Summary statement of New Zealand COVID-19 vaccine procurement process and contracts with suppliers

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Background

This summary is created on the Ombudsman's recommendation to address the unprecedented public interest in how New Zealand procured our supply of COVID-19 vaccines in a timely way. This summary aims to provide an overview of New Zealand's approach to purchasing COVID-19 vaccines during the pandemic and an overview of the purchasing contracts where possible.

This summary has been developed by the Ministry of Health (Manatū Hauora), Pharmac, and the Treasury, and in consultation with our vaccine suppliers (Pfizer/BioNTech, AstraZeneca, Novavax and Janssen). All parties agree on the importance of promoting transparency and public trust in government decision making. While reflecting these commitments, certain details and contract terms are confidential and covered in the contractual commitments and are therefore unable to be fully shared or described.

Procuring COVID-19 vaccines

The New Zealand Government took an elimination approach in response to the pandemic to prevent cases of COVID-19 and eliminate transmission in the community. A vaccine strategy was developed to ensure access for New Zealand to a safe and effective vaccine in order to implement our preferred immunisation strategy at the earliest possible time. The joint briefing on COVID-19 Vaccine Strategy – Purchasing Strategy and funding envelope were proactively released and available here: covid19.govt.nz/assets/Proactive-Releases/proactive-release-2020-october/HR28-2021-0139-COVID-19-Vaccine-Strategy-Purchasing-Strategy-and-funding-en....pdf.

A novel procurement approach was required to secure the supply of vaccines that could meet international standards for safety and efficacy, in advance of a COVID-19 vaccine being fully developed or available. In mid-2020 there were novel vaccine platforms which had been developed for other viruses, which indicated promising application for the new COVID-19 virus. However, there was significant uncertainty as to whether an effective vaccine was possible, the technologies involved, possible side effects, manufacturing at scale and the timelines for supply. This led New Zealand to invest, through Advanced Purchase Agreements (APAs), in a portfolio of different vaccines to manage the risk that any one vaccine might be ineffective, unavailable, or unsuitable. Early investment in a diverse portfolio of vaccines was important to ensure that New Zealanders had access to early vaccines (following regulatory approval) at a time when global demand was high.

A dedicated Vaccine Strategy Taskforce (the Taskforce), was set up early in the response to put in place a vaccine strategy "to promote access to a sufficient quantity of a safe and effective vaccine in order to implement the government's preferred immunisation strategy at the earliest possible time." The Science and Technical Advisory Group (later known as COVID-19 Vaccine Technical Advisory Group – "CV TAG") was also created. Consisting of members with specialisation in vaccinations and immunology, virology, and Māori health, CV TAG provided advice on vaccine development, manufacturing, and safety to the Taskforce.

The Ministry of Business Innovation and Employment (MBIE), The Ministry of Foreign Affairs and Trade (MFAT), and Pharmac engaged with international partners and pharmaceutical companies to gain information on vaccine research, manufacturing and supply to secure vaccines to New Zealand. Medsafe provided a regulatory advisory role to the Taskforce while also working with international colleagues to agree on international standards to assess vaccines for efficacy and safety and ensuring an efficient regulatory assessment process.

The Taskforce developed a robust process with clear roles and responsibilities for negotiating and signing advance purchase agreements, which involved:

- initial engagement (for example, identifying target vaccine candidates and signing Confidential Non-Disclosure Agreements for information with vaccine suppliers to preserve confidentiality of information especially intellectual property information about the potential vaccines). Confidential Non-Disclosure Agreements were signed to ensure that during negotiations information shared with New Zealand by the suppliers remained private and confidential
- scientific and commercial evaluation of the vaccine candidates (vaccine candidates are specific vaccines developed by different suppliers)
- negotiating the terms of a full contract
- an understanding that supply under all APAs were subject to Medsafe approval

The initial approach to obtaining a vaccine was to sign APAs to secure access to potential COVID-19 vaccines as they were developed. APAs were binding commitments between individual suppliers and the government to purchase not-yet available vaccine, provided certain conditions were met, regardless of the demand for the vaccine when they were available. The Government negotiated directly with the vaccine suppliers drawing on expertise from MBIE, MFAT, Pharmac, Treasury and Manatū Hauora, and assisted by external commercial and legal advisors. These contracts were non-exclusive (not limited to one supplier) to manage any possible vaccine development risks and the suitability of vaccines for our immunisation roll-out.

Cabinet agreed to APAs for maximising New Zealand's early access to vaccines. There were clear decision-making frameworks in place that guided how the New Zealand Government determined which vaccines should be purchased under the APAs. The criteria included accounting for situations where all the desired information was not yet available and

considered how the target vaccines would contribute to New Zealand's overall vaccine strategy and portfolio. The criteria also included considerations on:

- making investment and purchasing decisions based on evidence while recognising the limited availability of COVID-19 specific data
- taking a portfolio approach and keeping multiple options in play while ensuring the vaccines meet the immunity needs of New Zealand and the Pacific
- ensuring vaccines meet New Zealand regulatory requirements for quality, safety and efficacy (including Medsafe approval), prior to public use
- maintaining New Zealand's international reputation by operating based on transparency and in support of a rules-based system.

The Government agreed to make advance payments to secure potential supply under the APAs for four vaccines (Pfizer/BioNTech, AstraZeneca, Novavax and Janssen). Cabinet established a contingency that could be drawn upon[1] to purchase a portfolio of vaccines, and delegated decision-making purchases on specific vaccines to Joint Ministers (the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation, the Minister of Health and the Minister for COVID-19 Response).

Other approaches to secure vaccines early included exploring access through

- the COVAX Facility which negotiated access to vaccines directly with vaccine suppliers
- local manufacturers and vaccine developers.

Detailed steps taken by the New Zealand Government to secure COVID-19 vaccines are available in the Auditor-General's website here: oag.parliament.nz/2021/vaccines/part3.htm

Confidentiality commitments

Before New Zealand negotiated with the vaccine suppliers, the Government entered into initial non-disclosure agreements to understand the initial terms and properties of the vaccines. Additional confidentiality terms binding on suppliers and New Zealand were signed as contracts were finalised.

Certain details including the negotiations and terms within the contract were agreed to be within the scope of confidentiality. These include terms detailing price, supply, and delivery schedule clauses. Disclosure of any information from the contract was strictly limited, with specific exceptions to enable use of information in performance of the contract and for

[1] A tagged contingency is a ring-fenced fund set aside for a short period of time in advance of appropriation. For funding to be appropriated, and therefore able to be spent, certain conditions normally need to be met (such as further information being provided to Ministers). Once conditions are met, approval to spend is made by either Cabinet or specified Ministers. At this point, funding may be appropriated and spent. A contingency budget was set up to address any unforeseen circumstances due to the nature of the pandemic. This was also used for the costs of procuring COVID-19 vaccines once these became available.

compliance with legal obligations. All four contracts allowed for disclosure of information, if required, in accordance with the Official Information Act 1982.

The contracts recognised the role of COVAX facility in the global response and permitted transparency in good faith[2] during New Zealand participation in the COVAX facility.

Indemnities/exclusions from liabilities

An indemnity is an agreement between two parties where one agrees to provide compensation for any losses, damages or liability incurred by the other, dependent on the terms agreed to. It is important to note that it is not unexpected for pharmaceutical companies to seek indemnities from governments in circumstances where clinical trials are restricted or where an advance purchase agreement is concluded before full trials are completed.

The New Zealand Government, through the Minister of Finance, granted indemnities to the pharmaceutical companies to enable them to progress accelerated clinical trials and respond to the urgent need to develop safe and effective COVID-19 vaccines quickly. The need to grant these indemnities partly arose from supplier-inability to secure insurance for the COVID-19 vaccines in the context of the broader pandemic and the speed at which the vaccine products were being developed. To provide an indemnity, the Minister of Finance needs to be satisfied that the indemnity meets the public interest test under section 65ZD of the Public Finance Act 1989 which provides:

> *(1) The Minister, on behalf of the Crown, may give in writing, a guarantee or indemnity to a person, organisation, or government if it appears to the Minister to be necessary or expedient in the public interest to do so.*
> *(2) The Minister may—*
> *(a) give the guarantee or indemnity on any terms and conditions that the Minister thinks fit; and*
> *(b) in the case of a guarantee, give the guarantee in respect of the performance or non-performance of any duties or obligations by a person, organisation, or government.*

There is no legislative definition for determining whether an indemnity is necessary or expedient in the public interest under the Public Finance Act and this has to be determined on a case-by-case basis.

The Treasury provided advice to the Minister of Finance on each of the COVID-19 vaccine indemnity requests to help him assess whether they met the public interest test. This advice considered whether the benefits of indemnification outweighed any identified risks to New Zealand. Risks incurred by the Government as a result of the administration or use of a COVID-19 vaccine indemnity were partially mitigated by the independent regulatory

[2] Good faith means dealing with each other honestly, openly, and without misleading each other.

assessment of the safety, efficacy and quality of the vaccines by Medsafe and the no-fault accident compensation scheme in New Zealand.

Under the Accident Compensation Act 2001, the Accident Compensation Corporation (ACC) provides cover for treatment injury, and individuals cannot sue for compensatory damages for covered injuries. This means that even when a contractual indemnity is not provided to pharmaceutical companies, ACC assumes liability for a vaccine-related treatment injury.[3] You can find the Act online at Accident Compensation Act 2001. Information about COVID-19 and ACC is also available on ACC's website at COVID-19 (acc.co.nz).

The Accident Compensation Act 2001 already provides a broad immunity from liability for adverse events arising from vaccines. Consequently, indemnities provided to vaccine suppliers were concluded on the basis that there are a very limited range of circumstances where they would be triggered.

The indemnity clauses in the contract were not extended to certain circumstances, such as harm that is caused wilfully.

Warranties[4]

The contracts were subject to warranties for the New Zealand Government and for suppliers. It was agreed that suppliers were required to meet New Zealand's quality assurance and regulatory approval requirements (administered by Medsafe), which would impact our purchase and supply obligations with suppliers.

In return, the New Zealand Government acknowledged that the vaccines were the intellectual property rights[5] of the suppliers. The contracts did not seek exclusivity or limit the Government from purchasing vaccines from other suppliers, which was important due to the emergency circumstances of the COVID-19 pandemic. The Government acknowledged that due to the nature of the pandemic, vaccines were developed under pandemic circumstances which resulted in limits on suppliers' liabilities and supply obligations.

Contractual warranties between the supplier and the New Zealand Government included acknowledging that all parties had the power, authority and legal right to enter into the contracts and perform their obligations. Each party was also required to adhere and follow existing laws while performing their obligations according to the contract.

Safety and efficacy

The agreements required COVID-19 vaccines to have obtained Medsafe's approval before they could be distributed. New Zealand has well-established systems in place to monitor the

[3]Note that access to cover depends on the circumstances of the injuring. For instance, there must a be a clear causal link between the treatment and the injury, and the injury must not be a necessary or ordinary part of the treatment.

[4] A promise or guarantee from one party to another that the facts are true and reliable

[5] Intellectual property rights give creators and innovators the exclusive right, for a limited time, to control what others may do with their creations and innovations.

safety of medicines (including vaccines) used and assists in maintaining the public's trust in our National Immunisation Programme. Medsafe is part of a global network of regulators and assesses vaccines against internationally agreed standards for quality (manufacture), safety and efficacy. This network also considered the opportunities to accelerate or modify the regulatory process without compromising patient safety.

The evidential and scientific information in relation to safety, efficacy and quality for each vaccine was submitted to Medsafe. Approval status of COVID-19 vaccines applications received by Medsafe can be found here: www.medsafe.govt.nz/COVID-19/status-of-applications.asp. The nature of the pandemic and high global demand for vaccines meant the Government signed APAs to purchase vaccines before they were developed. This required the Government to acknowledge the rapid development of the vaccines in the emergency circumstance. For those vaccines that gained Medsafe approval, the Government agree to accept a certain amount of risk regarding long-term effects and efficacy of the vaccines including associated adverse effects before full long-term data was provided to Medsafe demonstrating acceptable safety, efficacy and quality. Further information on Medsafe vaccine evaluation and approval process can be found at www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

Donations to other nations

New Zealand's COVID-19 vaccine portfolio was established in a way that ensured it could support equitable access to vaccine for immunisation programmes in the Pacific. With suppliers' agreement, the contracts enabled New Zealand to coordinate the donation of our vaccines while managing liability and quality assurance concerns for the distribution and delivery of the immunisation programmes in the donee countries. Further donation agreements provided suppliers oversight of vaccine donations, requirements for the safe delivery and storage of vaccines, support for pharmacovigilance, and indemnification for claims arising from the vaccine use in certain donee countries through the New Zealand's Minister of Finance.

Supply and obligations to purchase

Given the pandemic state and lack of stocked inventory of vaccines, contracts included binding commitments to purchase vaccines based on the New Zealand Government's estimated needs. The contracts contained firm obligations for purchase and the New Zealand Government made non-refundable partial payments upfront. The contracts did not assign sovereign resources or take state assets as collateral for the purchase of vaccines.

Aggregation of financial liabilities assumed by the Government

In terms of the Crown's financial liabilities under COVID-19 indemnities, officials considered the total maximum aggregated liabilities to be unquantifiable. However, as the potential maximum exposure of each could exceed $10 million, the Minister of Finance presented a statement to the House of Representatives when each indemnity was granted under section

65ZD(3) of the Public Finance Act 1989. It is important to note that most of the Crown's liability under the COVID-19 vaccine indemnities is covered by ACC under the Accident Compensation Scheme, as outlined above.

In terms of the Crown's financial liabilities in respect of COVID-19 vaccines more generally, the joint Cabinet paper on COVID-19 Vaccine Strategy – Purchasing Strategy and funding were proactively released and available here: covid19.govt.nz/assets/Proactive-Releases/proactive-release-2020-october/HR02-CABINET-PAPER-AND-MINUTE-COVID-19-vaccine-strategy-10-August-2020.pdf

Matters not included in contracts

Apart from not seeking exclusivity or limiting the Government from purchasing vaccines from other suppliers (as noted above), or limiting the purchase of other COVID-19 treatments, the contracts did not include:

- commitments to purchase future COVID-19 vaccines beyond what the existing contracts covered, although the Government had the ability to agree to purchase further COVID-19 vaccines, including new formulations to deal with COVID-19 variants
- any requirement for the Government to purchase other types of vaccines or other medicines supplied by the suppliers
- any alteration to the existing terms of supply of other types of vaccines or other medicines supplied by the suppliers
- any provision for state assets or resources to be used as security or collateral to meet the Government's payment or indemnity obligations.

Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule

This Agreement specifies the terms on which the Pharmaceutical(s) specified in Annex 1 will be listed.

Parties

(1) Pharmaceutical Management Agency **(Pharmac)**; and

(2) [ ] **(You)**

Pharmaceutical(s)

This Agreement relates to the following Pharmaceutical(s), more fully described in Annex 1:

[ ]

Annexes

Annex 1

Table 1:

- Describes the Pharmaceutical(s).
- Specifies the Listing Date of the Pharmaceutical(s).

Table 2:

- Specifies the price at which the Pharmaceutical(s) are to be listed.
- Specifies the manufacturer's price of the Pharmaceutical(s).
- Specifies the purchase price of the Pharmaceutical(s).

Annex 2

- Specifies the special terms of listing of the Pharmaceutical(s).

Annex 3

- Specifies the standard terms of listing of the Pharmaceutical(s).

Annex 4

- Specifies the definitions and principles of interpretation relevant to this Agreement.

Precedence

The special terms in Annex 2 are to prevail if those terms conflict or are inconsistent with any other terms of this Agreement.

Acceptance

Pharmac and you confirm acceptance of this Agreement by signing below:

_____

Pharmaceutical Management Agency (Pharmac)

Name:

Position:

Date:

_____

[ ]

Name:

Position:

Date:

Annex 1: Pharmaceutical

Table 1

Pharmaceutical Reference	Pharmaceutical	Brand	Formulation	Pack Size	Listing Date	Community / Hospital / Both

Table 2

Pharmaceutical Reference	**Schedule List Price** (Exclusive of GST) ($NZ)	**Manufacturer's Price** (Exclusive of GST) ($NZ)	**CONFIDENTIAL Purchase Price** (Exclusive of GST) ($NZ)

The Price payable by Pharmac to you for the Pharmaceutical is stated in the 'CONFIDENTIAL Purchase Price' column in the table above and throughout this Agreement is referred to as the 'Price'. The Price is Confidential Information for the purposes of clause 5.4 of Annex Three.

The price stated in the Manufacturer's Price column for the Pharmaceutical is not Confidential Information; for the avoidance of doubt, the Manufacturer's Price can be used by Pharmac when publicly reporting on or otherwise disclosing expenditure on the Pharmaceuticals.

For the avoidance of doubt, this clause does not derogate from our legal rights and obligations under the Official Information Act 1982 or under clause 5.4 of Annex Three or otherwise.

Annex 2: Special Terms

1. Principal Supply Status for the Pharmaceutical

This clause applies to each Pharmaceutical respectively as specified in Annex 1.

Definitions

Alternative Brand Allowance means the alternative brand allowance relating to the Pharmaceutical, in relation to hospital and/or community supply, as indicated as a percentage amount of the Total Pharmaceutical Volume, in the column entitled "ABA Limit" in the table set out in clause 1.1(e) below;

Brand Allowance Indicator means the actual percentage of Brand Allowance Pharmaceutical subsidised in the community and/or purchased by Health NZ Hospitals relative to the Total Pharmaceutical Volume in the Principal Supply Period;

Brand Allowance Pharmaceutical means an alternative supplier's brand of the Pharmaceutical. For the avoidance of doubt, a Brand Allowance Pharmaceutical shall not be interpreted to be an Alternative Pharmaceutical for the purposes of this Agreement;

Brand Compensation means the compensation payable to you in accordance with clause 1.3(c) below;

Brand Differential means the difference between the Brand Allowance Indicator and the Alternative Brand Allowance;

Eligible Volume means the Volume Multiplier multiplied by the Brand Differential, being a volume of the Pharmaceutical eligible for Brand Compensation in [Units];

End Date means the last day of the Principal Supply Period;

Principal Supplier means you, being the principal supplier of the relevant Pharmaceutical in relation to community and/or hospital supply (subject to the Alternative Brand Allowance provisions);

Principal Supply Period means the period beginning on [ ] and ending on [ ];

Principal Supply Status means the status of being the Principal Supplier for community and/or hospital supply of the Pharmaceutical for the Principal Supply Period;

Total Brand Allowance Pharmaceutical Volume means the total volume of Brand Allowance Pharmaceutical purchased for use in the community and/or in Health NZ Hospitals in the Principal Supply Period, specified in [Units];

Total Pharmaceutical Volume means the total volume of the Pharmaceutical (inclusive of Brand Allowance Pharmaceutical purchased for use in the community and/or in Health NZ Hospitals in the Principal Supply Period, specified in [Units];

Units means [ ]; and

Volume Multiplier means the Total Pharmaceutical Volume divided by one hundred (100) (which shall equate to 1% of the Total Pharmaceutical Volume), specified in [Units].

1.1 Principal Supplier

(a) Subject to:

(i) Pharmac's other rights under this Agreement in relation to the Pharmaceutical; and

(ii) this clause relating to the Alternative Brand Allowance,

Pharmac will not list another supplier's brand of the Pharmaceutical and Pharmac will not delist the Pharmaceutical, at any time during the Principal Supply Period.

(b) This clause does not prohibit Pharmac from entering into negotiations or arrangements with, or inviting proposals from, other suppliers to be the principal supplier of any forms and strengths of the Pharmaceutical, if such supply to vaccinators commences after the end of the Principal Supply Period.

(c) You shall have Principal Supply Status during the Principal Supply Period, which shall be subject to the Alternative Brand Allowance, where other suppliers' brands of the Pharmaceutical may be purchased for use in the community and/or in Health NZ Hospitals.

(d) You acknowledge and agree that any other suppliers' brands of the Pharmaceutical may be concurrently listed at any time during the Principal Supply Period and your rights under this Agreement do not extend to an exclusive listing of the Pharmaceutical.

(e) The Alternative Brand Allowance referred to in paragraphs (a) and (c) above is specified as a percentage of the Total Pharmaceutical Volume for the Pharmaceutical, as set out in the column entitled "ABA Limit" in the table below:

Pharmaceutical	**ABA Limit**
[ ]	5 %

1.2 Exceptions to Principal Supply Status

(a) Pharmac may, from time to time during the Principal Supply Period, amend the Alternative Brand Allowance for the Pharmaceutical after consultation with a relevant medical adviser (being either the Ministry of Health, Public Health Agency, Health NZ, PTAC or its Specialist Advisory Committees), provided that Pharmac may only increase the Alternative Brand Allowance without your prior agreement if it has a direction to that effect from Medsafe or its successor, or a recommendation that it do so from PTAC or its Specialist Advisory Committees, based on a significant clinical issue.

(b) Subject to clause 1.3 below, you acknowledge and agree that while you have Principal Supply Status:

(i) other supplier brands of the Pharmaceutical may be purchased for use in the community and/or in Health NZ Hospitals, subject to the Alternative Brand Allowance; and

(ii) without derogating from any other rights available to Pharmac or Health NZ under this Agreement or otherwise, if you fail to supply the Pharmaceutical in accordance with this Agreement at any time during the Principal Supply

Period, then the Alternative Brand Allowance shall not apply and other supplier brands of the Pharmaceutical may be purchased for use in the community and/or in in Health NZ Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 1.3 below shall exclude that period of non-supply.

1.3 Principal Supply Status Monitoring

(a) If you reasonably believe that the percentage of other suppliers' brands of the Pharmaceutical is distributed to vaccinators in the community and/or in Health NZ Hospitals exceeds the Alternative Brand Allowance during the Principal Supply Period, you may at any date after a three (3) month period following the End Date, request that Pharmac carry out calculations for that Principal Supply Period in accordance with the procedure set out in this clause 1.3, and Pharmac may, acting reasonably, agree to carry out such calculations, provided that if Pharmac refuses to carry out such calculations, it will provide you with the reasons for refusing to do so. For the avoidance of doubt, where you have Principal Supply Status for both community and hospital supply of a Pharmaceutical, Pharmac will carry out any calculations for those markets in combination, with a single, combined figure to be used for each of Total Pharmaceutical Volume and Total Brand Allowance Pharmaceutical Volume when carrying out the calculations below.

(b) Within 30 Business Days of Pharmac accepting your request to carry out calculations in accordance with clause 1.3(a) above, Pharmac shall carry out the following calculation:

(i) (Total Brand Allowance Pharmaceutical Volume / Total Pharmaceutical Volume) x 100 = Brand Allowance Indicator;

(ii) Brand Allowance Indicator – Alternative Brand Allowance = Brand Differential

(c) In the event the Brand Differential is a number greater than zero i.e. a positive amount, Pharmac shall carry out the following calculation:

(i) Total Pharmaceutical Volume / 100 = Volume Multiplier;

(ii) Volume Multiplier x Brand Differential = Eligible Volume;

(iii) (Eligible Volume x $[ ]) / 2 = Brand Compensation

(d) Pharmac will notify you in writing of any Brand Compensation payable or not in accordance with clauses 1.3(b) and (c) above and will provide you with the details of the relevant party or parties to be invoiced for any Brand Compensation payable. Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.

(e) You acknowledge and agree that the data extracted from the records used by Pharmac are the best data and those records are the best records, for the purposes of carrying out the calculations.

(f) You may, within 10 Business Days following notification of the outcome of the calculations in accordance with clause 1.3(d) above (the "**Calculation**"), notify Pharmac in writing that you dispute the particular Calculation and that you require an audit of that Calculation to be carried out. If you do give a notice to Pharmac

under this clause within that 10-Business Day period, then the following provisions are to apply:

(i) The audit is to be carried out by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within 5 Business Days of the date of your notice under this clause, then by an independent person nominated for that purpose by the President for the time being of the Chartered Accountants Australia and New Zealand (CA ANZ).

(ii) The independent person is to audit the particular Calculation, which is disputed by you, based on all relevant electronic data which is extracted by Pharmac from the records maintained by it. For the avoidance of doubt, the independent person will have no right to inspect, review or have access to the written prescriptions on which the data extracted by Pharmac from those electronic records are based, nor any right to request copies of those written prescriptions.

(iii) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.

(iv) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 5 Business Days of receiving all the information required by the independent person to make a determination and, in any case, no later than 10 Business Days from the date of his or her acceptance of appointment or nomination under this clause, unless we agree otherwise. The independent person's determination of the particular Calculation is to be final and binding on both of us.

(v) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

1.4 Withdrawal of Principal Supply Status

(a) Pharmac may withdraw Principal Supply Status in relation to the Pharmaceutical (in which case clauses 1.1 and 1.3 above will no longer apply), by written notice to you at any time during the Principal Supply Period in the event of a Supply Issue or in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.

(b) Any withdrawal of Principal Supply Status is without prejudice to Pharmac's rights under Annex 3, clauses 4.5 and 4.6.

1.5 Suspension of Principal Supply Status

(a) Pharmac may suspend Principal Supply Status in relation to the Pharmaceutical, by written notice to you at any time during the Principal Supply Period in the event of a Supply Issue or in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.

(b) Any suspension of Principal Supply Status is without prejudice to Pharmac's rights under Annex 3, clauses 4.5 and 4.6.

(c) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 1.5 ceases and on which date:

(i) Principal Supply Status is to be re-implemented in respect of the Pharmaceutical; or

(ii) Principal Supply Status is to be withdrawn in accordance with clause 1.4 above.

1.6 Supply arrangements after the End Date

(a) Subject to clause 1.6(b) and (c) below, the Pharmaceutical is to continue to be the subject of a listing agreement between you and Pharmac with effect from the End Date, and accordingly:

(i) you will cease to have Principal Supply Status for that Pharmaceutical;

(ii) the Pharmaceutical will remain listed in the Pharmaceutical Schedule subject to the terms in Annex 3;

(iii) you may increase the price ex-manufacturer (exclusive of GST) at which you sell or supply, or make available for supply or sale, by you, to Pharmac, on giving Pharmac 12 months' written notice of that price increase. You may provide Pharmac with this written notice at any time after, but not before, the End Date, subject to sub-paragraphs (A) and (B) as follows:

(A) Pharmac reserves the right to consult on any price increases prior to determining whether to increase the price for the Pharmaceutical to the new price notified under this paragraph (a)(iii);

(B) Where you increase the price at which you supply the Pharmaceutical under this paragraph (a)(iii), you will not subsequently increase the price at which you supply the Pharmaceutical for at least 12 months from the effective date of the price increase.

(iv) if Pharmac does not increase the price for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than 12 months' prior written notice;

(v) if Pharmac does increase the price for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than 2 years' prior written notice (except where the withdrawal is due to a Force Majeure Event); and

(vi) if at the time of providing notice under paragraph (a)(v) above, you advise Pharmac that you are required to purchase a significant quantity of extra stock of the Pharmaceutical to enable you to continue to supply for the two-year period, and you advise Pharmac of the total cost of that stock, Pharmac will either:

(A) use reasonable endeavours to enter into an agreement to reimburse you for stock that remains unsold at the end of that two-year period; or

(B) release you from your obligations to supply under this clause 1.6(a).

(b) Pharmac may at its sole discretion, with effect from the End Date:

(i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case Pharmac will give you written notice not less than 6 months prior to the End Date; and/or

(ii) apply any of the strategies under Pharmac's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical).

(c) In the event Pharmac applies any of the strategies described in clause 1.6(b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than 12 months' prior written notice. You may provide Pharmac with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

1.7 Termination and restrictions for clinical reasons

Pharmac reserves the right, but only after consultation with you and a relevant medical adviser (being either Medsafe, PTAC or its Specialist Advisory Committees), to:

(a) terminate this Agreement at any time during the Principal Supply Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:

(i) a principal supplier for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; or

(ii) the Pharmaceutical as the principal pharmaceutical for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; and/or

(b) impose at any time during the Principal Supply Period restrictions on the prescribing or dispensing of the Pharmaceutical if those restrictions are necessary for clinical reasons.

2. Market Approval and Consents

(a) In addition to your obligation under clause 5.2 of Annex 3 to obtain and maintain Market Approval and any Consent for the Pharmaceutical for the duration the Pharmaceutical is listed, you will comply with the obligations stated in this clause 2.

(b) You agree that for any changes to the recommended strain(s), published by the World Health Organization (WHO) from time to time, for the Southern Hemisphere COVID-19 vaccine composition, you will, as soon as reasonably practicable, following the date of publication by the WHO of the changes, engage with Pharmac in good faith, in order for Pharmac to determine at its sole discretion, whether the WHO changes are to apply to New Zealand. In the event Pharmac determines that the WHO changes apply, you will:

(A) obtain any Market Approval required for the Pharmaceutical;

(B) obtain any other necessary Consent for the Pharmaceutical;

(C) keep Pharmac informed of progress towards gaining Market Approval and Consent.

(c) Subject to any Market Approval and any other Consent being required for the Pharmaceutical as set out in this clause 2, you will apply to Medsafe for such Market Approval and any other Consent as soon as reasonably practicable, and in any event within 6 weeks of Pharmac determining at its sole discretion, that the WHO changes are to apply to New Zealand for the Southern Hemisphere COVID-19 vaccine composition.

(d) Subject to any Market Approval and any other Consent being required for the Pharmaceutical as set out in this clause 2, you will, within 4 months of Pharmac determining at its sole discretion, that the WHO changes are to apply to New Zealand for the Southern Hemisphere COVID-19 Vaccine composition, provide all information as required by Medsafe in order for it to assess whether to grant the necessary Market Approval and Consent.

For the avoidance of doubt, the WHO may publish multiple changes to the recommended strain(s) for the Southern Hemisphere COVID-19 vaccine composition whilst the Pharmaceutical is listed.

(e) You acknowledge and agree that should you not obtain or maintain Market Approval and any other Consent, within 9 months of the date of your application to Medsafe, in accordance with paragraph (c) above, then:

(i) Pharmac may, in its absolute discretion, delist the Pharmaceutical; and

(ii) you will be liable for all costs associated with your failure to supply the Pharmaceutical, including (without limitation) under Annex 3, clauses 4.5 and 4.6.

3. Stock availability and Price for the Pharmaceutical

(a) The Pharmaceutical is to be made available by you at the Price, to the Designated Delivery Point, with effect from [date] and is to be purchased for listing on or after [date].

(b) Pharmac will use its reasonable endeavours to ensure the Pharmaceutical is the only brand of the Pharmaceutical distributed by the Service Provider on or after [date].

4. Eligibility Criteria

(a) The Pharmaceutical is to be listed from the Listing Date subject to eligibility criteria substantially as set out below:

[ ]

(b) Notwithstanding paragraph (a) above, Pharmac reserves the right at any time to review, change and/or impose new criteria for access to, and restrictions on the prescribing and dispensing of, the Pharmaceutical, including making them more restrictive, in accordance with any direction from Medsafe, or recommendation from Pharmac's clinical advisors, based on patient safety or any other clinical reason.

(c) For the avoidance of doubt, Pharmac reserves the right, in its absolute discretion, to review, change and/or impose new criteria for access to, and restrictions on the prescribing and dispensing of, the Pharmaceutical, including making them more restrictive or less restrictive, from time to time.

5. Superseding Previous Agreement (as applicable)

For the avoidance of doubt, this Agreement supersedes and extinguishes the agreement between Pharmac and you dated [ ] for the supply of the Pharmaceutical (the "[ ] **Agreement**") in relation to the Pharmaceutical with effect from [ ], provided that the [ ] Agreement continues in force in respect of the Pharmaceutical only for the purposes of ensuring, and for the time necessary to ensure, that you pay any amounts due on account of rebates contained in the [ ] Agreement.

6. Separate Agreement for the Pharmaceutical

In accordance with Annex 4, clause 2(o), the terms set out in this Agreement specify the terms of listing for each Pharmaceutical and the terms apply independently to each Pharmaceutical in Annex 1. This Agreement is not a single Agreement for the collective listing of the Pharmaceuticals in Annex 1.

Annex 3: Standard Terms

1. Pharmac's Role

1.1 Rights and Responsibilities

(a) You acknowledge that:

(i) Pharmac is required to pursue its statutory objectives, carry out its statutory functions and otherwise comply with its statutory obligations;

(ii) Pharmac is subject to a range of legal and administrative obligations, which govern Pharmac's decision-making processes;

(iii) Pharmac has OPPs, which provide guidance on the way in which Pharmac carries out its statutory role and functions;

(iv) the actions which Pharmac may take under its OPPs include (without limitation):

(A) listing new pharmaceuticals;

(B) changing the terms on which a pharmaceutical is listed; and

(C) delisting pharmaceuticals or delisting part or all of a therapeutic group or sub-group; and

(v) any action taken by Pharmac pursuant to its OPPs may impact on the listing of the Pharmaceutical.

(b) Pharmac agrees not to apply, amend or update its OPPs in order to avoid any of Pharmac's obligations under Annex 2 of this Agreement.

(c) Pharmac may terminate or amend this Agreement at its sole discretion in the following circumstances:

(i) Pharmac is issued a Crown Direction;

(ii) in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons;

(iii) a Supply Issue results in a failure to supply the Pharmaceutical;

(iv) any Consent or Market Approval is not held by you or is withdrawn for the Pharmaceutical;

(v) a Changed Medicine Notification is approved by Medsafe for the Pharmaceutical;

(vi) by providing 30 calendar days written notice to you if you breach any clause of this Agreement, provided that (without prejudice to termination being

effective at the end of the notice period) Pharmac agrees to negotiate with you during the notice period over possible alternatives to termination; or

(vii) the Pharmaceutical is delisted for any reason,

(d) In the event that:

(i) this Agreement is terminated (or notice of termination is given) or amended due to any of the circumstances set out in clause 1.1(c)(i) to (vi), Pharmac reserves the right to delist, or suspend or amend the listing of, the Pharmaceutical; or

(ii) the Pharmaceutical is delisted, or has its listing suspended, for any reason then, unless this Agreement is terminated under clause 1.1(c)(vii), this Agreement shall continue in full force and effect until expiry or termination in accordance with its terms and such delisting or suspension shall not constitute or be construed as a repudiation or breach of the terms of this Agreement by Pharmac. You agree that you do not have, and you expressly waive, any rights, at law, including in equity or under statute, and particularly under Part 2, subpart 3 of the Contract and Commercial Law Act 2017 (Contractual remedies), to terminate this Agreement as a result of the delisting, or suspension of the listing, of the Pharmaceutical.

1.2 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 the Pharmaceutical.

1.3 Conditions

(a) This Agreement is conditional on:

(i) Pharmac completing all consultation it considers necessary or appropriate; and

(ii) approval of its terms by Pharmac's board or its delegate.

(b) You may withdraw from this Agreement, or negotiate with Pharmac to amend its terms, if the consultation or a decision of Pharmac's board or its delegate described in clause 1.3(a) above results in a material change to the proposed listing of the Pharmaceutical.

1.4 Supplier Code of Conduct

You must comply with the New Zealand Government's Supplier Code of Conduct as amended or substituted from time to time.

2. Operational Supply

2.1 Price

(a) You must supply, or make available for supply, the Pharmaceutical, at the Price, to the Designated Delivery Point in accordance with this Agreement.

(b) The price at which the Pharmaceutical is supplied by you must not exceed the Price.

2.2 Invoicing and Payment

(a) You are to invoice Pharmac after Delivery, but no later than 1 calendar month after Delivery has occurred, specifying for all the Delivery of Pharmaceutical during that month:

(i) your delivery note reference number;

(ii) the particular purchase order reference number (if applicable);

(iii) the net amount payable in respect of the Pharmaceutical supplied to the Service Provider in accordance with this Agreement; and

(iv) full details in respect of the Pharmaceutical supplied to the Service Provider in accordance with this Agreement, including the:

(A) Service Provider's item codes;

(B) quantity of the Pharmaceutical supplied;

(C) Price of the Pharmaceutical;

(D) total cost for the total amount of the Pharmaceutical supplied; and

(E) any other information that Pharmac requires you to supply.

(b) Provided that the Pharmaceutical has been supplied in accordance with this Agreement, and Pharmac receives an invoice in accordance with clause 2.2(a) above, payment by Pharmac to you of the amount required to be paid is expected to occur:

(i) by electronic funds transfer or such other method of payment as is designated by Pharmac; and

(ii) 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 day of the month.

(c) 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.

(d) 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.

2.3 Delivery

(a) 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.

(b) You agree that each Delivery of the Pharmaceutical to the Service Provider:

(i) must be packed and transported so that the Pharmaceutical is maintained at its recommended storage temperature for the entire journey, in accordance with the distribution and storage requirements of your Licence to Sell by Wholesale, to the extent that they are applicable to the Pharmaceutical;

(ii) must be in compliance with Cold Chain;

(iii) must have Suitable Temperature Monitors capable of indicating whether the required storage temperatures have been maintained during transport of the Pharmaceutical.

(iv) must be marked with clearly visible instructions that the Pharmaceutical requires immediate refrigeration between 2 – 8°C (as applicable);

(v) must be receipted and signed for by an authorised person of the Service Provider at the Designated Delivery Point;

(vi) 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;

(vii) must have a certificate signed by an appropriate official of the national control laboratory of the manufacturer's country:

(A) 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;

(B) confirming that the Pharmaceutical(s) accompanying the certificate meets Part A of the then current WHO requirements applicable to such Pharmaceutical(s);

(C) advising the date of the last satisfactory test for potency of the Pharmaceutical(s) and the relevant lot number; and

(viii) must have a copy of the official national release document for the Pharmaceutical(s) contained in the Delivery; and

(ix) must be quality control released by you in New Zealand, prior to despatch for Delivery.

(c) 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, to the extent applicable.

(d) 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 2.3(e) below.

(e) 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 specification data loggers, which must be completed within two Business Days after Delivery. Until the earlier of two Business Days after Delivery or all of the activities set out in this clause have been carried out, all risk in the Pharmaceutical will remain with you.

(f) The Service Provider will advise you of any deliveries with visible damage at the time of delivery to the Designated Delivery Point or any Pharmaceutical volume shortage within five 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.

(g) You must, 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.

2.4 Defects

(a) In respect of delivery of the Pharmaceutical to New Zealand, where a delivery of the Pharmaceutical is defective (including, without limitation, non-compliance with your Licence to Sell by Wholesale, Cold Chain or where the temperature monitoring is inadequate to determine whether there has been compliance with Cold Chain), you shall:

(i) immediately notify Pharmac of the damage or defect;

(ii) immediately remedy the cause of the damage or defect to the satisfaction of Pharmac;

(iii) 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; and

(iv) obtain additional delivery of the Pharmaceutical, in order to meet your obligation to supply the Pharmaceutical in accordance with this Agreement.

2.5 Supplier Warranties

(a) You warrant and agree that the Pharmaceutical supplied under this Agreement:

(i) complies with Cold Chain;

(ii) complies with your Licence to Sell by Wholesale;

(iii) 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;

(iv) is of the particular standard, quality, value, grade, composition, style or model and has the particular history which you have represented;

(v) is free of defects and is of merchantable quality;

(vi) is fit for all the purposes for which the Pharmaceutical is required and for which the Pharmaceutical is commonly supplied;

(vii) 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;

(viii) 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

(ix) 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”.

2.6 Pandemic and Local Outbreak

(a) 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 at the Price.

(b) For the purpose of clause 2.6(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.

(c) You will, at all times, keep Pharmac informed of your ability to supply additional Pharmaceutical under this clause.

(d) For the purpose of clause 2.6(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.

(e) 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.

3. Reporting

3.1 Information

(a) You agree to provide any information related to the Pharmaceutical and its listing that Pharmac reasonably requests, in such manner and timeframe as Pharmac reasonably requests.

(b) In particular, and without limiting the generality of clause 3.1(a) above, you:

(i) acknowledge that Pharmac requires the provision of Unique Product Identifiers in order to implement the listing of each Pharmaceutical and you agree to obtain and notify Pharmac of the Unique Product Identifiers of each Pharmaceutical no later than 10 Business Days following your acceptance of this Agreement, unless that Pharmaceutical is already listed;

(ii) agree that in the event that you supply an Alternative Pharmaceutical in accordance with this Agreement, or in the event of a Changed Medicine Notification for a Pharmaceutical, you must notify Pharmac of any changed Unique Product Identifiers (or advise if there is no change) as soon as practicable;

(iii) acknowledge that in the event the listing of the Pharmaceutical includes special authority criteria or any other access criteria, you must, for the duration that the Pharmaceutical is listed:

(A) notify Pharmac in the event the Data Sheet is amended in a manner which, when considered in the context of any current special authority criteria or other current access criteria, could impact on patient safety; and

(B) provide Pharmac with a summary of the amendment to the Data Sheet as set out in clause 3.1(b)(iii)(A) above;

Following the notification in clause 3.1(b)(iii)(A) Pharmac reserves the right at its sole discretion to amend the special authority criteria or any other access criteria for the Pharmaceutical based on patient safety;

(iv) acknowledge that Pharmac may require stock reports and batch details held by you for the Pharmaceutical and you agree to provide all such stock reports and batch details to Pharmac upon request;

(v) acknowledge that Pharmac may require price and volume data held by you relating to sales of the Pharmaceutical and you agree to provide all such price and volume data to Pharmac upon request; and

(vi) agree that Health NZ may provide Pharmac and its agents with any price and volume data held by Health NZ in respect of the Pharmaceutical, and Pharmac may share any price and volume data held by Pharmac with Health NZ.

3.2 Supply Issues Reporting

(a) You must send a Supply Issues Report to Pharmac in accordance with clause 4.3(a)(ii) of this Agreement or otherwise at Pharmac's request.

(b) The Supply Issues Report must be provided to Pharmac in any form notified by Pharmac to you. Unless notified otherwise, the Supply Issues Report must include the following information:

(i) quantity of Pharmaceutical stock:

(A) held by you (or on your behalf) in New Zealand;

(B) held by you (or on your behalf) in other international markets, and available for supply in New Zealand; and

(ii) reason for the Supply Issue;

(iii) when the Supply Issue occurred;

(iv) expected delivery dates of the Pharmaceutical to New Zealand;

(v) expected date of authorised release into the New Zealand market (including the date on which the Pharmaceutical is expected to be available for supply) and any applicable supporting evidence, for example export and import licences or other official authorisations and customs formalities necessary for the exportation and importation of the Pharmaceutical;

(vi) the estimated duration of the Supply Issue; and

(vii) any steps that you have taken or will take to mitigate the risk that you may fail to supply a Pharmaceutical.

(c) You acknowledge that Pharmac may wish to engage with you in respect of any steps that you advise Pharmac of under clause 3.2(b)(vii) above or any other steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical, and you agree that you will engage and cooperate with Pharmac in relation to all such actual and proposed mitigation activities.

4. Supply Obligations and Managing Supply Issues

4.1 Stock Holdings

You must ensure you have sufficient stock of the Pharmaceutical to meet any Purchase Order requirements.

4.2 Continuity of Supply

(a) You must supply, and continue to supply, the Pharmaceutical on the terms set out in this Agreement to the Designated Delivery Point on the Agreed Delivery Date.

(b) You warrant that you have entered into all contractual and other arrangements to the extent necessary, including licence and supply agreements with third parties, to ensure that you will meet all of your obligations under clause 4.2(a) above and this Agreement generally.

(c) Without prejudice to clauses 4.5 and 4.6 below, you agree that a discount of 10% will apply to the Price for each unit of Pharmaceutical delivered 20 Business Days after the Agreed Delivery Date. A further discount of 10% will then apply to the Price for each unit of Pharmaceutical for each subsequent 15 Business Day period following the 20 Business Day period stated in the clause, where a Pharmaceutical has not been delivered in accordance with the Agreed Delivery Date.

4.3 Notification

(a) You must:

(i) notify Pharmac as soon as you become aware of a Supply Issue; and

(ii) send a Supply Issues Report to Pharmac within 2 Business Days of becoming aware of a Supply Issue.

(b) In the event that you consider (acting reasonably) that any circumstances or events may result in a Supply Issue you must notify Pharmac in writing as soon as practicable, including (but not limited to) any of the following circumstances:

(i) you plan any changes to your supply chain, for example but not limited to a change in manufacturing site, in respect of the Pharmaceutical;

(ii) you plan any changes to your ordering or delivery systems;

(iii) you plan to re-structure your organisation; or

(iv) you plan to change the presentation of the Pharmaceutical, including the brand name, pack size, packaging and strength.

(c) After giving Pharmac notice in accordance with clauses 4.3(a)(i) and/or 4.3(b), you must comply with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

4.4 Managing Supply Issues

(a) In addition to your obligations set out in clause 4.3 you must comply with the obligations set out in this clause 4.4.

(b) In the event of:

(i) a decision or notification by Medsafe or any other authorities to recall the Pharmaceutical; or

(ii) the withdrawal of any Consent or Market Approval for the Pharmaceutical,

you must use your best endeavours to engage and co-operate with Medsafe and any other relevant authorities and must, at all times, meet all your regulatory obligations.

(c) In the event a Supply Issue actually results in a failure to supply, or you have reason to believe may cause you to fail to supply, the Pharmaceutical in accordance with the terms of this Agreement, then

(i) subject to the prior written consent of Pharmac, you must use your best endeavours to procure, within what Pharmac considers to be a reasonable period of time, an Alternative Pharmaceutical for supply to the Designated Delivery Point: at the Price; and

(ii) if you fail to procure an Alternative Pharmaceutical at the Price and within the timeframe in accordance with clause 4.4(c)(i) above then 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 Pharmac any additional costs, fees and/or expenses incurred by Health NZ or Pharmac as a result of the purchase of the Alternative Pharmaceutical over and above the costs that would have been incurred by Pharmac had you supplied the Pharmaceutical.

(d) In the event Pharmac receives information that indicates that you may fail to supply a Pharmaceutical in accordance with this Agreement (whether you notify Pharmac under this Agreement or otherwise), you agree that Pharmac may inform other interested parties who may be impacted, including providing other suppliers with sufficient information to allow those suppliers to adequately prepare for a potential change in demand.

4.5 Indemnity

You agree to indemnify Pharmac and Health NZ (as applicable) for any damages, liability, loss, cost (operational or otherwise) or expense awarded against, incurred or suffered by Pharmac and/or Health NZ as a result of or arising from a Supply Issue (other than a Supply Issue resulting directly from a Force Majeure Event). This indemnity shall be deemed to indemnify Pharmac and Health NZ for all additional costs, including all costs incurred by Pharmac and/or Health NZ as a result of the purchase of the Alternative Pharmaceutical that are additional to any costs specified in clause 4.6.

4.6 Liquidated Damages

(a) Subject to clause 4.6(c) and clause 4.6(d), for each and every Supply Issue which actually results in a failure to supply the Pharmaceutical (other than a Supply Issue resulting directly from a Force Majeure Event) you must pay to Pharmac liquidated

damages (plus GST (if any)) of $50,000 to cover Pharmac's administrative and/or operational costs.

(b) You acknowledge that Pharmac's right to claim the full liquidated damages amount specified in clause 4.6(a) in these circumstances reflects Pharmac's legitimate interests in securing delivery of the Pharmaceutical by the relevant date and in accordance with the terms of this Agreement and is proportionate to those interests during the period, and in the circumstances, in which the liquidated damages are payable under this clause 4.6.

(c) Liquidated damages are payable where you have not:

(i) notified Pharmac under and in accordance with clause 4.3; and/or

(ii) complied with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

(d) Pharmac may, in its sole discretion, require you to pay less than the amount specified as liquidated damages in clause 4.6(a) if Pharmac is satisfied that the actual costs in the circumstances are less than this amount.

4.7 Interest

If payment of any amount required to be paid by you under clauses 4.5 or 4.6 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:

(a) interest will accrue on such sum as remains unpaid at a rate per annum equal to the Default Interest Rate, 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 does not limit any other right or remedy of Pharmac; and

(b) Pharmac may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 5.5, to recover that unpaid amount and you agree to pay to Pharmac actual enforcement costs incurred in relation to that action.

5. General Obligations

5.1 Shelf-life of Pharmaceutical

You will not supply the Pharmaceutical:

(a) if the remaining shelf-life of that Pharmaceutical is less than 12 months; or

(b) where the total shelf-life of that Pharmaceutical is less than 12 months, the remaining shelf-life is less than 75% of that Pharmaceutical's total shelf-life,

without prior written agreement from Pharmac or the applicable Health NZ Hospital. In the event Pharmac's or the applicable Health NZ Hospital's agreement is obtained, you will provide Pharmac with a credit for the Price paid, for any of this Pharmaceutical stock which is unused at the time of expiry.

5.2 Consents

(a) Prior to the Listing Date you must obtain:

(i) Market Approval for the Pharmaceutical;

(ii) any Consent required for the supply of the Pharmaceutical; and

(iii) any other Consent Pharmac requires you to have or hold.

(b) You must maintain Market Approval and any other Consent specified in clauses 5.2(a)(ii) and 5.2(a)(iii) for the Pharmaceutical for the duration the Pharmaceutical is listed.

5.3 Health and Safety

Where delivery of the Pharmaceutical (or provision of any related services described in this Agreement) occurs within the facilities of a Health NZ Hospital, you and your Personnel will comply with all relevant health and safety requirements, including:

(a) the Health and Safety at Work Act 2015 and all regulations made under that Act; and

(b) any policies and procedures communicated to you by the Health NZ Hospital.

5.4 Confidentiality

(a) Confidential Information is confidential to you, Pharmac, Health NZ and those parties' respective Personnel (as applicable).

(b) You acknowledge that Pharmac may be required to disclose Confidential Information in accordance with:

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

(ii) any other legal and administrative obligations,

and you consent to such disclosure.

(c) Where Pharmac reaches a preliminary view that Confidential Information must be disclosed for the purposes stated in clause 5.4(b)(i) above, Pharmac will consult with you, and will act in good faith, before deciding whether to disclose the Confidential Information.

(d) To the extent permitted by law, Pharmac will inform you if Confidential Information is disclosed for the purposes stated in clause 5.4(b)(ii) above, including any disclosure to a court, inquiry or ombudsman.

(e) Confidential Information must not be disclosed by you, Pharmac, Health NZ or those parties' respective Personnel unless:

(i) the information is publicly available or enters the public domain through no fault of the applicable parties; or

(ii) the disclosure is:

(A) required or permitted for the purposes of this Agreement;

(B) required or permitted by law; or

(C) agreed to between the applicable parties.

5.5 Dispute Resolution

If there is a dispute between you and Pharmac arising out of, or in connection with, this Agreement, neither of the parties 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) You and Pharmac will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.

(c) If you and Pharmac have not resolved the dispute within 14 days after the date notice of a dispute was given, the parties may agree that the dispute is to be:

(i) mediated according to the standard mediation agreement of the Resolution Institute (a body corporate incorporated in Australia and registered as an overseas company in New Zealand), and the Chair of the Resolution Institute (or the Chair's nominee) will select the mediator and determine the mediator's remuneration, if you and Pharmac are unable to agree on such matters; or

(ii) submitted to arbitration in accordance with the Arbitration Act 1996, with such arbitration being conducted by a single arbitrator to be agreed on by the parties or, failing agreement, the Chair of the Resolution Institute (or the Chair's nominee) will select the arbitrator.

(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 the parties' respective rights and remedies (including Pharmac's rights under its OPPs).

5.6 Litigation Support

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

(a) give rise to proceedings being issued, or any claim being made, against Pharmac; or

(b) results in Pharmac being made a party to any proceedings issued, or claim made, by a third party,

you will give Pharmac all assistance it reasonably requires for the purpose of the handling of any negotiations and/or litigation related to those proceedings or any claim.

5.7 Insurance

(a) You shall arrange and maintain insurance policies for:

(i) public liability insurance with a minimum cover of NZ$10 million for any one occurrence; and

(ii) products liability insurance with a minimum cover of NZ$50 million for any one occurrence.

(b) 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.

(c) You will do nothing to invalidate the insurance policies that you hold as required under clause 5.7(a) above or to prejudice your entitlement under those insurance policies.

6. General Terms

6.1 No Derogation

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

6.2 No Waiver

A failure or delay by either you or Pharmac 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.

6.3 Remedies Cumulative

Except as is expressly stated otherwise in this Agreement:

(a) the rights, powers and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers or remedies provided by law or under this Agreement; and

(b) the exercise of any of the rights, powers and remedies provided in this Agreement will not prejudice the exercise of any other right, power or remedy under this Agreement or existing at law.

6.4 Entire Agreement

This Agreement:

(a) is the entire agreement between you and Pharmac regarding the terms on which the Pharmaceutical is listed; and

(b) supersedes and extinguishes all prior agreements and understandings between you and Pharmac, and between you and Health NZ, and any prior agreements and understandings originally entered into between you and district health boards (as applicable), regarding the Pharmaceutical and the subject matter contained herein.

6.5 Advertising

You must ensure that any Advertisement aimed at consumers of the Pharmaceutical does not breach any applicable statute, regulation or industry standard, including the Advertising Standards Authority Codes of Practice and the Medicines New Zealand Code of Practice.

6.6 Contracts Privity

(a) You and Pharmac acknowledge that your obligations in this Agreement constitute promises and obligations which confer or are intended to confer a benefit on Health NZ and related persons, and are enforceable by Health NZ and any such persons pursuant to Part 2, subpart 1 of the Contract and Commercial Law Act 2017 (Contractual Privity).

(b) Except as expressly provided in clause 6.6(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) 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 Health NZ.

6.7 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.

6.8 Amendments

Amendments to this Agreement must be in writing.

6.9 Assignment

You will not permit this Agreement, or any part of this Agreement, to be transferred or assigned (either directly or due to a change of 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.

6.10 Further Assurances

You and Pharmac agree to execute any further documents and do any further acts as may be reasonably necessary from time to time to give effect to the terms and intentions of this Agreement.

6.11 Specific Performance

You acknowledge that in the event of any breach or threatened breach of this Agreement by you, damages may not be an adequate remedy and Pharmac may seek specific performance of the terms of this Agreement or injunctive relief or any other similar remedy, in addition to any other rights, powers or remedies provided under this Agreement or by law (including equity).

6.12 Agreement Prevails

Where any of your terms of supply, for example on invoices or any purchase orders, conflict or are inconsistent with any of the terms of this Agreement, the terms of this Agreement will prevail.

6.13 Governing Law and Jurisdiction

This Agreement is governed by New Zealand law and each party submits to the exclusive jurisdiction of the New Zealand courts.

Annex 4: Definitions and Interpretation

1. Definitions

In this Agreement:

Advertisement means any advertisement as defined in the Medicines Act 1981;

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;

Agreement means this agreement, including all Annexures;

Alternative Pharmaceutical means an alternative Pharmaceutical that Pharmac has expressly agreed in writing constitutes an acceptable substitute for that Pharmaceutical;

Business Day means a day of the week, which excludes Saturday, Sunday, and national public holidays in New Zealand. A Business Day starts at 8.30am and ends at 5pm;

Changed Medicine Notification means a notification provided by you, in accordance with the Medicines Act 1981, to the Director-General of Health, of a planned material change to the Pharmaceutical, and the reasons for the change;

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 distribution and storage requirements of your Licence to Sell by Wholesale, to the extent that they are applicable to the Pharmaceutical;

Confidential Information means information relating to the terms of this Agreement that is agreed in writing by you and Pharmac as being confidential, including but not limited to the Price, but excludes:

(a) information regarding the Pharmaceutical that does not identify you, or that cannot reasonably be expected to identify you, and you agree that such information is not Confidential Information and that Pharmac may use and publish such information; and

(b) information released by Pharmac in accordance with clause 5.4 of Annex 3 of this Agreement, and you agree that such information ceases to be Confidential Information and that Pharmac may release that information again at any time in future without consulting with you or obtaining your prior agreement;

Consent means registrations, consents, permits, licences and authorisations, whether statutory or otherwise;

Crown Direction means any direction given to Pharmac under statutory authority;

Data Sheet means the Pharmaceutical data sheet published by Medsafe on your behalf;

Default Interest Rate means the base rate of ASB Bank Limited plus 5% per annum;

Delivery means the delivery by you of the Pharmaceutical to, and the receipt of, the Pharmaceutical 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;

Force Majeure Event means any cause preventing the affected party from performing any or all of its obligations under this Agreement which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the affected party, which:

(a) was not reasonably foreseeable;

(b) could not have been avoided or mitigated through the exercise of good industry practice and due care, skill and diligence; and

(c) was not caused by the affected party, its affiliates, officers, Personnel or suppliers,

but does not include any lack of finance or financial means or any changes in market conditions;

Health NZ means Health New Zealand | Te Whatu Ora, a Crown agent established under section 11 of the Pae Ora (Healthy Futures) Act 2022;

Health NZ Hospital means a hospital operated by Health NZ;

Listing Date means the date on which Pharmac will list, or amend the listing of (as applicable), the Pharmaceutical as recorded in Annex 1 of this Agreement or otherwise determined in accordance with this Agreement;

Local Outbreak means the occurrence of a vaccine preventable disease greater than would otherwise be expected at a particular time and place;

Market Approval means regulatory approval for sale and marketing in New Zealand;

Medsafe means the business unit within the Ministry of Health that has responsibilities in relation to the safety of medicines and medical devices used and supplied in New Zealand;

New Zealand Government's Supplier Code of Conduct means the New Zealand Government's supplier code of conduct (as updated from time to time);

OPPs means Pharmac's Operating Policies and Procedures (as updated from time to time);

Pandemic means the worldwide spread of a disease;

Personnel means all individuals engaged by the relevant party, including the parties' employees, contractors, representatives, legal advisors, clinical advisors and other consultants;

Pharmaceutical means each pharmaceutical described in Annex 1, in the form(s), strength(s) and pack size(s) set out in Annex 1;

Pharmaceutical Schedule means the schedule listing all the medicines funded for New Zealanders (as updated from time to time);

Price means the confidential price (exclusive of GST) of the Pharmaceutical as set out in the Purchase Price column stated in Annex 1, Table 2;

Purchase Order means an order for Pharmaceutical issued by Pharmac to you in accordance with Schedule 1;

Quarter means the periods of each calendar year being 1 January – 31 March, 1 April – 30 June, 1 July – 30 September and 1 October - 31 December;

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 Pharmaceutical 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;

Supply Issue means an event which may result, or has resulted, in a failure to supply the Pharmaceutical in accordance with this Agreement, including but not limited to:

(a) you recall (or have reason to believe you may recall), or are (or have reason to believe you may be) required by Medsafe or any other authorities to recall, the Pharmaceutical;

(b) any Consent or Market Approval, required in accordance with clause 5.2 of Annex 3 is withdrawn, revoked, suspended or withheld;

(c) you fail to meet Cold Chain requirements;

(d) you supply the Pharmaceutical after the Agreed Delivery Date;

(e) you become aware of any issue that may impact on your ability to fulfil any orders for the Pharmaceutical;

(f) you plan to withdraw the Pharmaceutical from supply;

(g) you fail to supply (or have reason to believe you may fail to supply) the Pharmaceutical from the Listing Date; and/or

(h) any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.

Supply Issues Report means a report provided by you to Pharmac in accordance with clause 3.2 of Annex 3 of this Agreement; and

Unique Product Identifiers means for each Pharmaceutical:

(a) the 'CTPP', which is the Containered Trade Product Pack SNOMED CT code, which is the unique identifier that describes the packaged, branded product and the container it is dispensed in, as used within the New Zealand Medicines Terminology;

(b) the 'GTIN' (if available), which is the Global Trade Item Number for a Pharmaceutical;

(c) the 'Pharmacode', which is the unique identifier assigned to a Pharmaceutical and notified to you by the Pharmacy Guild; and

(d) the 'Supplier Code', which is the unique product identifier assigned by you to the Pharmaceutical, if applicable.

2. Interpretation

In this Agreement, unless the context requires otherwise:

(a) references to **"Health NZ"** encompass Health NZ Hospitals;

(b) references to **"Health NZ Hospitals"** may reflect that certain operational matters can in practice occur at a local hospital level notwithstanding that Health NZ Hospitals are part of, and not separate legal entities from, Health NZ;

(c) references to clauses are to clauses in this Agreement;

(d) the headings to clauses will be ignored in construing this Agreement;

(e) the plural includes the singular and vice versa;

(f) any organisations (including government agencies) referenced in this Agreement include their successors;

(g) a reference to any statute includes that statute, and regulations made under it, as amended from time to time;

(h) a reference to any statute includes any statute passed in substitution for that statute;

(i) an obligation not to do anything includes an obligation not to suffer, permit or cause that thing to be done;

(j) derivatives of any defined word or term have a corresponding meaning;

(k) all references to dollars are references to New Zealand dollars unless provided otherwise;

(l) "including" and similar words do not imply any limitation;

(m) references to **"you"** include any third parties acting on your behalf, including sub-contractors;

(n) 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);

(o) the terms set out in this Agreement specify the terms of listing for each Pharmaceutical and the terms apply independently to each Pharmaceutical in Annex 1; and

(p) none of the terms are to be construed against a party by reason of the fact that that term was first proposed or was drafted by that party.

Schedule 1

Estimated Annual Rolling 24-month Forecast

Pharmac will provide you within the first 10 Business Days of each Quarter, an estimated rolling 24 month forecast for the Pharmaceutical(s).

Purchase Orders

(a) Purchase Orders shall specify (without limitation):

(i) a Purchase Order number and date;

(ii) Pharmac's name;

(iii) the volume of Pharmaceutical ordered;

(iv) 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);

(v) the contact details of Pharmac's designated representative(s) responsible for the Purchase Order;

(vi) the name(s) of the person(s) of the Service Provider authorised to sign for a Delivery; and

(vii) the Service Provider's address for Delivery of the Pharmaceutical.

(b) The process for the issuing and receipt of Purchase Orders from Pharmac to you shall be as follows:

(i) Pharmac shall issue an indicative Purchase Order to you, which shall include the information specified in paragraph (a) above;

(ii) upon receipt of an indicative Purchase Order from Pharmac, you shall confirm in writing to Pharmac within 5 Business Days whether that indicative Purchase Order is accepted by you or not. In the event the indicative Purchase Order is:

A. accepted by you then that indicative Purchase Order becomes a Purchase Order under the terms of this Agreement; or

B. not accepted by you, you will notify Pharmac of the proposed change(s) to the indicative Purchase Order and you will negotiate with Pharmac in good faith the terms of that Purchase Order.

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 acceptance of the Purchase Order as stated in paragraph (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 proposed to Pharmac shall be the Agreed Delivery Date.