[*Date*]

[*Name and address*]

Dear [ ]

**TERMS OF LISTING OF [*insert brand name(s) of pharmaceutical(s)*] ON THE PHARMACEUTICAL SCHEDULE**

PHARMAC agrees to:

* list in Section I of the Pharmaceutical Schedule, with effect from [*insert* date], the pharmaceutical [*insert chemical entity*] (under the brand name **[*insert brand name*]**), as supplied by you in the form[s] and strength[s] set out in Annex One;
* list in Section H of the Pharmaceutical Schedule[, with effect from [*insert* date],] the pharmaceutical [*insert chemical entity*] (under the brand name **[*insert brand name*]**), as supplied by you in the form[s] and strength[s] set out in Annex One;
* amend[, with effect from [*insert* date],] the terms on which the pharmaceutical [*insert chemical entity*] (under the brand name **[*insert brand name*]**), as supplied by you in the form[s] and strength[s] set out in Annex One, is listed in Section I of the Pharmaceutical Schedule;
* amend[, with effect from [*insert* date],] the terms on which the pharmaceutical [*insert chemical entity*] (under the brand name **[*insert brand name*]**), as supplied by you in the form[s] and strength[s] set out in Annex One, is listed in Section H of the Pharmaceutical Schedule,

on the terms set out in this letter and the attached Annexes (together forming this “**Agreement**”).

In this Agreement:

* **“Funder”**, being a term used in this Agreement in relation to the subsidising of community pharmaceuticals, means the body or bodies responsible, pursuant to the New Zealand Public Health and Disability Act 2000, for the funding of pharmaceuticals listed in Sections A to G and I of the Pharmaceutical Schedule (which may be one or more District Health Boards and/or the Ministry of Health) and their successors acting through PHARMAC as agent for this purpose. References in this Agreement to the Pharmaceutical being “subsidised” for purposes of community supply may (according to the context) relate to the purchase price payable for the Pharmaceutical by the Funder, although the Pharmaceutical may in fact be listed in Section I of the Pharmaceutical Schedule at $0.00 to reflect the fact that the Pharmaceutical is provided free to vaccinators, such that no subsidy is claimed in respect of the cost of the Pharmaceutical (the cost of the service of vaccinating is, however, subsidised separately from this Agreement in the form of an immunisation benefit);
* “**Pharmaceutical**” means the pharmaceuticals described in Annex One, in the forms and strengths set out in Annex One, which for the avoidance of doubt includes vaccines or antigens;
* “**Section I**” means the relevant section or sections of the Pharmaceutical Schedule relating to the National Immunisation Schedule;
* “**Section H**” means the relevant section or sections of the Pharmaceutical Schedule relating to hospital pharmaceuticals;
* for a community Pharmaceutical that is subsidised by the Funder, references to the “**listing**” of a pharmaceutical are to the listing of that pharmaceutical on the Pharmaceutical Schedule (and references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly); and
* for a hospital Pharmaceutical that can be purchased by DHB Hospitals, references to the “**listing**” of a Pharmaceutical are to the listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule and are deemed to include any written notification by PHARMAC of that Pharmaceutical being the subject of a national supply contract negotiated by PHARMAC on behalf of DHBs, where such written notification is in advance of the actual listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule (and references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly).

**Annexes**

* Annex One describes each Pharmaceutical.
* Annex Two specifies the price at which each Pharmaceutical:
* listed in Section I of the Pharmaceutical Schedule is to be supplied, or made available for supply, by you to the Designated Delivery Point to thereafter be supplied to doctors and vaccinators, and at which that Pharmaceutical is to be subsidised by the Funder acting through its agent PHARMAC, unless another price is determined under Annex Three or Annex Four; and
* listed in Section H of the Pharmaceutical Schedule is to be supplied, or made available for supply, by you to the Designated Delivery Point to thereafter be supplied to DHB Hospitals, and at which the Pharmaceutical is to be paid for by the DHB Hospital acting through PHARMAC as agent for this purpose, unless another price is determined under Annex Three or Annex Four.
* Annex Three specifies the standard terms of listing of each Pharmaceutical listed in Section H and Section I of the Pharmaceutical Schedule.
* Annex Four specifies the special terms of listing for each Pharmaceutical listed in Section H and Section I of the Pharmaceutical Schedule.
* The special terms in Annex Four are to prevail if they conflict with any other terms of this Agreement.

**Acceptance**

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

|  |  |
| --- | --- |
| Yours faithfullyLisa WilliamsManager, Pharmaceutical Funding  | Signed and agreed by **[*insert name of pharmaceutical supplier*]** by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:Position:Date: |

**ANNEX ONE**

The Pharmaceutical means the following pharmaceutical[s], individually or collectively, according to the context:

**Table One: New listing in Section I of the Pharmaceutical Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Pharmaceutical* | *Defined Name* | *Form* | *Strength* | *Pack Size* |
|  |  |  |  |  |

**Table Two: New listing in Section H of the Pharmaceutical Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Pharmaceutical* | *Defined Name* | *Form* | *Strength* | *Pack Size* |
|  |  |  |  |  |

**Table Three: Amendment to listing in Section I of the Pharmaceutical Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Pharmaceutical* | *Defined Name* | *Form* | *Strength* | *Pack Size* |
|  |  |  |  |  |

**Table Four: Amendment to listing in Section H of the Pharmaceutical Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Pharmaceutical* | *Defined Name* | *Form* | *Strength* | *Pack Size* |
|  |  |  |  |  |

**ANNEX TWO**

**Price of Pharmaceutical**

|  |  |
| --- | --- |
| *Presentation of Pharmaceutical* | *Purchase Price**(Exclusive of GST)**($NZ)* |
|  |  |
|  |  |

**Note:**

Please refer to clause 4 of Annex Four which states the manufacturer’s price.

**ANNEX THREE**

**Terms of Listing in Section H and Section I of the Pharmaceutical Schedule**

1. **Definitions.**

In this Annex Three:

“**Agreed Delivery Date**” means the date of delivery of the Pharmaceutical to the Designated Delivery Point in accordance with the process set out in Schedule 1 for Purchase Orders;

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

**“Business Day**” means any day of the week, other than Saturday or Sunday, on which registered banks are open for business in Wellington;

“**Cold Chain**” means the validated system of transporting and storing vaccines within the safe temperature range of +2 degrees to +8 degrees Celsius and in accordance with the “New Zealand Immunisation Advisory Centre (IMAC) Vaccine Storage and Distribution National Standards” (available from <http://www.immune.org.nz/health-professionals/cold-chain>), as amended from time to time, to the extent that they are applicable to the Pharmaceutical;

**“Crown Direction”** means any Ministerial direction given to PHARMAC under section 103 of the Crown Entities Act 2004;

**“Delivery”** means the delivery by you of the Pharmaceuticals to, and the receipt of, the Pharmaceuticals at the Designated Delivery Point;

“**Designated Delivery Point**”means the address in New Zealand to which you must deliver a Pharmaceutical, which will be the Service Provider’s address stated in a Purchase Order;

**“DHB Hospital”** means a DHB, including its hospital or associated provider unit for which that District Health Board purchases pharmaceuticals;

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

**“Local Outbreak”** means the occurrence of a vaccine preventable [disease](http://en.wikipedia.org/wiki/Disease) greater than would otherwise be expected at a particular time and place;

“**Pandemic”** means the worldwide spread of a disease;

**“Pharmacode”** means the unique six or seven digit identifier assigned to a Pharmaceutical and notified to you by the Pharmacy Guild;

 “**Potential Out-of-Stock Event**” means:

* + 1. in respect of community supply, you have reasonable cause to believe you will be unable to supply the Pharmaceutical to PHARMAC’s Service Provider within 1 month following confirmation of an Agreed Delivery Date; or
		2. in respect of hospital supply, you have reasonable cause to believe you have insufficient supplies of the Pharmaceutical to maintain continuous supply for the New Zealand market.

“**Price**” means the price (exclusive of GST) at which a Pharmaceutical is to be sold and supplied, or made available for sale and supply, by you as set out in Annex Two to PHARMAC;

**“PTAC”** means the Pharmacology and Therapeutics Advisory Committee;

“**Purchase Order**”means an order for Pharmaceutical issued by PHARMAC to you in accordance with Schedule 1;

“**Service Provider**” means the service provider designated by PHARMAC to act on its behalf (which for interpretation purposes of this Agreement includes the authorised person of the Service Provider) in relation to the storage and distribution of the Pharmaceuticals and any other services required by PHARMAC from time to time (if any);

“**Suitable Temperature Monitor**”means a recording thermometer or thermochromatic indicator capable of indicating elevated temperatures and temperatures below 0◦C if appropriate; and

“**WHO/V&B/01.05**” means the World Health Organisation Guidelines on the international packaging and shipping of vaccine.

1. **Operating Policies and Procedures.**
	* 1. You acknowledge that:
			1. 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;
			2. PHARMAC is subject to other statutory and public law obligations, which govern PHARMAC’s decision-making processes;
			3. 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;
			4. PHARMAC’s OPPs may be amended or updated from time to time, following consultation with relevant groups;
			5. the actions which PHARMAC may take under its OPPs include (without limitation):
				1. listing new pharmaceuticals;
				2. changing guidelines or restrictions on the prescribing and dispensing of listed pharmaceuticals;
				3. 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;
				4. amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups;
				5. delisting pharmaceuticals, or delisting all or part of a therapeutic group or sub-group;
				6. changing the market dynamics for pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in the OPP’s;
			6. any action taken by PHARMAC pursuant to its OPPs may impact on the listing of a Pharmaceutical.
		2. PHARMAC agrees not to apply, amend or update its OPPs in order to avoid any of PHARMAC’s obligations under Annex Four of this Agreement.
2. **Amendments to Pharmaceutical Schedule.**

PHARMAC will consult with you before amending the Pharmaceutical Schedule if a proposed amendment would have a material adverse effect on the listing of a Pharmaceutical.

1. **Supply Price.**

The Price at which a Pharmaceutical is supplied by you must not exceed the Price set out in Annex Two and, for the avoidance of doubt, if it does exceed the Price set out in Annex Two that is a breach of the Agreement.

1. **Warranty that Not Less Than Cost Price.**

You warrant that the price at which you are required to supply a Pharmaceutical under this Agreement is greater than the cost price of that Pharmaceutical (including, without limitation, the costs of manufacturing that Pharmaceutical and of supplying it to you for supply in New Zealand).

1. **Continuity of Supply.**
	* 1. You must supply, and continue to supply, the Pharmaceutical(s) on the terms set out in, and in accordance with, this Agreement to the Designated Delivery Point.
		2. Without prejudice to clauses 8 and 9 below, you agree that a discount of 10% will apply to the Pharmaceutical Price for each unit of Pharmaceutical delivered 10 Business Days after the Agreed Delivery Date. A further discount of 10% will then apply to the Pharmaceutical Price for each unit of Pharmaceutical for each subsequent 5 Business Day period following the 10 Business Day period stated in the clause, where a Pharmaceutical has not been delivered in accordance with the Agreed Delivery Date.
		3. You warrant that you have entered into contractual and other arrangements to the extent necessary to ensure that you meet your obligations under paragraph (a) above. You therefore acknowledge that any failure to meet these obligations that is attributable (without limitation) to:
			1. any failure on the part of a person in the relevant Pharmaceutical supply chain; or
			2. any act or omission by a related entity of yours,

is not considered by PHARMAC to be a reason outside your control for the purposes of clauses 7, 8, 9 and 11 below.

1. **Notification of Potential Out-of-Stock Event and supply of Alternative Pharmaceutical.**
	* 1. You must:
			1. notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Pharmaceutical in accordance with this Agreement; and
			2. notify PHARMAC if at any time a Potential Out-of-Stock Event occurs.
		2. If you fail to supply a Pharmaceutical in accordance with this Agreement for more than 1 business day following the Agreed Delivery Date to the Designated Delivery Point, then:
			1. you must procure, within what the relevant Funder or DHB Hospital consider to be a reasonable period of time, an Alternative Pharmaceutical for supply to the Designated Delivery Point at the Price; and
			2. if you fail to procure an Alternative Pharmaceutical at the Price in accordance with sub-clause (i) above (other than for reasons that PHARMAC considers to be wholly outside your control) then, at PHARMAC’s option:
				1. you must pay to all relevant Funders or DHB Hospitals any additional costs incurred by such Funders or DHB Hospitals as a result of the purchase of the Alternative Pharmaceutical; or
				2. PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply), and you must pay to all relevant Funders or DHB Hospitals any additional costs incurred by such Funders or DHB Hospitals as a result of the purchase of the Alternative Pharmaceutical.
2. **Indemnity for Failure to Supply.**
	* 1. You must notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement.
		2. You agree to indemnify the Funder and DHB Hospital if for any reason you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement, including but not limited to a failure to meet Cold Chain requirements (other than for reasons PHARMAC considers to be wholly outside your control), and (only in the case of any non-supply of a Pharmaceutical) if PHARMAC considers that such failure will result in the requirements of any patients for the Pharmaceutical not being met. This indemnity covers all additional costs (including costs relating to securing and/or subsidising a pharmaceutical of similar therapeutic effect to that Pharmaceutical, dispensing fees, and all actual legal expenses) incurred by the Funder and DHB Hospital (or by PHARMAC on its behalf) as a result of your failure to supply that Pharmaceutical in accordance with this Agreement.
3. **Liquidated Damages.**
	* 1. If you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement (other than for reasons that PHARMAC considers to be wholly outside your control), whether as a result of your inability to meet demand for supply of that Pharmaceutical, your withdrawal of the Pharmaceutical from supply, any failure to have and maintain a Consent as specified in clause 12 below, a failure to meet Cold Chain requirements or a Pharmaceutical being recalled in accordance with clause 15, or for any other reason and (only in the case of any non-supply of a Pharmaceutical) if PHARMAC considers that such failure will result in the requirements of any patients for the Pharmaceutical not being met, and:
			1. you have not notified PHARMAC under clause 7(a) and clause 8(a), then in addition to your obligations under clause 7 (b)(i) and (ii) and clause 8(b) , you must pay to PHARMAC (for the benefit of PHARMAC and the Funder and DHB Hospital) liquidated damages for the administrative, operational and/or loss of opportunity costs incurred by PHARMAC and the Funder and DHB Hospital as a result of your failure to supply in the amount of $50,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; or
			2. you have notified PHARMAC under clause 7(a) and clause 8(a), then in addition to your obligations under clause 7 (b)(i) and (ii) and clause 8( b), you must pay to PHARMAC (for the benefit of PHARMAC, the Funder and DHB Hospitals) liquidated damages, being a contribution towards the administrative, operational and/or loss of opportunity costs incurred by PHARMAC and the Funder and DHB Hospitals as a result of your failure to supply, in the amount of $25,000 per Pharmaceutical in respect of which you notified PHARMAC.
		2. You acknowledge and agree that:
			1. subject to the fact that only a contribution is being sought where paragraph (a)(ii) above applies, the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative, operational and the loss of opportunity costs incurred by PHARMAC the Funder and DHB Hospitals (including the use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on PHARMAC’s the Funder’s and DHB Hospitals previous experience; and
			2. the amounts referred to as liquidated damages are not intended to, and do not, include any penalty element nor any amount for costs relating to the securing of an Alternative Pharmaceutical, or the purchasing of an Alternative Pharmaceutical nor any amount for costs relating to securing and subsidising, a pharmaceutical of a similar therapeutic effect to that Pharmaceutical, additional dispensing fees, and all actual legal expenses.
		3. Where you notify PHARMAC under clause 7 above of a Potential Out-of-Stock Event, PHARMAC agrees to recover as liquidated damages under clause 9(a)(ii) only the amounts specified in clause 9(a)(ii), which represent only a portion of PHARMAC’s, the Funder’s and DHB Hospitals’ costs actually incurred.
		4. All amounts referred to in this clause are plus GST (if any).
4. **Default Interest and Recovery Costs.**

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

* + 1. interest will accrue on such sum as remains unpaid at a rate per annum equal to the business base rate of the 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 PHARMAC for such default interest; and
		2. PHARMAC may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 29 below, to recover that amount and you agree to pay to PHARMAC actual enforcement costs incurred in relation to that action.
1. **PHARMAC’s Rights Reserved.**

If you fail to supply a Pharmaceutical on the terms set out in, and in accordance with, this Agreement (other than for reasons that PHARMAC considers to be wholly outside your control), and the benefit of this Agreement to the Funder and DHB Hospital is substantially reduced as a result, then:

* + 1. without limiting PHARMAC’s rights or your liabilities and obligations under clauses 7, 8 and 9, PHARMAC may enter into negotiations, and alternative supply arrangements, with other suppliers for the supply of a pharmaceutical of similar therapeutic effect to that Pharmaceutical; and
		2. PHARMAC may, on 30 calendar days’ written notice to you, delist that Pharmaceutical, provided that if you have failed to supply that Pharmaceutical on the terms set out in, and in accordance with, this Agreement on more than one occasion then PHARMAC may delist that Pharmaceutical without needing to provide 30 calendar days’ written notice to you.

Subject to paragraph (b) above, PHARMAC will not delist a Pharmaceutical under this clause if, within the 30 day notice period, you recommence supply of that Pharmaceutical, on the terms set out in, and in accordance with, this Agreement.

1. **Consents.**

You warrant that you have, and will maintain, all consents (including Ministry of Health market approval) necessary for you to supply a Pharmaceutical in New Zealand for the treatment of each indication for which it is subsidised or specified for that Pharmaceutical in its listing in Section H of the Pharmaceutical Schedule (each a “Consent”). If you are required by the Minister or Ministry of Health or any other New Zealand governmental authority to recall a Pharmaceutical or withdraw a Pharmaceutical from supply, whether temporarily or otherwise, that will be deemed to be a failure to hold a Consent. If a Consent is not held by you or is withdrawn, or a Pharmaceutical is no longer approved for the treatment of an indication for which it is subsidised or listed in Section H of the Pharmaceutical Schedule then:

* + 1. PHARMAC is entitled to terminate this Agreement by 14 calendar days’ written notice to you; and
		2. you acknowledge and agree that the provisions of clauses 8 and 9 are to apply.
1. **Changed Medicine Notification.**

If the Ministry of Health approves a changed medicine notification for a Pharmaceutical, or for a variant of a Pharmaceutical:

* + 1. you must immediately notify PHARMAC; and
		2. PHARMAC may review:
			1. the listing of the Pharmaceutical; and
			2. whether the Funder will subsidise or DHB Hospital may purchase a variant of that Pharmaceutical.
1. **Pharmacode.**

You agree to obtain and notify PHARMAC of the Pharmacode for a Pharmaceutical as soon as the Pharmacode is notified to you, and in any event before the date on which that Pharmaceutical is listed in Section H or Section I of the Pharmaceutical Schedule.

1. **Pharmaceutical Recall.**
	* 1. In the event that you are required by the Ministry of Health or any other authorities to recall a Pharmaceutical, you will notify PHARMAC and the relevant Funder or DHB Hospitals immediately you become aware of the need to recall that Pharmaceutical.
		2. You will use your best endeavours to provide replacement Pharmaceuticals to Funders or DHB Hospitals as soon as possible.
		3. If you fail to provide replacement Pharmaceuticals to Funders or DHB Hospitals in accordance with paragraph (b) above, then the provisions of clause 7(b) are to apply, provided that if clause 7(b)(ii)(B) applies and if PHARMAC is also unable to secure the supply of an Alternative Pharmaceutical within what the relevant Funders or DHB Hospitals consider to be a reasonable period of time, then Funders or DHB Hospitals may purchase an Alternative Pharmaceutical elsewhere and any additional costs incurred by Funders or DHB Hospitals in purchasing such Alternative Pharmaceuticals must be met by you on demand by PHARMAC or the Funders or DHB Hospitals and will be recoverable from you as a debt due to the Funder or DHB Hospitals.
		4. In the event that a Pharmaceutical is recalled as contemplated by paragraph (a) above, you must immediately refund to Funders or DHB Hospitals all money paid by them to you for or on account of that Pharmaceutical and such money will be recoverable from you as a debt due to Funders or DHB Hospitals, unless you have provided a replacement Pharmaceutical to the Funders or DHB Hospitals’ satisfaction.
2. **Shelf-life of Pharmaceutical.**
	* 1. You will not supply a Pharmaceutical if:
			1. the remaining shelf-life of that Pharmaceutical is less than 6 months; or
			2. where the total shelf-life of that Pharmaceutical is less than 6 months, the remaining shelf-life is less than 75% of that Pharmaceutical’s total shelf-life,

without prior agreement from the relevant Funder or DHB Hospital.

* + 1. If you have an agreement with the relevant Funder or DHB Hospital to supply a Pharmaceutical, where the total shelf-life of that Pharmaceutical is less than 6 months and the remaining shelf-life is less than 75% of that Pharmaceutical’s total shelf-life, and that Funder or DHB Hospital does not use that Pharmaceutical before its expiry or use-by date, you agree to allow that Funder or DHB Hospital to return that Pharmaceutical to you and to provide that Funder or DHB Hospital with a credit for that Pharmaceutical.
1. **Emergency and Disaster Supply.**

Subject to clause 23 in the event of an emergency or disaster affecting any Funder or DHB Hospital, or an emergency or disaster on a national level, you will use your best endeavours to provide such quantities of the Pharmaceutical as are required by the relevant Funders or DHB Hospital(s). Your obligations under this clause include, but are not limited to, using your best endeavours to:

* + 1. source the Pharmaceutical from other suppliers and distributors within New Zealand; and
		2. source the Pharmaceutical or a pharmaceutical that is the same brand as the Pharmaceutical from any overseas manufacturer, supplier or distributor, and air-freighting that stock to New Zealand (for which the relevant Funder or DHB Hospital will meet all reasonable costs) for supply, either under Medsafe’s explicit consent to import, sell or distribute the Pharmaceutical or under section 29 of the Medicines Act 1981, to Funders or DHB Hospitals.
1. **Access to Price and Volume Data.**
	* 1. You acknowledge that PHARMAC and its agents will require access to price and volume data held by you, Funder’s and DHB Hospitals in respect of each Pharmaceutical covered by this Agreement to assist PHARMAC to carry out its statutory function in relation to managing the purchasing of pharmaceuticals on behalf of Funders and DHBs.
		2. Notwithstanding any other provisions in this Agreement, including clause 26 regarding confidential information, you agree that where the circumstances in this clause apply, a Funder or DHB Hospital may provide PHARMAC and its agents with any price and volume data held by that Funder or DHB Hospital in respect of a Pharmaceutical covered by this Agreement and PHARMAC and its agents may provide such data to Funders or DHB Hospitals.
		3. You agree that within 10 Business Days following any request from PHARMAC, you will provide PHARMAC with volume data, in respect of each Pharmaceutical covered by this Agreement for each month of the period specified in that request.
2. **Invoicing and Payment.**
	* 1. You are to invoice PHARMAC at the end of each month, but no later than the second Business Day following the month to which the invoice in respect of the Pharmaceutical relates, specifying for all the Delivery of Pharmaceutical during that month:
			1. your delivery note reference number;
			2. the Purchase Order(s) reference number(s) (if applicable);
			3. the net amount payable in respect of the Pharmaceutical supplied to the Service Provider in accordance with this Agreement; and
			4. full details in respect of the Pharmaceutical supplied to the Service Provider in accordance with this Agreement, including the:
				1. the Service Provider’s item codes;
				2. quantity of the Pharmaceutical supplied;
				3. price of the Pharmaceutical;
				4. total cost for the total amount of the Pharmaceutical supplied; and
				5. any other information that PHARMAC requires you to supply.
		2. Provided that the Pharmaceutical has been supplied in accordance with this Agreement, and PHARMAC receives an invoice in accordance with paragraph (a) above, payment by PHARMAC to you of the amount required to be paid by it is expected to occur:
			1. by electronic funds transfer or such other method of payment as is designated PHARMAC; and
			2. on the 20th day of the month following the month to which the invoice for the Pharmaceutical 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.
		3. 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.
		4. 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.
3. Purchase and Delivery of Pharmaceutical.
	* 1. You agree that each Delivery of the Pharmaceutical shall comply with the Purchase Order issued from PHARMAC to you for that Pharmaceutical in accordance with the process set out in Schedule 1, unless otherwise agreed between the parties.
		2. You agree that each Delivery of the Pharmaceutical to the Service Provider:
			1. must be packed and transported so that the Pharmaceutical is maintained at its recommended storage temperature for the entire journey, in accordance with WHO/V&B/01.05;
			2. must be in compliance with Cold Chain;
			3. must have Suitable Temperature Monitors capable of indicating whether the required storage temperatures have been maintained during transport of the Pharmaceutical, which should be:
				1. placed at the bottom and at the top of all Pharmaceutical transportation containers; and
				2. must be in place until that order of the Pharmaceutical is delivered to the Designated Delivery Point;
			4. must be marked with clearly visible instructions that the Pharmaceutical requires immediate refrigeration between 2 – 8°C (as applicable);
			5. must be receipted and signed for by an authorised person of the Service Provider at the Designated Delivery Point.
			6. must have a certificate of analysis giving full details of all testing carried out by the Pharmaceutical manufacturer’s quality control department, (if the delivery comprises more than one batch of Pharmaceutical, a certificate is required for every batch in the delivery). For the avoidance of doubt you shall retain a copy of the certificate of analysis and any quality control documents, which you shall provide to PHARMAC upon request;
			7. must have a certificate signed by an appropriate official of the national control laboratory of the manufacturer’s country:
				1. confirming that the Pharmaceutical(s) accompanying the certificate meets all regulatory requirements of the manufacturer’s country and all standards set by the national control laboratory of the manufacturer’s country;
				2. confirming that the Pharmaceutical(s) accompanying the certificate meets Part A of the then current WHO requirements applicable to such Pharmaceutical(s); and
				3. advising the date of the last satisfactory test for potency of the Pharmaceutical(s) and the relevant lot number; and
			8. must have a copy of the official national release document for the Pharmaceutical(s) contained in the Delivery; and
			9. must be quality control released by you in New Zealand, prior to despatch for Delivery.
		3. You agree to notify the Service Provider, as applicable, two Business Days prior to the dispatch of the Pharmaceutical, such advice to include flight details.
		4. Ownership of the Pharmaceutical will pass to PHARMAC upon Delivery, provided that the Delivery is in accordance with this Agreement, including but not limited to the passing of risk as set out in clause (e) below.
		5. Risk in the Pharmaceutical will pass to the Service Provider after the Pharmaceutical has been receipted and signed for by the Service Provider at the Designated Delivery Point and has been checked by the Service Provider on unpacking to ensure the Pharmaceutical is free of any damage relating to packing or out of date specification data loggers. Until all the activities set out in this clause have been carried out, all risk in the Pharmaceutical will remain with you.
		6. The Service Provider shall advise you of any deliveries with visible damage at the time of delivery to the Designated Delivery Point or any Pharmaceutical volume shortage within 5 Business Days of becoming aware of the volume shortage in comparison to any delivery documentation. The Service Provider shall advise you of any latent defects in the Pharmaceutical following delivery promptly after becoming aware of them.
		7. You shall, at your own risk and expense, obtain all export and import licences or other official authorisation and carry out all customs formalities necessary for the exportation and importation of the Pharmaceutical, provided that PHARMAC shall give you such reasonable assistance as is required to enable you to comply with such obligations.
4. **Defective Pharmaceutical.**
5. In respect of delivery of the Pharmaceutical to New Zealand, where a delivery of the Pharmaceutical is defective (including, without limitation, non-compliance with WHO/V&B/01.05, Cold Chain or where the temperature monitoring is inadequate to determine whether there has been compliance with Cold Chain), you shall:
	* + 1. immediately notify IMAC and PHARMAC of the damage or defect;
			2. immediately remedy the cause of the damage or defect to the satisfaction of IMAC and/or PHARMAC;
			3. remove the entire affected delivery so that no Pharmaceutical included in the affected delivery is delivered to the Service Provider, at your own risk and expense (which for the purposes of clause 8 (b) above shall be classified as non-supply of a Pharmaceutical); and
			4. obtain additional delivery of the Pharmaceutical, in order to meet your obligation to supply the Pharmaceutical in accordance with this Agreement.
6. For the avoidance of doubt, you acknowledge that a defective delivery under paragraph (a) above is not considered by PHARMAC to be a reason wholly outside your control for the purposes of clauses 8 and 9 above, unless such defective delivery is directly caused by an event that PHARMAC reasonably considers, following discussion with you, to be:
	* + 1. wholly outside your control; and
			2. was unable to be prevented by your reasonable care or contingency planning.
7. Supplier Warranties.
8. You warrant and agree that the Pharmaceutical supplied under this Agreement:
	* + 1. complies with Cold Chain;
			2. complies withWHO/V&B/01.05;
			3. is manufactured, produced, processed, prepared and packaged, labelled, presented and described so as to comply with all legislation, regulations, relevant manufacturing principles, industry codes, the British, European and United States Pharmacopoeia Standards and Medsafe requirements which apply to or affect the Pharmaceutical;
			4. is of the particular standard, quality, value, grade, composition, style or model and have the particular history which you have represented;
			5. is free of defects and is of merchantable quality;
			6. is fit for all the purposes for which the Pharmaceutical is required and for which the Pharmaceutical is commonly supplied;
			7. will be subject to post marketing surveillance to assess safety and putative efficacy in accordance with Medsafe requirements. You agree that you will cooperate with Medsafe and other New Zealand Government agencies to facilitate this process;
			8. complies with the British and European Pharmacopoeia and the closure, which is latex free, complies with the toxicity testing requirements of the US Pharmacopoeia; and
			9. complies with the guidelines for tamper evident packaging, as proposed in the draft document (or as finalised or updated from time to time) “Code of Practice for the Tamper Evident Packaging (TEP) of the Therapeutic Goods”.
9. **Pandemic and Local Outbreak Supply.**
	* 1. In the event of a Pandemic and/or Local Outbreak of disease which is preventable by any Pharmaceutical purchased by PHARMAC, in accordance with this Agreement, you agree to supply additional supplies of the Pharmaceutical for the management of the Local Outbreak at the price listed in Annex Two of this Agreement.
		2. For the purpose of clause (a) above PHARMAC will notify you of a Pandemic and/or Local Outbreak, or the threat of a Pandemic and/or Local Outbreak and may place one or more Purchase Orders with you as a result.
		3. You will, at all times, keep PHARMAC informed of your ability to supply additional Pharmaceutical under this clause.
		4. For the purpose of clause(a) above, PHARMAC agrees that for additional supplies of the Pharmaceutical it will approach you first for supply but any such supplies will be subject to market availability and at market cost.
		5. Notwithstanding any other provision of this Agreement PHARMAC reserves the right to source the Pharmaceutical or equivalent pharmaceutical from another supplier in the event you cannot supply additional Pharmaceutical in the circumstances set out in this clause to PHARMAC’s specifications.
10. Insurance
11. You shall arrange and maintain insurance policies for:-
	1. Public liability insurance with a minimum cover of NZ$10 million for any one occurrence;
	2. Products liability insurance with a minimum cover of NZ$50 million for any one occurrence; and
	3. Professional indemnity insurance with a minimum cover of NZ$10 million for any one occurrence.
12. 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.
13. You will do nothing to invalidate the insurance policies that you hold as required under clause (a) above or to prejudice your entitlement under those insurance policies.
14. **Termination**

(a) PHARMAC may terminate this Agreement by providing 30 calendar 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 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 8, 9 and 10 survive termination of this Agreement

1. **Confidentiality.**

Information relating to the terms of this Agreement, or any other information exchanged during negotiation of this Agreement or otherwise, that is agreed in writing by both of us as being confidential (“Confidential Information”) is confidential to us and our employees, legal advisers and other consultants (including PTAC and its sub-committees), the Ministry of Health and DHB’s (if applicable)) and Funder employees (if applicable). You acknowledge that it may be necessary or appropriate for PHARMAC to disclose Confidential Information:

* + 1. pursuant to the Official Information Act 1982; or
		2. in the course of consultation on this Agreement; or
		3. in publicly notifying any approval by the PHARMAC Board of this Agreement; or
		4. 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) to (d) 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) to (d) above, Confidential Information must not be disclosed by either of us (or by our employees, legal advisers and other consultants) unless:

* + 1. the information is publicly available without any cause attributable to the disclosing party; or
		2. the other party has been reasonably informed prior to disclosure, and the disclosure is:
			1. for the purposes of this Agreement; or
			2. required by law; or
			3. in a form, and of content, agreed to by us.

For the avoidance of doubt:

* + 1. generalised aggregated information regarding the Pharmaceutical(s) that does not identify you, or that cannot reasonably be expected to identify you, is not Confidential Information and PHARMAC may use and publish such information as it sees fit;
		2. information released by PHARMAC in accordance with paragraphs (a) to (d) 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.
1. **Consultation.**

This Agreement is conditional on:

* + 1. PHARMAC completing all consultation it considers necessary or appropriate (including consultation under its Operating Policies and Procedures); and
		2. following consultation, 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).

You may withdraw from this Agreement, or negotiate with PHARMAC to amend its terms, if consultation or a decision of PHARMAC’s Board results in a material change to the terms of this Agreement.

1. **Litigation Support.**

If this Agreement or its terms (including the basis on which a Pharmaceutical is listed):

* + 1. give rise to proceedings being issued against PHARMAC; or
		2. 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 (including expert medical and clinical evidence) for the purpose of those proceedings.

1. **Dispute Resolution.**

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

* + 1. The party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute.
		2. We will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.
		3. If we do not agree on a dispute resolution technique within 14 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.
		4. 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.
		5. 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 2).
1. **Crown Direction.**
	* 1. You acknowledge that PHARMAC must comply with any Crown Direction.
		2. PHARMAC may terminate or amend the Agreement, or impose restrictions on the prescribing or dispensing of aPharmaceutical, at any time, if the termination, amendment or imposition of restrictions is required to give effect to a Crown Direction.
		3. In the event that a Crown Direction is issued to PHARMAC that requires an amendment to be made to this Agreement to give effect to that direction:
			1. PHARMAC will give you as much notice as practicable of the Crown Direction and of any amendments to this Agreement that are required to give effect to that direction; and
			2. the Agreement will be deemed to be amended so as to give effect to the Crown Direction from the date when such direction is due to take effect.
2. **PHARMAC’s Rights Reserved Regarding Patient Safety.**

Notwithstanding any other provision of this Agreement, and without prejudice to any other of PHARMAC’s legal rights and remedies, whether under this Agreement or otherwise, PHARMAC reserves the right at any time to take any action in relation to the listing of a Pharmaceutical, or the basis on which it is listed, including (without limitation):

* + 1. changing or imposing restrictions on the prescribing or dispensing of a Pharmaceutical;
		2. delisting a Pharmaceutical;
		3. terminating the Agreement; and/or
		4. any other action that PHARMAC decides, in its sole discretion, is necessary or appropriate,

without your agreement, in accordance with any direction from Medsafe, or recommendation from PTAC, or relevant PTAC sub-committee, based on patient safety.

1. **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.

1. **No Waiver.**

A failure or delay by either of us 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.

1. **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.

1. **Entire Agreement.**

This Agreement:

* + 1. is the entire agreement between us regarding the terms on which the Pharmaceutical(s) is/are listed in Section I and Schedule H of the Pharmaceutical Schedule and purchased by Funder’s and DHB Hospitals; and
		2. supersedes and extinguishes all prior agreements and understandings between us regarding the Pharmaceutical(s).
1. **Advertising.**

You must not procure, or in any way participate or assist in, the publishing of any Advertisement that:

* + 1. is aimed at consumers of pharmaceuticals; and which
		2. breaches any applicable:
			1. statute or regulation, including the Fair Trading Act 1986, Medicines Act 1981 and Medicines Regulations 1984; or
			2. industry standard, including the Advertising Standards Authority Codes of Practice and the Researched Medicines Industry Code of Practice.

For the purposes of this clause:

* + 1. "**Advertisement**" means any words, whether written, printed or spoken, any pictorial representation or design, any sounds or visual images, or combination of sounds and visual images, or any other form of communication used or appearing to be used to promote:
			1. the sale of a Pharmaceutical; or
			2. the use of a method of treatment involving a Pharmaceutical; and
		2. references to a statute, regulation or industry standard include that statute, regulation or industry standard as amended or replaced from time to time.
1. **Contracts Privity.**
	* 1. 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 the Funder or DHB Hospital and related persons, and are enforceable at the suit of the Funder or DHB Hospital and any such persons.
		2. 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.
		3. 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 and/or on behalf of the Funder or DHB Hospital, in respect of any form of loss or damage incurred by PHARMAC and/or the Funder or DHB Hospital.
2. **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.

1. **Amendments.**

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

1. **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 or sub-contractor.

1. **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 intentions of this Agreement.

1. **Governing Law.**

This Agreement is governed by New Zealand law.

1. **Jurisdiction.**

We each submit to the exclusive jurisdiction of the New Zealand courts.

**ANNEX FOUR**

**Special Terms of Listing**

1. **Stock Availability and Price in the Market**
	* 1. [*Pharmaceutical Name* C] is to be available for purchase by you at the applicable Price ex-manufacturer (exclusive of GST) specified for [*Pharmaceutical Name* C] in Annex Two with effect from [*insert relevant date*] and is to be purchased for listing in Section I by the Funder at that Price from [*insert relevant date*].
		2. [Pharmaceutical Name H] is to be available for supply or sale by you, and is to be available for purchase by DHB Hospitals, at the applicable Price ex-manufacturer (exclusive of GST) specified for [*Pharmaceutical Name* H] in Annex Two, with effect from [*insert relevant date*].
		3. The Price must be effective in the market and you must have stock of [Pharmaceutical Name] available for supply or sale, and you must supply or sell [*pharmaceutical* name] at that Price from [insert date]
2. **Eligibility Criteria for the Pharmaceutical**
	* 1. The eligibility criteria as at the date of this Agreement are broadly as follows, subject to consultation:

[*Insert relevant criteria depending on the vaccine*]

* + 1. The Pharmaceutical is to be listed in Section I and Section H of the Pharmaceutical Schedule subject to the eligibility criteria. PHARMAC reserves the right, in its absolute discretion, to change the eligibility criteria for subsidised access to the Pharmaceutical at any time during this Agreement, which may include substantially widening access during a Pandemic or Local Outbreak or otherwise, or making the criteria more restrictive.
		2. Where we provide you with written notice notifying you of any change to the eligibility criteria, you will make arrangements to ensure that you maintain continuity of supply as required under clause 6 of Annex Three.
		3. If PHARMAC changes the eligibility criteria in accordance with paragraph (b) above, regardless of whether it provides you written notice to this effect, you must use all reasonable endeavours to obtain additional stock of the Pharmaceutical, if required, to ensure that every person who meets the then applicable eligibility criteria has access to the Pharmaceutical and to ensure that you maintain continuity of supply as required under clause 6 of Annex Three.
1. **Restrictions on Subsidised Access.**

You and PHARMAC acknowledge and agree that the Pharmaceutical is only to be subsidised or purchased by the Funder for patients who meet the Eligibility Criteria.

**Further Special Terms**

1. **Manufacturer’s Price**
	* 1. The Price payable by PHARMAC to you for the Pharmaceutical is Confidential Information for the purposes of clause 26 of Annex Three. The manufacturer’s price payable for the Pharmaceutical is stated in the table below and is not Confidential Information. For the avoidance of doubt, this clause 4 does not derogate from our legal rights and obligations under the Official Information Act 1982 or under clause 26 of Annex Three or otherwise.

|  |  |
| --- | --- |
| *Presentation of Pharmaceutical* | *Manufacturer’s Price* *(Exclusive of GST)**($NZ)* |
|  |  |

[For example only but not limited to terms relating to sole supply, payment mechanisms, and any health system collaboration activities to develop a model for the administration of medicines in general practice[[1]](#footnote-1)]

**SCHEDULE 1**

## Purchase Orders

1. Purchase Orders shall specify (without limitation):
2. a Purchase Order number and date;
3. PHARMAC’s name;
4. the volume of Pharmaceutical ordered;
5. an indicative date by which a Delivery is to occur (which date is to be not less than 180 calendar days after the date of the Purchase Order, unless supply is for control of a Pandemic or Local Outbreak);
6. the contact details of PHARMAC’s designated representative(s) responsible for the Purchase Order;
7. the name(s) of the person(s) of the Service Provider authorised to sign for a Delivery; and
8. the Service Provider’s address for Delivery of the Pharmaceutical.
9. The process for the issuing and receipt of Purchase Orders from PHARMAC to you shall be as follows:-
	1. PHARMAC shall issue an indicative Purchase Order to you;
	2. Upon receipt of an indicative Purchase Order from PHARMAC, you shall confirm to PHARMAC within 5 Business Days whether that Purchase Order can be met;
	3. Following feedback from you on the indicative Purchase Order, PHARMAC shall issue you a Purchase Order and, within 5 Business Days of receipt of that Purchase Order, you shall confirm to PHARMAC:-
		* 1. the Purchase Order number and date;
			2. the volume of Pharmaceutical to be supplied; and
			3. the confirmed date by which Delivery is to occur.
10. PHARMAC or its Service Provider may contact you if the delivery date you have proposed is not acceptable, and will do so within 2 Business Days of receiving your confirmation of the Purchase Order as stated in clause (b) above and you shall use your best endeavours to accommodate any proposed delivery date of PHARMAC. If you are not contacted by PHARMAC then the delivery date you have confirmed to PHARMAC shall be the Agreed Delivery Date.
1. See <http://www.pharmac.govt.nz/news/notification-2016-02-09-access-in-primary-care/> [↑](#footnote-ref-1)