PHARMAC
Pharmaceutical Management Agency

20 November 2018

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Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF VARIOUS VACCINES AND INFLUENZA VACCINES

PHARMAC invites proposals for the supply of Various Vaccines and Influenza Vaccines in New Zealand.

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

- Schedule 1 specifies the vaccines 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 funded market for the Various Vaccines and Influenza Vaccines;
- 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 supply of Various Vaccines and Influenza 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 December 2018**.

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 non-influenza vaccines and a diagnostic agent ("Various Vaccines") and influenza vaccines ("Influenza Vaccines") set out in Tables 1 and 2 below:

Table 1. Currently funded vaccines

Vaccine description	Currently funded brand(s)
Various Vaccines	
Adult diphtheria and tetanus vaccine	ADT Booster
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	HBvaxPRO
Human papillomavirus vaccine	Gardasil 9
Measles, mumps and rubella vaccine	Priorix
Meningococcal (groups A, C, Y and W-135) conjugate vaccine	Menactra
Meningococcal C congugated vaccine	Neisvac-C
Pneumococcal (PCV10) conjugate vaccine	Synflorix
Pneumococcal (PCV13) vaccine	Prevenar 13
Pneumococcal (PPV23) polysaccharide vaccine	Pneumovax 23
Poliomyelitis vaccine	IPOL
Rotavirus oral vaccine	Rotarix
Varicella vaccine	Varilrix
Tuberculin PPD (Mantoux) test (a diagnostic agent)	Tubersol
Influenza Vaccines	
Influenza vaccine (quadrivalent inactivated)	Influvac Tetra & Fluarix Tetra

Table 2. Currently unfunded vaccines

Vaccine description
Various Vaccines
Meningococcal B vaccine
Measles, mumps, rubella and varicella vaccine
Influenza Vaccines
Adjuvanted influenza vaccine (quadrivalent or trivalent)
High dose influenza vaccine (quadrivalent or trivalent)
Live attenuated influenza vaccine (intranasal)

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

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 any changes to the National Immunisation Schedule vaccines, including the eligibility criteria, funding of new vaccines and managing the supply of vaccines needed for localised and national disease outbreaks.

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://www.pharmac.govt.nz/wwwtrs/ScheduleOnline.php?code=A45

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

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

PHARMAC first issued an RFP for the supply of Various Vaccines in June 2013, which resulted in agreements with five suppliers. The first Influenza Vaccines RFP was also issued in June 20004 and resulted in agreements with two suppliers.

PHARMAC released its second RFP for the supply of Various Vaccines in February 2016, which resulted in agreements with five suppliers (GSK, MSD, Pfizer, Sanofi and Seqirus), sole supply status for the Various Vaccines covered by these agreements expires on 30 June 2020.

A separate RFP for the supply of Influenza Vaccines was issued in February 2016 and resulted in a sole supply agreement with one supplier. Sole supply status for Influenza Vaccines expires on 31 December 2019. Influenza Vaccines supply covers a different period to Various Vaccines as it aligns with the seasonal influenza season and the circulating influenza strains and vaccine must be manufactured for each influenza season.

PHARMAC is now seeking proposals for the supply of Various Vaccines and Influenza Vaccines as stated in Table 1 and 2 above, including proposals for sole supply of:

- Various Vaccines during the period 1 October 2020 to 30 June 2024; and
- Influenza Vaccines for the 2020, 2021, 2022 and 2023 influenza seasons.

In preparation for this RFP, in March 2018 PHARMAC requested that suppliers submit applications to PHARMAC for funding of any new or alternative brands of vaccines they may have available for supply from 2020 and any proposed changes to the funding eligibility criteria for the National Immunisation Schedule.

PHARMAC subsequently sought clinical advice from the Immunisation Subcommittee of PTAC on:

- the suitability of new vaccines recently approved by Medsafe or planned to be approved in time for 2020 supply;

- interchangeability of alternative brands; and
- possible funding eligibility criteria changes.

The Immunisation Subcommittee of PTAC minutes are available on our website at:

http://www.pharmac.health.nz/about/committees/ptac/ptac-subcommittees/

The minutes of the September 2018 meeting of the Immunisation Subcommittee of PTAC are expected to be published on our website by early December 2018.

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 which are funded are on our website:

https://www.pharmac.govt.nz/wwwtrs/ScheduleOnline.php?code=A452501.

As part of this RFP process, PHARMAC may consider listing new vaccines or amending the eligibility criteria, subject to clinical advice, for the Various Vaccines described below:

Meningococcal B vaccine

PHARMAC is interested in proposals that would enable inclusion of a meningococcal B vaccine in the Infant Immunisation Schedule with a 2+1 dosing schedule and the immunisation of high-risk groups and close contacts of cases, possibly with catch-up programme.

Meningococcal (groups A, C, Y and W-135) conjugate vaccine

PHARMAC is interested in proposals that would enable widening of access for the meningococcal conjugate vaccine to include children aged 1-4 years old, possibly with catch-up programme. For some meningococcal vaccines, children under 24 months of age require a 2-dose schedule.

Measles, mumps, rubella and varicella vaccine

MMR vaccination and varicella vaccination are currently funded for certain populations as separate vaccines. PHARMAC is interested in proposals that would enable inclusion of a combined vaccine for MMR and varicella in the Immunisation Schedule for certain populations in addition to the separate vaccines.

Distribution

Suppliers are required to comply with the WHO guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23), as amended from time to time, and 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) for Various Vaccines as a result of this RFP process would be evergreen and would include a maximum sole supply period, from no earlier than 1 October 2020 to no later than 30 June 2024. During this period the eligibility criteria may change and would be subject to any contractual provisions.

Transition periods

Where new brands of Various Vaccines are awarded sole supply 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 periods of these transition periods are as follows:

(a) 1st transition period from 1 July 2020 to 30 September 2020; and

(b) 2nd transition period from 1 July 2024 to 30 September 2024.

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

2.2 Influenza Vaccines

Eligibility Criteria

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

https://www.pharmac.govt.nz/wwwtrs/ScheduleOnline.php?osq=Influenza vaccine&code=C4525013804.

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

Adjuvanted influenza vaccine

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

High dose influenza vaccine

PHARMAC is interested in proposals that would enable funding for adults aged 65 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 listing the above products from a later date if not Medsafe approved in time for the 2020 Southern Hemisphere influenza season.

Distribution

Suppliers are required to comply with the WHO guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23), as amended from time to time, and all storage and cold chain distribution requirements under their Licence to Sell by Wholesale.

It is PHARMAC's preference that 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, free fax and online ordering system that immunisation providers could use to place orders. The ordering system would need to be in place by 1 February 2020 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 District Health Board (DHB) area, not just the total sales for the country. The reports would be required to be supplied to PHARMAC on a monthly basis in an electronic Excel spreadsheet format with sales volumes reported on a per week basis. Suppliers would also endeavour to meet any reasonable data requests from PHARMAC, this could include stock on hand data.

Claiming – influenza vaccine

Currently, the immunisation provider purchases influenza vaccine from the supplier's distributor and the provider is reimbursed through claims made to the DHBs' payment agent, Sector Services, 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 a period of four influenza immunisation programme years from 2020 until the end of 2023 (31 December 2023). During this period the eligibility criteria may change and would be subject to any contractual provisions.

Promotion

The Ministry of Health 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 exclusivity to be suspended in the event of an influenza pandemic. The provisions would reflect compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

3. **Types of proposals sought**

Various Vaccines

Sole Supply

Sole supply status would entail both sole subsidised supply in the community via a listing in Section I of the Pharmaceutical Schedule (i.e. the National Immunisation Schedule) and hospital supply status in Part II of Section H of the Pharmaceutical Schedule.

PHARMAC is willing to consider the following types of proposals for sole supply status, where the supplier is expected to meet the demand for all doses of that vaccine, from no earlier than **1 October 2020** to no later than **30 June 2024**:

(a) Proposals for a single vaccine with sole supply status.

(b) Proposals that bundle multiple vaccines (including Influenza Vaccines) with sole supply status provided that if a bundle includes a currently unfunded vaccine a version of the bundle must also be submitted without the unfunded vaccine.

Suppliers may submit multiple proposals for a single vaccine or bundles of vaccines as described in clause 3 (a) and (b) above.

Please note if you wish to submit a bundle proposal for vaccines, you must also submit at least one individual proposal for each of the vaccines included in the bundle.

Please also note that if a bundle proposes sole supply status for the influenza vaccine a dual supply option must also be included.

Outbreak supply

(a) PHARMAC also seeks proposals for the supply of the vaccines stated below to be used in the event of a disease outbreak. Suppliers of such vaccines would be required to guarantee delivery within a short timeframe.

  (i) Meningococcal A, C, Y and W135 or Meningococcal C conjugate vaccines

  (ii) Meningococcal B

  (iii) Measles

  (iv) Hepatitis A

(b) Proposals should outline the supplier's or nominated distributor's capabilities in meeting any delivery timeframes, requirements (e.g. 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 (see Schedule 5). The proposed provisions reflect compliance with any Ministry of Health and WHO requirements with regard to pandemic supply situations.

Other types of proposals

Suppliers may also wish to submit other types of proposals, for example:

(a) proposals that include rebate arrangements, where the purchase price may be different from the net price offered to PHARMAC for the vaccine; and

(b) Proposals that 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 access, you must also submit a proposal for the current access 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 that could be listed in Section I or Part II of Section H of the Pharmaceutical Schedule to allow for any pilot for vaccine distribution, which may occur.

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 sole supply period ending on 30 June 2024. Any resulting contract(s) would specify the supply arrangements after the sole supply period.

Influenza Vaccine – Quadrivalent inactivated influenza vaccine

Suppliers must submit two proposals for inactivated quadrivalent influenza vaccine, being one for each of the following:

- subsidised supply for a maximum period of four annual influenza immunisation programmes until the end of 2023 (31 December 2023), where the supplier meets the demand for doses of influenza vaccine ("Routine Supplier"), other than up to 250,000 initial doses that would be supplied by an alternative supplier; and

- a proposal to be the supplier of a fixed volume of an initial 250,000 doses that are to be supplied by 15 March of the relevant annual influenza immunisation programme, which would occur prior to the supply of the annual influenza vaccine by the Routine Supplier.

Suppliers may in addition to the above two proposals exercise an option to submit a proposal in relation to a sole subsidised supply arrangement for:

- sole subsidised supply for a maximum period of four annual influenza immunisation programmes until the end of 2023 (31 December), where the supplier meets the demand for all funded doses of annual inactivated quadrivalent influenza vaccine.

Note that if other influenza products are funded for specific populations this would impact the market size of the inactivated quadrivalent influenza vaccine market.

Any award of sole subsidised supply would include hospital sole supply (HSS), however DHB purchases for their own occupational health requirements would not be subject to HSS provisions. For the avoidance of doubt, DHBs would be permitted to purchase any brand of Influenza Vaccine for their occupational health use.

Suppliers may also exercise an option to submit other types of proposals, including but not limited to:

- supply of a fixed volume of doses per year. Note, it is possible agreement(s) would be necessary with other suppliers to ensure sufficient stock was supplied to cover the entire market and therefore if a proposal of this type is submitted there could be no restriction on any other supplier also being subsidised.

- listed subsidised supply at a secured price for a period to be specified in the proposal. Note this type of proposal could not involve any restriction on any other supplier also being subsidised.

PHARMAC is aware that, under a multiple supplier arrangement, it is possible PHARMAC would be required to have some co-ordination role in the distribution of the influenza vaccines; this would be negotiated with the applicable suppliers if necessary. However, please note that PHARMAC does not intend to contract with a distributor itself or to manage any payments for distribution services.

In addition to the above proposals for fixed volume supply or listed subsidised supply, 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

Note that the above vaccines would be listed in addition to the quadrivalent inactivated influenza vaccine.

Suppliers must submit proposals that do not include any change to the current Pharmaceutical Schedule list price of influenza vaccines ($9.00 per unit) for inactivated quadrivalent inactivated influenza vaccines.

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*

(iii) vaccines for disease outbreaks described in clause 3 above.

(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.

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

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 December 2018**. 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.

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 PTAC, its relevant subcommittee, 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, its relevant subcommittee, 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 Board approval (or approval by the Board's delegate acting under delegated authority).

(b) PHARMAC will not consider any counter-offers received during consultation.

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

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

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

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

(ii) the termination of the RFP process.

6. Miscellaneous

(a) PHARMAC reserves the right, 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 its relevant subcommittee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such

time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your proposal.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of 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 DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

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

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

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

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

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

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in January 2019;

(ii) negotiating with submitter(s) of one or more preferred proposals in March/April 2019;

(iii) consulting on any provisional agreement in April/May 2019;

(iv) PHARMAC's Board, or the Board's delegate, making a decision in June 2019

(v) Public notification of any decisions in June/July 2019,

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(b) Under this indicative timetable, PHARMAC expects to have changes made to the Pharmaceutical Schedule by 1 July 2020 for Various Vaccines and by January 2020 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.

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		
		2016 FYR	2017 FYR	2018 FYR
Adult diphtheria and tetanus vaccine	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml	172,000	160,000	164,000
Bacillus Calmette-Guerin vaccine	Inj *Mycobacterium bovis* BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent	10,000	0*	0*
Diphtheria, tetanus and pertussis vaccine	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	103,000	106,000	113,000
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 virus in 0.5ml syringe	68,000	67,000	65,000
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	180,000	180,000	179,000
Haemophilus influenzae type B vaccine	Inj 10 mcg vial with diluent syringe	62,000	60,000	61,000

Hepatitis A vaccine	Inj 1440 ELISA units in 1 ml syringe	600	800	1,000
	Inj 720 ELISA units in 0.5 ml syringe	300	200	300
Hepatitis B recombinant vaccine	Inj 5 mcg per 0.5 ml vial	7,700	7,500	5,000
	Inj 10 mcg per 1 ml vial	10,200	9,900	4,500
	Inj 40 mcg per 1 ml vial	1,200	1,300	1,600
Human papillomavirus vaccine	Inj 120 mcg in 0.5 ml syringe	79,000	115,000	173,000
Measles, mumps and rubella vaccine	Inj 1000 TCID50 measles, 12500 TCID50 mumps and 1000 TCID50 rubella vial with diluent 0.5 ml vial	151,000	142,000	153,000
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	1,600	1,800	2,300
Meningococcal C conjugate vaccine	Inj 10 mcg in 0.5 ml syringe	100	200	200
Pneumococcal vaccine	Inj 30.8 mcg in 0.5 ml syringe	239,000	236,000	243,000
Pneumococcal (PPV23) polysaccharide vaccine	Inj 575 mcg in 0.5 ml vial (25 mcg of each 23 pneumococcal serotype)	5,000	4,000	5,000
Poliomyelitis vaccine	Inj 80D antigen units in 0.5 ml syringe	5,000	5,000	5,000
Rotavirus live reassortant oral vaccine	Oral susp G1, G2, G3, G4, P1(8)11.5 million CCID50 units per 2 ml, tube	167,000	166,000	116,000

Varicella vaccine	Inj 2000 PFU vial with diluent	1,000	13,000	66,000
Tuberculin PPD (Mantoux) test	Inj 5 TU PPD-S per 0.1ml, 1ml vial	0	0	6,000

* Bacillus Calmette-Guerin vaccine was affected by a global stock shortage

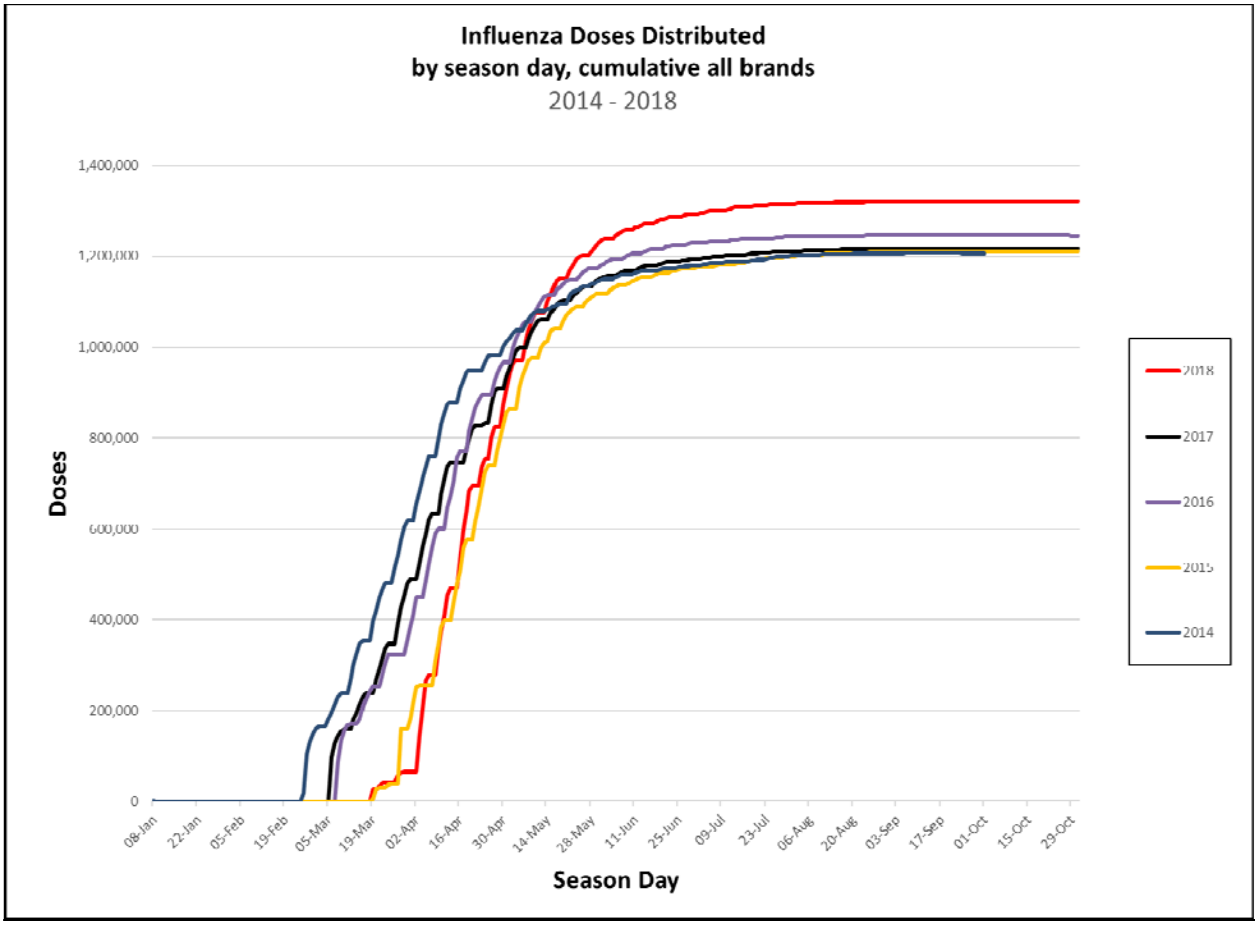
The following information relates to the estimated subsidised market size for Influenza Vaccine. The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of Influenza Vaccine and, while PHARMAC 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.

Year	Total vaccines distributed (private and funded)	Total vaccines subsidised in the community
2013	1,250,000	718,000
2014	1,210,000	687,000
2015	1,210,000	707,000
2016	1,270,000	767,000
2017	1,220,000	673,000
2018*	1,330,000	Not currently available

*Data up to 12 November 2018

The Ministry of Health currently aims to have 1.2 million vaccines distributed each year (private and funded). The Ministry could alter this target in the future.

In a typical annual influenza immunisation programme, half of all vaccines are ordered within the first month. After approximately two months, we typically see demand becoming much flatter, and orders in the latter half of the programme are much lower. Demand patterns are also affected by weekends and public holidays.



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*]

Andrew Oliver
Therapeutic Group Manger
PHARMAC

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

Dear Sir

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

In response to your request for proposals (**RFP**) dated 20 November 2018, we put forward the following proposal in respect of the supply of vaccine(s).

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

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of vaccine presentation(s):

- 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

Brand name	
Vaccine (e.g Hepatitis A)	
Full description of the vaccine formulation and potency (label claim)	
Presentation (e.g pre-filled syringe, individual vial, multi-dose vial)	
Needle specification	
Needle included or available separately	

Route of administration (e.g. subcutaneous, intramuscular)	
Pack size (e.g. 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	

(c) 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 sole supply status.
    - Proposals that bundle multiple vaccines with sole 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 bundle proposal for vaccines, you must also submit at least one individual proposal for each of the vaccines included in the bundle.
- 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 access criteria.
- When submitting pricing please refer to Schedule 1 Proposal Pricing:

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

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

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

(g) Information about our previous supply performance and relevant expertise:

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

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

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.