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.