

APPENDIX 4

Draft services agreement

[Date]

[Address]

Dear []

PHARMAC agrees to contract with **[name of service provider]** for the supply of national vaccine storage and distribution services on the terms set out in this letter and the attached General Terms and Schedules (together forming this “**Agreement**”).

Schedules

- Schedule 1 – Special Obligations
- Schedule 2 – Service Specification

Acceptance

To confirm your acceptance of this Agreement, please sign and return the attached copy of this Agreement to PHARMAC by **[insert time]** pm on **[insert date]**.

Yours faithfully

Signed and agreed by:

[PHARMAC signatory]

[service provider signatory]

Name:

Position:

Date:

GENERAL TERMS

Definitions

In these General Terms unless the context otherwise requires:

“Agreement” means this agreement including all Schedules;

“Alternative Vaccine” means additional stock of the Vaccine or an alternative brand of a Vaccine that PHARMAC, following such consultation as it considers necessary with PTAC and its sub-committees considers to be an acceptable substitute for that Vaccine;

“Authorised Agent” means PHARMAC’s agent who is supplied the Vaccine from a pharmaceutical supplier, as notified to you by PHARMAC from time to time;

“Business Day” means Monday to Friday, excluding public holidays;

“Cold Chain” means the validated system of transporting and storing Vaccines within the safe temperature range of +2 degrees to +8 degrees Celsius (°C) in full compliance with the Cold Chain Standards;

“Cold Chain Conditions” means the storage of Vaccines in accordance with Cold Chain;

“Cold Chain Standards” means the “New Zealand Immunisation Advisory Centre (IMAC) National Guidelines for Vaccine Storage and Distribution 2012”, as amended from time to time, to the extent that they are applicable to the Vaccine;

“DHB Hospital” means a DHB, including its hospital;

“District Health Board” (or **“DHB”**) has the same meaning as in the New Zealand Public Health and Disability Act 2000;

“Force Majeure Event” means an event that is beyond the reasonable control of the party immediately affected by the event. A Force Majeure Event does not include any risk or event that the party claiming could have prevented or overcome by taking reasonable care, including by managing such risk in any sub-contracting arrangements. Examples include:

- (a) acts of God, lightning strikes, earthquakes, tsunamis, volcanic eruptions, floods, storms, explosions, fires, pandemics and any natural disaster;
- (b) acts of war (whether declared or not), invasion, actions of foreign enemies, military mobilisation, requisition or embargo;
- (c) acts of public enemies, terrorism, riots, civil commotion, malicious damage, sabotage, rebellion, insurrection, revolution or military usurped power or civil war; or
- (d) contamination by radioactivity from nuclear substances or germ warfare or other hazardous properties,

and for the avoidance of doubt:

- (a) any failure on the part of a person in the relevant pharmaceutical supply chain; or
- (b) any act or omission by a related entity or sub-contractor of yours,

is not considered by PHARMAC to constitute a Force Majeure Event;

“Immunisation Provider” means individuals or organisations licenced by the Ministry of Health to administer vaccines;

“National Cold Chain Audit” means the audit conducted by the Authorised Agent to monitor the Cold Chain accreditation process and other existing or new Cold Chain management interventions;

“PHARMAC” means the Pharmaceutical Management Agency established under the New Zealand Public Health and Disability Act 2000;

“Services” means the services to be provided by you to PHARMAC which are set out in Schedule 2; and

“Vaccine” means the vaccines currently described in Schedule 1 and as notified to you by PHARMAC from time to time, in the form and strength set out in Schedule 1, which term for the avoidance of doubt includes vaccines or antigens.

1. Operating Policies and Procedures

You acknowledge that:

- (i) PHARMAC is required to pursue the objectives, carry out the functions, and otherwise comply with the statutory obligations, prescribed for PHARMAC in the New Zealand Public Health and Disability Act 2000;
- (ii) PHARMAC is subject to other statutory and public law obligations, which govern PHARMAC’s decision-making processes;
- (iii) PHARMAC has Operating Policies and Procedures (“OPPs”), which provide guidance on the way in which PHARMAC carries out its statutory responsibilities in relation to the management of the Pharmaceutical Schedule;
- (iv) PHARMAC’s OPPs may be amended or updated from time to time, following consultation with relevant groups;
- (v) the actions which PHARMAC may take under its OPPs include (without limitation):
 - (A) listing new pharmaceuticals;
 - (B) changing guidelines or restrictions on the prescribing and dispensing of listed pharmaceuticals;

- (C) changing the subsidy levels for pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in the OPPs or by any other means;
- (D) amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups;
- (E) delisting pharmaceuticals, or delisting all or part of a therapeutic group or sub-group;
- (F) changing the market dynamics for pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in the OPPs;
- (G) any action taken by PHARMAC pursuant to its OPPs may impact on the listing of a pharmaceutical;
- (H) PHARMAC agrees not to apply, amend or update its OPPs in order to avoid any of PHARMAC's obligations under this Agreement.

2. Term

This Agreement commences upon 1 July 2017 and expires on 30 June 2020 (inclusive) unless otherwise terminated in accordance with Clause 14.

3. Vaccine Services

You are to provide the Services as set out in Schedule 2.

4. Vaccine Recall and Disengagement Services

- (a) In the event the Ministry of Health or any other authority recalls a Vaccine, you shall co-operate fully and comply with any instruction provided to you by PHARMAC.
- (b) Upon the expiry or termination of this Agreement you shall co-operate fully and comply with any instruction provided to you by PHARMAC in respect of any disengagement services required.

5. Emergency and Disaster Supply Arrangements

In the event of an emergency or disaster affecting you, any DHB district, any DHB Hospital, or an emergency or disaster on a national level, you will use your best endeavours to provide such quantities of the Vaccine as are required by any DHB Hospital(s) and in accordance with your disaster recovery contingency plans.

6. Invoicing and Payments

- (a) The payments required to be made by PHARMAC to you are set out in Schedule 1 for the provision of the Services.
- (b) The cost structure of the budget for the Services is set out in Clause 3 of Schedule 1.

- (c) You are to provide a proforma invoice to PHARMAC on **[insert date of invoice]** for the amounts specified in Clause 2 (a) of Schedule 1.
- (d) Provided that the Services have been supplied in accordance with this Agreement, and PHARMAC receives an invoice in accordance with paragraph (c) above, payment by PHARMAC to you of the amount required to be paid by it is expected to occur:
 - (i) by electronic funds transfer or such other method of payment as is designated by PHARMAC;
 - (ii) on the 20th day of the month following the month to which the invoice for the Services relates, or, if the 20th day of the month is not a Business Day, then on the next Business Day following the 20th of the month.
- (e) PHARMAC's failure to dispute any invoice prior to payment does not prejudice PHARMAC's right subsequently to dispute the correctness of such an invoice, nor its ability to recover any amount of overpayment from you.
- (f) PHARMAC may withhold, deduct or set off the amount of any overpayment or any amount recoverable by it from you under this Agreement from any future amount owing to you.

7. Information and Reporting

- (a) You will report to PHARMAC, in a form to be prescribed by PHARMAC, on a monthly basis in relation to the matters specified below:
 - (i) Total Vaccine stock holding in packs (balance) for each pharmacode;
 - (ii) Total number of Vaccine (packs) distributed to each DHB by pharmacode;
 - (iii) Total number of Vaccine orders distributed to each DHB; and
 - (iv) Number of returned and destroyed Vaccine packs for each pharmacode, together with the reasons the Vaccine packs have been returned and the original despatch details.

The information to be provided in accordance with Clause 7 (a) above shall be provided within 10 Business Days of the end of the month relating to that information.

- (b) You will report to PHARMAC, in a form to be prescribed by PHARMAC on a six monthly basis, or upon request by PHARMAC, the number of Vaccine packs by pharmacode distributed to each Immunisation Provider.
- (c) You will report to the Ministry of Health or its nominated agent and PHARMAC in writing and otherwise in a form to be prescribed by PHARMAC, on a six monthly basis in relation to the matters specified below:
 - (i) Monthly number of data loggers distributed in actual numbers and as a percentage of orders dispatched;

- (ii) Historical monthly comparison over the previous 12 months; and
 - (iii) Number of data loggers returned out of spec including this number as a percentage of loggers distributed nationally.
- (d) You will provide Vaccine stock volume data to the Ministry of Health and the Authorised Agent on an ad-hoc basis if requested.
 - (e) You will report monthly, to the authorised agent responsible for conducting the National Cold Chain Audit with a list of Immunisation Providers that have been issued a National Cold Chain Audit monitoring card.
 - (f) You will reconcile all Vaccine insurance claims on a six monthly basis and provide details to PHARMAC.
 - (g) You will assist PHARMAC, the Ministry of Health and its nominated agent and the Authorised Agent with the distribution of information on Vaccines, Vaccine changes and funding changes.
 - (h) You will maintain an accurate database of Immunisation Providers and Immunisation Provider addresses in accordance with Clause **[Insert clause reference]** of Schedule 2 and PHARMAC accepts that the Medical Council website may be used for this purpose.

8. Audit

- (a) PHARMAC may, from time to time, review your records and any other information you hold that relates to this Agreement with regard to stock levels, registration information, and supply and Cold Chain issues, for the purposes of auditing your compliance with this Agreement. In these circumstances, PHARMAC, in consultation with you, will determine the terms and manner of any such audit (including at PHARMAC's sole discretion which party is accountable for the costs of the audit), which as a minimum, must include the following:
 - (i) the audit will be conducted by an auditor authorised by PHARMAC;
 - (ii) you agree to co-operate fully with PHARMAC and provide PHARMAC and the auditor with all reasonable assistance to ensure that any audit conducted under this clause is fully and properly completed to PHARMAC's satisfaction, including:
 - (A) allowing the auditor access to your premises, records and other information you hold that relates to this Agreement (including, without limitation, records that relate to stock levels, registration information and supply and Cold Chain issues) for the purposes of, and during the course of, conducting the audit; and
 - (B) answering promptly any questions from PHARMAC or the auditor concerning any aspect of your compliance with this Agreement; and
 - (iii) PHARMAC will give you ten 10 Business Days' notice of its intention to conduct an audit under this clause and will ensure that the conduct of any

such audit, and access in terms of sub-paragraph (A) above, does not unreasonably disrupt your business operations.

- (b) PHARMAC will notify you in writing if an audit under this clause reveals any non-compliance with this Agreement. You agree to remedy any non-compliance within 10 Business Days of receiving such notice from PHARMAC.
- (c) PHARMAC may terminate the Agreement if you fail to remedy any area of non-compliance in accordance with paragraph (b) above.

9. Notification

- (a) You shall advise PHARMAC immediately:
 - (i) of anything which may or is likely to materially reduce or affect your ability to provide the Services, including but not limited to loss of Vaccine stock due to a Cold Chain failure or anything relating to any premises or equipment used by you or your key personnel;
 - (ii) if you materially fail to comply with any of your obligations in this Agreement;
 - (iii) of any serious complaints or disputes which directly or indirectly relate to the provision of the Services; and
 - (iv) of any issues concerning the Services that might have high media or public interest.

10. Insurance

- (a) You shall arrange and maintain (including for a 12 month period after this Agreement ends, should it do so for any reason) adequate insurance policies for all Services under this Agreement with a minimum level of cover of NZD \$5 million per any one occurrence. You must notify PHARMAC of the level of each type of insurance held by you as soon as practicable after entering into this Agreement. If requested you will send a copy of the relevant policy renewals to PHARMAC. Whether or not insurance policies exist shall not derogate from your potential liability under this Agreement.
- (b) You will do nothing to invalidate the insurance policies that you hold as required under paragraph (a) above or to prejudice your entitlement under those insurance policies.
- (c) The payment of any excess relating to the insurance policies referred to in Clause 10 (a) shall be paid by you.
- (d) For the avoidance of doubt, this Clause 10 survives for a period of 12 months after this Agreement ends, should it do so for any reason.

11. Risk and Title

- (a) Risk in the Vaccines will pass to you upon delivery of the Vaccines to your designated premises as agreed by both parties and the signing of the consignment delivery note furnished with the Vaccines from the Authorised Agent who has

delivered the Vaccines to your premises and then only after the Vaccines have been quality inspected by you on unpacking to ensure the Vaccine is free of any damage relating to packing or out of specification data loggers ("Defective Vaccine"). For the avoidance of doubt an inspection shall be undertaken within 1 Business Day of receipt of the Vaccine and otherwise the risk in the Vaccine shall have been passed to you.

- (b) In the event that you find any Defective Vaccine, you will inform the Authorised Agent of such defects to allow the Authorised Agent to lodge a potential claim against the Authorised Agent's carrier.
- (c) Risk in the Vaccines will pass from you to the Immunisation Provider when the Immunisation Provider has signed the delivery note furnished with the Vaccines from you.
- (d) Title in the Vaccine will remain with PHARMAC at all times.

12. Indemnity

- (a) In addition to the obligations set out in Clause 9 above you must notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to distribute or store a Vaccine on the terms set out in, and in accordance with, this Agreement.
- (b) You agree to indemnify PHARMAC if for any reason you fail to distribute or store a Vaccine on the terms set out in, and in accordance with, this Agreement (other than for reasons where PHARMAC reasonably considers it to be wholly outside your control). This indemnity covers the purchase value of an Alternative Vaccine.

13. Default Interest and Recovery Costs

If payment of any amount required to be paid by PHARMAC or you under this Agreement is not made by either party, in full, by the due date for payment of that amount as notified by either party in writing, then:

- (a) interest will accrue on such sum as remains unpaid at a rate per annum equal to the business base rate of ASB Bank Limited plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from either party for such default interest; and
- (b) either party may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in Clause 19 below, to recover any outstanding amount and the party who owes the outstanding payment agrees to pay the actual enforcement costs incurred in relation to that action.

14. Termination

- (a) PHARMAC may terminate this Agreement by providing 30 Business Days written notice if you breach any clause of this Agreement, provided that (without prejudice to termination being effective at the end of the notice period in the absence of any written agreement to the contrary) PHARMAC agrees to negotiate with you during the 30 Business Day notice period over possible alternatives to termination.

- (b) Termination pursuant to paragraph (a) above will not affect any rights or obligations of either party arising from this Agreement prior to such termination, nor will it derogate from any other legal right or remedy available to PHARMAC under this Agreement or otherwise in respect of such breach.
- (c) For the avoidance of doubt, Clauses 10, 12 and 15 survive termination of this Agreement.

15. Confidentiality

The information stated in Clause 2 and 3 of Schedule 1 of this Agreement (“Confidential Information”) is confidential between you and PHARMAC, including each party’s employees, legal advisers, consultants and the Ministry of Health, the DHBs and their employees (if applicable). The parties acknowledge that it may be necessary or appropriate for PHARMAC to disclose Confidential Information:

- (a) pursuant to the Official Information Act 1982; or
- (b) 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 paragraphs (a) or (b) above, in order to ascertain any objections you may have to the disclosure of any of the Confidential Information. 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. Outside the circumstances described in paragraphs (a) and (b) above, Confidential Information must not be disclosed by either party (or by the party’s respective employees, legal advisers and other consultants) unless:

- (c) the information is publicly available without any cause attributable to the disclosing party; or
- (d) the other party has been reasonably informed prior to disclosure, and the disclosure is:
 - (i) for the purposes of this Agreement; or
 - (ii) required by law; or
 - (iii) in a form, and of content, agreed to by us.

For the avoidance of doubt information released by PHARMAC in accordance with paragraphs (a) or (b) above ceases to be “Confidential Information” and you agree that PHARMAC may release that information again at any time in future without consulting with you or obtaining your prior agreement.

16. Conflict of Interest

In the event that any conflict of interest arises during the term of this Agreement, you shall notify PHARMAC and PHARMAC shall at its sole discretion determine whether that conflict has an effect on this Agreement.

17. Consultation

This Agreement is conditional on:

- (a) PHARMAC completing any consultation it considers necessary or appropriate (including consultation under its Operating Policies and Procedures); and
- (b) in the event any such consultation takes place, approval of its terms by PHARMAC's Board (or by its delegate acting under delegated authority pursuant to section 73 of the Crown Entities Act 2004, where applicable).

18. Litigation Support

If this Agreement or its terms:

- (a) give rise to proceedings being issued against PHARMAC; or
- (b) result in PHARMAC being made a party to proceedings issued by a third party,

you will give PHARMAC all assistance it reasonably requires to gather evidence for the purpose of those proceedings.

19. Dispute Resolution

If there is a dispute between the parties arising out of, or in connection with, this Agreement, neither party is to commence any proceedings relating to that dispute until the following procedure has been complied with:

- (a) The party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute.
- (b) The parties will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.
- (c) In the event the parties do not agree on a dispute resolution technique within 10 Business Days after the date notice of a dispute was given, the dispute is to be mediated according to the standard mediation agreement of LEADR & IAMA (a body corporate incorporated in Australia, registered as an overseas company in New Zealand in accordance with Part 18 of the Companies Act 1993, trading as the Resolution Institute), and the Chair of LEADR & IAMA (or the Chair's nominee) will select the mediator and determine the mediator's remuneration.
- (d) A party seeking urgent interlocutory relief may, by notice to the other party, elect not to comply with the provisions of this clause, but only to the extent of the relief sought, and only for the period required to dispose of the application for interlocutory relief.
- (e) Pending resolution of the dispute, this Agreement will remain in full effect without prejudicing our respective rights and remedies (including PHARMAC's rights under Clause 1).

20. Force Majeure

- (a) Neither party will be liable to the other for any failure to perform its obligations under this Agreement during the time and to the extent that such performance is prevented, wholly or substantially, by reason of any Force Majeure Event. The party subject to the Force Majeure Event must:
- (i) notify the other party as soon as practicable after the Force Majeure Event occurs and to the extent it is able, provide full information concerning the Force Majeure Event, including the extent of its inability to perform, an estimate of time likely to be required to overcome the Force Majeure Event and the steps the party subject to the Force Majeure Event will take to comply with Clauses 20(a) (ii) and 20(a) (iii);
 - (ii) use its best endeavours to mitigate and remedy the effect of the Force Majeure Event and minimise the impact of the event on the other party; and
 - (iii) use its best endeavours to perform its obligations under this Agreement as far as is practicable,
- and PHARMAC will not be required to pay the payments stated in Schedule 1 to the extent that you have failed to perform your obligations due to a Force Majeure Event.
- (b) If the party affected by the Force Majeure Event is you, and the Services have been delayed by more than 30 Business Days, PHARMAC may terminate the Agreement by notice to you at no cost to PHARMAC.

21. Notices

Any notice under this Agreement may be made by email, letter or facsimile to the addresses advised by one party to the other.

22. Amendments to Pharmaceutical Schedule

- (a) PHARMAC will notify you prior to amending the Pharmaceutical Schedule where an amendment will result in a change to the volume of Vaccine supplied under this Agreement.
- (b) In the event you are notified under Clause 22 (a) the parties will enter into good faith negotiations in order to review the costs stated in **[Insert clause reference]** of Schedule 1.

23. Consents

You must maintain all consents necessary to fulfil your obligations under this Agreement, including but not limited to having a valid medicines wholesalers licence and comply with the New Zealand Code of Good Manufacturing and Warehousing Practice for Manufacture and Distribution of Therapeutic Goods, Parts 4 and 5.

24. No Derogation

The express provision of a remedy for, or consequence of, failure to comply with any term of this Agreement does not derogate from any other legal right or remedy available to PHARMAC under this Agreement or otherwise in respect of such breach.

25. No Waiver

A failure or delay by either party to exercise any right arising under this Agreement is not a waiver of that right, and a waiver of a breach of this Agreement is not a waiver of any other breach.

26. **Agreement Prevails**

Where any of your terms of supply, whether recorded on your invoices or in credit arrangements entered into or elsewhere, conflict with or detract from any of the terms of this Agreement, the terms of this Agreement will prevail and will apply to the exclusion of any of your terms or documentation.

27. **Entire Agreement**

This Agreement:

- (a) is the entire agreement between us regarding the terms on which the Services are supplied by you to PHARMAC; and
- (b) supersedes and extinguishes all prior agreements and understandings between us regarding the Services.

28. **Contracts Privity**

- (a) For the purposes of the Contracts (Privity) Act 1982, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on DHB Hospitals and Ministry of Health and related persons.
- (b) Except as expressly provided in paragraph (a) above, the parties do not intend to create rights in, or grant remedies to, any third party as a beneficiary to this Agreement, and all of the provisions of this Agreement shall be for the sole and exclusive benefit of the parties.
- (c) For the avoidance of doubt, you acknowledge that PHARMAC may pursue damages or any other claim (including injunctive or other such relief) under this Agreement on its own account in respect of any form of loss or damage incurred by PHARMAC and/or DHB Hospitals or the Ministry of Health.

29. **No Reliance**

You acknowledge that you have entered into this Agreement in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made, or any information made available to you, by PHARMAC.

30. **Amendments**

Amendments to this Agreement are only effective if in writing and signed by both of us.

31. **Assignment**

You will not permit this Agreement or any part of this Agreement, to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without PHARMAC's prior written consent (such consent not to be unreasonably withheld). Any

such consent may be given subject to such reasonable conditions as PHARMAC sees fit but no such consent will relieve you from any liability or obligation under the terms of the Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee, employees, agents or sub-contractors.

32. **Further Assurances**

We both agree to execute any further documents and do any further acts within our power as may be reasonably necessary from time to time to give effect to the terms and conditions of this Agreement.

33. **Governing Law and Jurisdiction**

This Agreement is governed by New Zealand law. We each submit to the exclusive jurisdiction of the New Zealand courts.

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Schedule 1
Special Obligations

1. Vaccines

| Vaccine | Proprietary name (manufacturer) of currently supplied vaccine | No of doses per pack |
|----------------|--|---------------------------------|
| | | |

2. Payments

- a. The following payment will be made to you by PHARMAC in accordance with Clause 6 (c) of the General Terms of this Agreement for all Services.

| | |
|--|--|
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3. Budget for the services

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Schedule 2

Service Specification

[Please refer to Appendix 1 of the RFP for the proposed Service Specification]

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