppliers (GSK, MSD, Sanofi and Seqirus) for sole supply status, until 30 June 2024, for most of the Various Vaccines and diagnostic agent stated in Table 1 above.

That RFP also resulted in an agreement with Seqirus for sole supply status, until 31 December 2023, for the Influenza Vaccines stated in Table 1 above. Influenza Vaccine supply covers a different period to other vaccines as it aligns with the seasonal influenza season, as a vaccine matching Medsafe's annually recommended composition must be manufactured for each influenza season.

Pharmac is now seeking proposals for the supply of Various Vaccines, Influenza Vaccines and a diagnostic agent as stated in Table 1 and 2 above for:

- Principal supply status ("PSS")[2] for Various Vaccines and a diagnostic agent during the period 1 December 2024 to 30 June 2027; and

- PSS or dual supply[3] for Influenza Vaccines in the community for the 2024 and 2025 influenza seasons with two consecutive optional extension periods of one year each, covering the 2026 and 2027 influenza seasons. Each influenza season is from 1 April until 31 December. These extension periods would be

[2] PSS is described on page 5 of this RFP document.
[3] Dual supply is described on page 6 of this RFP document

exercised independently and separately, upon notice, at the sole discretion of Pharmac, provided that any supply period does not extend beyond 31 December 2027. For the avoidance of doubt, this is subject to clause 3 of Schedule 1 in respect of any fixed volume supply and routine supply proposals being accepted by Pharmac.

In preparation for this RFP, Pharmac communicated with suppliers in early 2022 and in July 2022 a Future Procurement Opportunity (FPO) was released on the Government Electronic Tender Service (GETS). Pharmac requested that suppliers submit applications to Pharmac for funding of any new or alternative brands of vaccines they may have available for supply and any proposed changes to the funding eligibility criteria for the National Immunisation Schedule. For the avoidance of doubt, suppliers may still submit a response to this RFP including an alternative brand where they have not yet submitted an application to Pharmac.

Pharmac sought clinical advice in May 2022 and September 2022 from the Immunisation Advisory Committee on:

- the suitability of new vaccines recently approved by Medsafe or that may be approved in time for 2023 supply;
- interchangeability of alternative brands; 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

The record of the September 2022 meeting of the Immunisation Advisory Committee is expected to be published on our website by mid-November 2022.

Below are some matters that you should consider in preparing a response to this RFP.

2.1 Various Vaccines

Eligibility Criteria

The current eligibility criteria for the Various Vaccines that are funded are on our website:

https://schedule.pharmac.govt.nz/ScheduleOnline.php?code=A45

As part of this RFP process, Pharmac may consider amending the eligibility criteria, subject to clinical advice, for the Meningococcal ACWY vaccine for the following patient groups:

- children 1 year of age, with or without a catch-up for children 1 to 4 years of age
- individuals at 14 years of age with or without a catch-up for either:
    - individuals 5 to 21 years of age; or
    - individuals 13 to 21 years of age.

Pharmac may also consider amending the eligibility criteria for diphtheria, tetanus and pertussis vaccine for patients aged 45 and 65 years and over, should an adult diphtheria and tetanus vaccine be funded as part of this RFP process.

Principal Supply Status

Through this RFP, Pharmac may award PSS to a supplier.

The award of PSS means that the successful supplier's vaccine would be the principal funded brand in the New Zealand subsidised market 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.

The successful supplier would be awarded PSS for a vaccine, following a transition period of five months.

Pharmac would retain the right at its sole discretion to widen funded eligibility to a vaccine at any time during the PSS period.

Transition periods

Where new brands of a vaccine are awarded PSS as a result of this RFP process, there would be dual brand listings in the Pharmaceutical Schedule, to allow for an orderly transition between brands. The anticipated transition periods are as follows:

(a) 1st transition period from 1 July 2024 to 30 November 2024; and

(b) 2nd transition period from 1 July 2027 to 30 November 2027.

For the avoidance of doubt a special term shall be included in any provisional agreement, which shall state the applicable transition periods.

Distribution

Suppliers are 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. Currently Pharmac's storage and distribution service provider is:

Pharmac c/o HealthCare Logistics
HealthCare Logistics
58 Richard Pearse Drive, Airport Oaks
Mangere
Auckland 2022
New Zealand

Contract term

Any contract(s) awarded as a result of this RFP process would be evergreen and would include a maximum PSS period, from no earlier than 1 December 2024 to no later than 30 June 2027. During this period the eligibility criteria may change and would be subject to any contractual provisions.

2.2 Influenza Vaccines

Eligibility Criteria

The current eligibility criteria for the Influenza Vaccines which are funded are on our website as follows:

https://schedule.pharmac.govt.nz/ScheduleOnline.php?osq=Influenza%20vaccine&code=C4525013804

As part of this RFP process, Pharmac may consider amending the eligibility criteria for quadrivalent inactivated influenza vaccine for the following patient groups which have already been assessed by Pharmac:

- Children up to 18 years of age
- All people 50 years of age and over
- Māori and Pacific people 50 years of age and over
- Open listing (no restrictions)

As part of this RFP process, in addition to any funding of quadrivalent inactivated influenza vaccine, we may consider listing or awarding PSS to new types of Influenza Vaccines with indicative eligibility criteria as described below.

Adjuvanted quadrivalent influenza vaccine

Pharmac is interested in proposals that would enable funding for adults aged 65 years and over.

High dose quadrivalent influenza vaccine

Pharmac is interested in proposals that would enable funding for adults aged 65 years and over and for Māori and Pacific people aged 60 years and over.

Live attenuated influenza vaccine

Pharmac is interested in proposals that would enable funding for children aged from 5 to 12 years of age inclusive.

We would consider proposals that included a transition from a supplier's listing for standard quadrivalent inactivated influenza vaccine to one of the above products from a later date if not Medsafe approved in time for the 2024 Southern Hemisphere influenza season.

PSS or Dual Supply

Through this RFP, Pharmac may award PSS to a supplier or dual supply to two suppliers.

The award of PSS means that the successful supplier's vaccine would be the principal funded brand in the New Zealand subsidised market and would be guaranteed at least 95% of the specific vaccine market as described in the Various Vaccine section above.

The award of dual supply means that one supplier would supply a Fixed Volume of 400,000 doses of influenza vaccine for each immunisation programme (the "Fixed Volume Supplier"), and an alternative supplier ("Routine Supplier") would meet any demand for funded doses of influenza vaccine above that supplied by the Fixed Volume Supplier.

Distribution

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

It is Pharmac's preference that the supplier(s) continue to manage influenza vaccine distribution under any proposals received as a result of this RFP. Proposals should therefore include the cost of distribution to immunisation providers within the price of the Influenza Vaccine. Please note pharmacists now also administer and claim for funded Influenza Vaccine, which increases the number of provider delivery points for the distributor.

Proposals should contain information on the distribution capabilities in managing the annual influenza immunisation programme including delivery timeframes, returns policy and any minimum order requirements.

The supplier's distributor must provide a free phone, and online ordering system (with free fax optional) that immunisation providers could use to place orders. The ordering system would need to be in place by 1 March 2024 to allow immunisation providers to order influenza vaccine prior to the start of the influenza programme from 1 April each year.

Stock should be available for immunisation providers to order by 15 March in each year, to enable the annual influenza immunisation programme to commence from 1 April.

Suppliers should be aware of the high demand for the vaccine in the early stages of each annual influenza immunisation programme. Data shows that each year about half of all vaccines ordered are ordered within the first month of the programme, and suppliers should be prepared for this busier period. Supply and payment conditions would be included in any contract as a result of this RFP, to take into account the importance of delivery timeframes.

Reporting – influenza vaccine

The supplier(s) would be required to provide comprehensive reports to Pharmac throughout the relevant annual influenza immunisation programme including details of sales broken down by vaccinator provider type (GP practice, pharmacy, other) and Te Whatu Ora regional subdivisions (similar to previous DHB areas), not just the total sales for the country. The reports would be required to be supplied to Pharmac on a weekly basis in an electronic Excel spreadsheet format with sales volumes reported on a per day basis. Suppliers would also need to meet any reasonable data requests from Pharmac, this could include stock on hand data.

Claiming – influenza vaccine

Currently, immunisation providers purchase influenza vaccine from the supplier's distributor and the provider is reimbursed through claims made to the Ministry of Health's payment agent, Sector Operations Group, for the cost of the vaccine and the immunisation service. It is proposed that this purchase and claiming mechanism would remain unchanged.

Private (patient funded) vaccinations

For those patients that do not meet the eligibility criteria, annual influenza vaccination is available at a cost to the patient through the private market. In some cases, these are funded by an employer.

There is no requirement for the private market influenza vaccine to be purchased from the same supplier as the subsidised influenza vaccine

However, for simplicity, Pharmac is aware that many immunisation providers only stock the subsidised brands and therefore the subsidised brands supply a large proportion of the private influenza vaccine market as well. Suppliers would need to consider the impact this may have on the volumes of vaccines required. They are expected to ensure that private market demand does not affect their ability to supply the subsidised market.

Contract term – influenza vaccine

The contract(s) for Influenza Vaccines as a result of this RFP process would be for supply in the community for a period of two influenza immunisation programme years from 1 April 2024 until 31 December 2025 with two consecutive optional extension periods of one year each, covering the 2026 and 2027 influenza seasons. During this period the eligibility criteria may change and would be subject to any contractual provisions. For the avoidance of doubt, this is subject to clause 3 of Schedule 1 in respect of any fixed volume supply and routine supply proposals being accepted by Pharmac.

Promotion

Te Whatu Ora contracts the Immunisation Advisory Centre (IMAC) to coordinate influenza immunisation promotion, including the Influenza Kit. It is anticipated that supplier(s) would provide information and work with IMAC when requested. Further information about IMAC can be found at www.influenza.org.nz.

Pandemic Supply

Any contract(s) resulting from this RFP process would include provisions allowing supply to be suspended in the event of an influenza pandemic. The provisions would reflect compliance with any Manatū Hauora (Ministry of Health) and World Health Organization (WHO) requirements with regard to pandemic supply situations.

Price

Pharmac is proposing to change the Pharmaceutical Schedule list price of influenza vaccines on the Pharmaceutical Schedule from $11.00 per dose to $12.00 per dose. For the avoidance of doubt, the supplier may offer a list price different to $12.00 per dose. However, Pharmac strongly prefers no changes to the proposed $12.00 per dose list price and reserves the right to negotiate the final list price with suppliers during contracting. Any proposed price change would also be subject to public consultation. Please note, the net price submitted may be different to the list price via a rebate type arrangement.

Underwriting of Influenza Stock

Pharmac is proposing to underwrite a proportion of influenza vaccine stock for each influenza season. Please see page 10 below for further details.

3. **Types of proposals sought**

Various Vaccines

Principal Supply Status

PSS would entail 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.

Pharmac is willing to consider the following types of proposals for PSS, where the supplier is expected to meet the demand for all doses of that vaccine, from no earlier than **1 December 2024** to no later than **30 June 2027.**

Outbreak supply

(a) The vaccines stated below 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.

  (i) Meningococcal ACWY or Meningococcal C conjugate vaccines

  (ii) Measles, Mumps and Rubella

  (iii) Hepatitis A

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

(c) Any contract(s) resulting from this RFP process, for any of the vaccines listed in Table 1 or 2, 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 Manatū Hauora (Ministry of Health) and WHO requirements with regard to pandemic supply situations.

Other types of proposals

Suppliers may also wish to submit additional proposals would enable Pharmac to fund changes to eligibility criteria as outlined in Schedule 1.

Please note if you wish to submit a proposal for widened eligibility, you **MUST** also submit a proposal for the current eligibility criteria.

Proposal Pricing

When submitting pricing please note the following:

(a) Pharmac is seeking a *purchase price* from suppliers for each vaccine. This is the price that Pharmac would be invoiced by a supplier, which is expected to 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) Pharmac also requests suppliers provide a *manufacturer's price*, which is not confidential and could be used by Pharmac for public reporting and any funded vaccine distribution, which may occur where a price is required, such as for pharmacy distribution (currently limited to MMR).

For the avoidance of doubt the *manufacturer's price* may be the same as the *purchase price*; this would depend on a supplier's sensitivity around the price for the vaccine being listed publicly.

Please note that supplier(s) of any vaccines would be required to continue to supply beyond any PSS period ending on 30 June 2027. Any resulting contract(s) would specify the supply arrangements after the PSS supply period.

Influenza Vaccine – Quadrivalent inactivated influenza vaccine

Suppliers **MUST** submit three proposals for inactivated quadrivalent influenza vaccine, being one for each of the following:

- PSS in the community for a period of two annual influenza immunisation programmes from 1 April 2024 until 31 December 2025 with two consecutive optional extension periods of one year each, covering the 2026 and 2027 influenza seasons, where the supplier meets the demand for all funded doses of annual inactivated quadrivalent influenza vaccine. Pharmac would underwrite 75% of the net cost of 100,000 doses of the listed brand per influenza season if they are not distributed by the end of the influenza season.

- FIXED VOLUME SUPPLY: a proposal to be the supplier of a fixed volume of 400,000 doses for each of two annual influenza immunisation programmes from 1 April 2024 until 31 December 2025 with two consecutive optional extension periods of one year each, covering the 2026 and 2027 influenza seasons. Pharmac would underwrite the total net cost of the Fixed Volume Supply. The Fixed Volume Supply would need to be available for immunisation providers to order by 15 March in each year; however, Pharmac would direct when this stock would be supplied to vaccinators. This differs to historical implementation approaches, where the Fixed Volume Supply has solely been used at the start of each immunisation season.

- ROUTINE SUPPLY: subsidised supply for a period of two annual influenza immunisation programmes from 1 April 2024 until 31 December 2025 with two consecutive optional extension periods of one year each, covering the 2026 and 2027 influenza seasons, where the supplier meets the demand for doses of influenza vaccine ("Routine Supplier"), other than 400,000 doses that would be supplied by the Fixed Volume Supplier described above. Pharmac would underwrite 75% of the net cost of 100,000 doses per influenza season provided by the Routine Supplier if they are not distributed by the end of the influenza season.

In any or all of the above proposals, Pharmac would be willing to consider proposals for:

- egg-based inactivated quadrivalent influenza vaccine

- cell-based inactivated quadrivalent influenza vaccine

- an arrangement whereby egg-based inactivated quadrivalent influenza vaccines are supplied for the first seasonal campaign, followed by the supply of cell-based

inactivated quadrivalent influenza vaccines. Suppliers are able to submit a different price for the supply of an egg-based vaccine in comparison to a cell-based vaccine.

Any award of PSS supply would be for community supply only and PSS would not apply for hospital supply.

We are aware that, under any arrangement, Pharmac would have some co-ordination role in the season planning, including confidential discussions with other potential private market suppliers to ensure that sufficient stock is planned to be available. Te Whatu Ora would similarly have some co-ordination role with any supplier(s) to the extent needed for implementation of the annual influenza immunisation programme.

Pharmac does not intend to contract with a distributor itself or to manage any payments for distribution services; this would be the supplier's responsibility.

Proposals **MAY** include changes to the proposed Pharmaceutical Schedule list price of influenza vaccines ($12.00 per dose) for PSS, Fixed Volume Supply and Routine Supply. Due to the impact on vaccinators, Pharmac strongly prefers no changes to the proposed $12.00 per dose list price. Pharmac also reserves the right to negotiate the final list price with suppliers during contracting and any proposed price change would be subject to public consultation.

In addition to the above proposals, suppliers may wish to offer to supply the following vaccines subject to the eligibility criteria described in section 2.2 of this document:

- Adjuvanted influenza vaccine
- High dose influenza vaccine
- Live attenuated influenza vaccine

Please note if you wish to submit a proposal for adjuvanted influenza vaccine or high dose influenza vaccine you **MUST** also submit a proposal for inactivated quadrivalent influenza vaccine for the high risk under 65 patient group according to the current eligibility criteria. This would be considered as a bundled proposal and therefore one supplier would be responsible for both the over 65 year and under 65 year markets. For the avoidance of doubt, we would not contract with different suppliers for the over 65 year and the under 65 year markets.

Please note if you wish to submit a proposal for widened eligibility, you **MUST** also submit a proposal for the current eligibility criteria.

Suppliers **MAY** put forward other risk mitigations strategies for Pharmac to consider, provided any such strategies would not be considered confidential to allow for appropriate consultation (and visibility for future procurement processes).

Pharmac is not willing to consider the following types of proposals

(a) Any proposal that involves pharmaceuticals, vaccines or services other than the:

(i) vaccines set out in Schedule 1, *Table 1. Currently funded vaccines; or*

(ii) vaccines set out in Schedule 1, *Table 2. Currently unfunded vaccines; or*

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

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

(d) Proposals where the supplier would not pay for the distribution costs for Influenza Vaccines.

(e) Proposals that bundle more than one vaccine which require Pharmac to purchase all vaccines in that bundle to have access to the pricing option, with the exception of:

(1) high dose influenza vaccine or adjuvanted influenza vaccine for patients over 65 years bundled with inactivated quadrivalent influenza vaccine (egg-based or cell-based) for currently eligible patients under 65 years (including paediatric patients).

For avoidance of doubt, where a vaccine requires paediatric and adult presentations to cover the eligible population, this would be considered one individual bid (with two line items) rather than a bundle.

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 **22 December 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 Catherine Kingsbury 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 Operating Policies and Procedures (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 emphasis will be given to those aspects of proposals that demonstrate "health outcomes", and those aspects of proposals that demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors that 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 structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

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

(b) If Pharmac requests further information from or about you, it is not obliged to request the same or any other information from or about any other party, provided that in Pharmac's judgment this would not be unfair to any other party.

4. **Negotiation**

(a) Pharmac may negotiate with the submitter(s) of one or more preferred proposals, in the latter case only where the acceptance of either supplier's proposal would not exclude acceptance of the other 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 counteroffers received during consultation.

(c) The provisional agreement and responses to consultation will be considered by Pharmac's Board (or by the Board's delegate acting under delegated authority) in accordance with Pharmac's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(d) If the Board or its delegate does not approve the provisional agreement, then Pharmac may initiate negotiations for a provisional agreement with any other supplier(s).

(e) The RFP process will be complete once Pharmac has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

6. **Miscellaneous**

(a) Pharmac reserves the right, 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, Manatū Hauora (the Ministry of Health, including its operating unit Medsafe), the Minister of Health (or any Associate Ministers), Te Whatu Ora 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, the Ministry of Health and Te Whatu Ora (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for Pharmac to release Confidential Information:

    (i) pursuant to the Official Information Act 1982; or

    (ii) in the course of consultation on a provisional agreement entered into with a supplier; or

    (iii) in publicly notifying any approval by the Pharmac Board of that agreement; or

    (iv) otherwise pursuant to Pharmac's public law or any other legal obligations.

    Pharmac may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for Pharmac to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that Pharmac shall act in good faith in disclosing any Confidential Information.

7. **Anticipated timetable**

(a) Following receipt of proposals, Pharmac anticipates:

(i) the Evaluation Committee evaluating proposals in January 2023;

(ii) negotiating with submitter(s) of one or more preferred proposals in March/April 2023;

(iii) consulting on any provisional agreement in April/May 2023;

(iv) Pharmac's Board, or the Board's delegate, making a decision in June 2023;

(v) Public notification of any decisions in July 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, Pharmac expects to have changes made to the Pharmaceutical Schedule by 1 July 2024 for Various Vaccines and by January 2024 for Influenza Vaccines.

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 Various Vaccines under the current eligibility criteria and restrictions. Of note, the global COVID-19 pandemic and associated public health measures may have affected the uptake of some of these vaccines.

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.

Vaccine	**Formulation**	**Units per year[4]**			
		2019 FYR	**2020 FYR**	**2021 FYR**	**2022 FYR**
Bacillus Calmette-Guerin vaccine[5]	Inj *Mycobacterium bovis* BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent	25,000	14,400	14,600	16,000
Diphtheria, tetanus and pertussis vaccine[6]	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml syringe	123,812	119,342	262,410	258,200
Diphtheria, tetanus, pertussis and polio vaccine	Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis	66,580	64,530	66,310	55,520

[4] Financial Year ended 30 June

[5] Usage of Bacillus Calmette-Guerin vaccine were impacted by global shortages of this vaccine in 2020 - 2022.

[6] In 2019, the adult diphtheria and tetanus (DP) vaccine was delisted and eligibility to diphtheria, tetanus and pertussis (DTaP) vaccine was widened to include patients aged 45, and 65 and over. Should the adult DP vaccine be relisted as a result of the RFP we anticipate that its usage would be similar to its previous usage rates (17,000 (2016 FYR), 160,000 (2017 FYR), 164,000 (2018 FYR) and the DTaP would reduce by a similar amount.

	virus in 0.5ml syringe				
Diphtheria, tetanus, pertussis, polio, hepatitis B and *Haemophilus influenzae* type B vaccine	Inj 30IU diphtheria toxoid with 40IU tetanus toxoid, 25mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-AgU poliovirus, 10 mcg hepatitis B surface antigen in 0.5ml syringe	174,710	177,130	171,240	177,080
Haemophilus influenzae type B vaccine	*Haemophilus influenzae* type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; prefilled syringe plus vial 0.5 ml	63,781	58,605	54,019	53,490
Hepatitis A vaccine	Inj 720 ELISA units in 0.5 ml syringe	346	372	168	194
	Inj 1440 ELISA units in 1 ml syringe	1,167	1,287	841	818
Hepatitis B recombinant vaccine	Inj 10 mcg per 0.5 ml prefilled syringe	5,687	6,221	2,789	3,419
	Inj 20 mcg per 1 ml prefilled syringe	14,420	16,290	15,342	12,190
Human papillomavirus vaccine	Inj 270 mcg in 0.5 ml syringe	160,930	184,390	167,460	126,930
Measles, mumps and rubella vaccine	Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml[7]	228,600	276,262	240,343	196,770
Meningococcal (groups A, C, Y and W-135) conjugate vaccine	Inj 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial	20,328	15,257	13,418	12,515

[7] Usage of measles, mumps and rubella vaccine were impacted by a measles outbreak in 2019, and subsequent catch-up programmes in 2020 and 2021.

Meningococcal C conjugate vaccine	Inj 10 mcg in 0.5 ml syringe	255	174	120	127
Pneumococcal (PCV10) conjugate vaccine[8]	Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe	231,970	230,050	180,330[9]	173,890
Pneumococcal vaccine (PCV13)	Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5 ml syringe	3,101	4,743	3,863	4,336
Pneumococcal (PPV23) polysaccharide vaccine	Inj 575 mcg in 0.5 ml vial (25 mcg of each 23 pneumococcal serotype)	5,035	6,884	4,878	3,484
Poliomyelitis vaccine	Inj 80D antigen units in 0.5 ml syringe	7,567	8,231	5,857	5,582
Rotavirus oral vaccine	Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator	106,900	109,910	107,210	111,520
Varicella vaccine	Inj 1350 PFU prefilled syringe	71,170	64,347	55,201	64,077
Tuberculin PPD (Mantoux) test	Inj 5 TU per 0.1ml, 1ml vial	7,980	3,140	5,630	4,280

[8] From 1 December 2022 Pharmac has widened eligibility to the PCV13 vaccine to allow all children to receive three doses of PCV13 instead of PCV10. We anticipate usage rates of PCV13 or PCV15 would be similar to those noted for PCV10 and PCV13 combined above.
[9] PCV10 was changed from a 4 dose regimen to a 3 dose regimen in 2021.

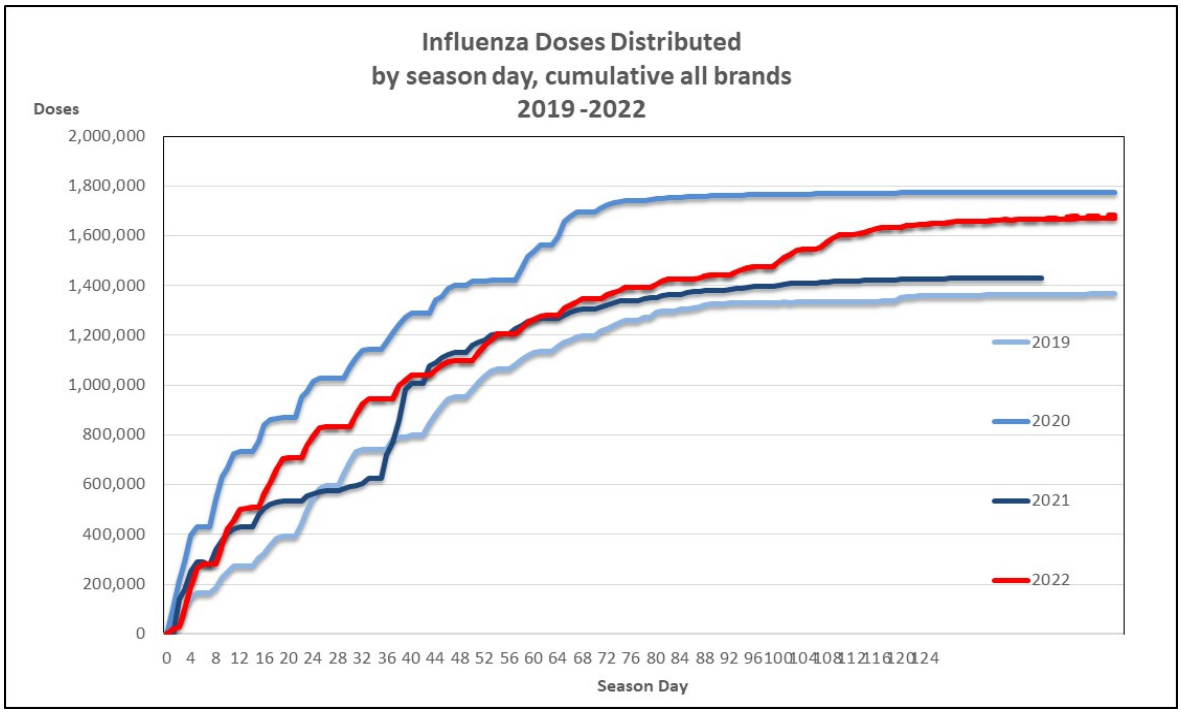
The following information relates to the estimated subsidised market size for Influenza Vaccine. Of note, the global COVID-19 pandemic and associated public health measures will have affected the uptake this vaccine. The information is approximate and indicative only. Pharmac makes no representation as to the accuracy of this information or as to the level of sales or likely sales of Influenza Vaccine 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.

Vaccine	**Formulation**	**Units Distributed Per Calendar Year (funded and private markets)**			
		2019	**2020**	**2021**	**2022** [10]
Influenza vaccine	Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) [11]	n/a	20,643	10,738	20,000
	Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine / adjuvanted quadrivalent vaccine)	1,371,028	1,754,823	1,421,418	1,656,000

Year	Total influenza vaccines distributed (private and funded)	Total vaccines subsidised in the community and purchased by DHB (Te Whatu Ora) hospitals
2013	1,250,000	718,000
2014	1,210,000	699,000
2015	1,210,000	693,000
2016	1,250,000	695,000
2017	1,220,000	693,000
2018	1,310,000	739,000
2019	1,370,000	764,000
2020	1,780,000	928,000
2021	1,430,000	795,000
2022	1,660,000	*Not available*

[10] Approximate – data is subject to change due to stock returns and some minor late season distribution.
[11] In 2019, inj 60 mcg in 0.5 ml syringe (Influvac Tetra) was indicated for the paediatric population. In 2020, inj 30 mcg in 0.25 ml syringe (Afluria Quad Junior) was indicated for paediatrics aged between 6-59 months. In 2021, inj 30 mcg in 0.25 ml syringe (Afluria Quad Junior) was indicated for paediatrics aged between 6-35 months.

As illustrated by the figure below, in a typical annual influenza immunisation programme, half of all vaccines are ordered within the first month. After approximately two months, demand for vaccines typically becomes flatter, and orders in the latter half of the programme are much lower. Demand patterns are also affected by weekends and public holidays.



In 2022 influenza vaccine was distributed to primary care, pharmacies, Te Whatu Ora hospitals and private providers. The breakdown is given in the table below:

Provider Type	**% of total distributed in 2022**
Primary Care	55%
Pharmacy	26%
Te Whatu Ora Hospitals	12%
Private Providers	7%

Schedule 4: Proposal form

An electronic version of this form is available on GETS.
You should expand the boxes as necessary.

[*Supplier to insert date*]

Pharmac Director of Operations
C/- Catherine Kingsbury
Procurement Specialist
Pharmac

Tēnā koe

Proposal for the supply of vaccine(s) – commercial in confidence

In response to your request for proposals (**RFP**) dated **11 November 2022** we put forward the following proposal in respect of vaccines.

Set out below is further information in support of our proposal.

a) 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]*
Postal address:	*[e.g. P.O Box address]*
Registered office:	*[if you have a registered office insert the address here]*
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 e.g. NZBN number]*

Does your organisation identify as being a Māori business? 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).	*[Yes / No]* *As part of adopting a progressive procurement policy, Pharmac are committed to understand and support 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	*[Yes / No]*

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.	

b) Our point of Contact

Contact person:	*[i.e., who communications relating to the response(s) should be made to]*
Position:	
Phone number:	
Mobile number:	
Email address:	

c) Information about our organisation:

Information about our Organisation structure:	*[you may embed organisational charts or similar]*
Information about our management and technical skills:	
Information about our financial resources:	
Information about our quality assurance processes:	
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	
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: • 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	

d) Details of pharmaceutical presentation:

Pharmac's preference is for all of the vaccine details to be submitted in the embedded spreadsheet (also available via GETS):

Schedule 4
Question (b) Form.xl

Chemical name	
Vaccine (eg Hepatitis A)	
Full description of the vaccine formulation and potency (label claim)	
Presentation (eg pre-filled syringe, individual vial, multi-dose vial)	
Needle specification	
Needle included or available separately	
Route of administration (eg subcutaneous, intramuscular)	
Pack size (eg 1's, 10's)	
Shelf life/storage of the vaccine	
Lead time	
Batch size	
Preferred order size	
Approximate manufacture time	
Approximate time for shipping (Air)	
Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
OR Expected date of dossier submission to Medsafe	
Insert any other consents required for vaccine	
If the vaccine is not currently registered in New Zealand, what countries is it registered in?	

Name and address of manufacturer(s) of the vaccine	

e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for Pharmac (for example but not limited to price in return for sole supply):

- Suppliers are welcome to submit more than one proposal, each will be considered separately. Proposals must be clear about what the price relates to, for example:
    - Proposals for a single vaccine with principal supply status.
    - Current eligibility criteria or any potential eligibility criteria changes outlined in Schedule 1 Clause 2.1 of this RFP.
- If you wish to submit a proposal for any potential eligibility criteria changes outlined in Schedule 1 Clause 2.1, you must submit a proposal for the current eligibility criteria.
- When submitting pricing please refer to Schedule 1 Proposal Pricing:

f) Key features of our proposal not detailed elsewhere in our response:

g) Information supporting the stability of offered vaccines when exposed to temperatures outside of the cold chain (2-8C).

h) Information about our ability to ensure the continuity of supply of the vaccine:

i) Information about our previous supply performance and relevant expertise:

j) Proposals/suggestions regarding the vaccine not expressly identified in this RFP that we would like Pharmac to consider as part of our proposal:

k) Any feedback on the proposed terms and conditions for the supply of vaccines attached as Schedule 5 via GETS:

l) Information about labour and human rights:

How much visibility does your Organisation have over your supply chain? Please select one of the below options and explain why you have selected this option: **High:** you have mapped the full supply chain for key products and services used by your organisation and have identified key suppliers at all levels of your supply chain. **Moderate**: you have identified major suppliers and have partially or fully mapped the supply chains for key products and services of your supply chain. **Developing**: you have identified major suppliers. You have very limited or no visibility of your supply chains for key products and services of your supply chain. **Other**: outline the current status of your supply chain visibility				
Does your organisation have a policy or policies in place to deal with modern slavery and worker exploitation	Yes		No	
Does your organisation have systems to monitor compliance with	Yes		No	

these policies?				
If you said yes to either of the two above questions, please attach or link. If the answer is no, please provide information on what your organisation is doing, or plan to do, to manage modern slavery and worker exploitation risk.				
Does your organisation perform due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains?	Yes		No	
If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns. If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future?				
Does your organisation comply with any recognised standards?	Yes		No	
If yes, please identify the standard and outline the degree to which your organisation complies.				

m) Information about environmental sustainability aspects of our company:

Does our Organisation have an environmental/sustainability policy?	Yes		No	
Does our Organisation have a sustainability report?	Yes		No	
If yes to either of the two above questions, please				

attach or link:					
How does our Organisation contribute to environmental sustainability?	*Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this Invitation*				
Has our Organisation received any environmental/sustainability award(s)?		Yes		No	
If yes, provide details:					
Has our Organisation received any environmental fine/prosecution(s)?		Yes		No	
If yes, provide details:					
Has our Organisation received any environmental audit(s) or does it comply with a recognised standard?		Yes		No	
If yes, provide details:					

Schedule 5: Proposed terms and conditions for supply of vaccines

Proposed terms and conditions for the Various Vaccines can be found in Attachment One. Please note that these terms only apply to Various Vaccines.

Proposed terms and conditions for the Influenza Vaccines can be found in Attachment Two. These terms and conditions are based on Pharmac's standard terms and conditions for listing pharmaceuticals on the Pharmaceutical Schedule. In addition, special terms shall be included in any provisional agreement, including but not limited to those provisions set out in Schedule 1, clause 2.2 of this RFP.