

Briefing

Supply agreement for the purchase of additional COVID-19 vaccines from Pfizer New Zealand Ltd in 2022

Date due to MO:	15 October 2021	Action required by:	20 October 2021	
Security level:	Commercially Sensitive	Health Report number:	HR20211937	
То:	Rt Hon Jacinda Ardern, Pri	me Minister	G	
	Hon Grant Robertson, Mir	ister of Finance		
	Hon Chris Hipkins, Ministe	er for COVID-19 Response		
	Hon Andrew Little, Minister of Health			
	Hon Nanaia Mahuta, Minis	ster of Foreign Affairs		
	Hon Dr Megan Woods, M	inister of Research, Science	and Innovation	
	Hon Aupito William Sio, M	linister for Pacific Peoples		
	Hon Dr Ayesha Verrall, Ass	sociate Minister of Health		
	Hon Peeni Henare, Associa	ate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	9(2)(a)
Maree Roberts	Deputy Director-General, System Strategy and Policy	9(2)(a)

Minister's office to complete:

□ Approved	□ Decline	\Box Noted
\Box Needs change	□ Seen	\Box Overtaken by events
\Box See Minister's Notes	□ Withdrawn	

Comment:

Supply agreement for the purchase of additional COVID-19 vaccines from Pfizer New Zealand Ltd in 2022

Security level:	Commercially Sensitive Date: 15 October 2021		
То:	Rt Hon Jacinda Ardern, Prime Minister		
	Hon Grant Robertson, Minister of Finance		
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	Hon Aupito William Sio, Minister for Pacific Peoples		
	Hon Dr Ayesha Verrall, Associate Minister of Health		
	Hon Peeni Henare, Associate Minister of Health		

Purpose of report

- 1. To seek your agreement to an amendment to the existing advance purchase agreement (APA) with Pfizer New Zealand Ltd (Pfizer) for the purchase of an additional 4.7 million doses of COVID-19 vaccine in 2022.
- 2. We also seek agreement to appropriate funds for the purchase.

Summary

- 3. We anticipate that that there is likely to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (children under 12 years of age) and for a potential booster programme, if evidence determines this is required.
- 4. Given efficacy data, and public perception of a highly safe and effective vaccine resulting from New Zealand's Pfizer-based approach to date, we expect to continue to need an mRNA vaccine over the longer term.
- 5. Following Cabinet approval to progress negotiations to secure additional COVID-19 vaccines in 2022, officials have finalised negotiations with Pfizer to secure an additional 4.7 million Pfizer doses for delivery in 2022 through an amendment to our current APA.
- 6. s 9(2)(b)(ii)
- 7. We are seeking your agreement to purchase 4.7 million doses of the Pfizer vaccine because:

- a. this would provide continuation of supply of an mRNA vaccine (specifically Pfizer's vaccine) for the CVIP for those who do not access a vaccine in 2021 and who may require a third dose in 2022;
- b. we have a strong working relationship with Pfizer already, have confidence in Pfizer's ability to manufacture and deliver a high-quality vaccine; and
- c. we have worked closely with the Ministry for Foreign Affairs and Trade, Pharmac, and have been supported by legal advice from Bell Gully to ensure that the terms and conditions of this purchase are acceptable and are in line with global trends for COVID-19 vaccine advance purchase arrangements.
- 8. If you agree to this purchase, and the Minister of Finance agrees to the indemnity required by Pfizer, the Director-General will sign and execute the amendment. Following this, officials recommend that you announce up to 4.7 million doses have been secured to support the COVID-19 Immunisation Programme, but do not recommend communicating the delivery dates until they have been confirmed closer to the time of delivery.
- 9. All communication will be required to be carried out in coordination between New Zealand and Pfizer.

Recommendations

We recommend you:

- a) **Note** that in May 2020, Cabinet agreed to the COVID-19 Vaccine Strategy [CAB-20-MIN-0229 refers] which enabled New Zealand to successfully secure access to four COVID-19 vaccines and enabled the roll-out of the Pfizer vaccine.
- b) **Note** that the Vaccine Strategy continues to be applied in a changing context to ensure New Zealanders are best protected against COVID-19.
- c) **Note** that there is almost certainly going to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (paediatric doses) and for a potential booster programme, if evidence determines this is required.
- d) **Note** that on 30 August 2021, Cabinet agreed that New Zealand will continue to support the Cook Islands, Niue, and Tokelau, and work in coordination with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022 [CAB-21-MIN-0350 refers].
- e) **Note** that to support ongoing uptake in New Zealand and immunisation needs in the Pacific in 2022, we continue to need access to an mRNA vaccine over the longer term.
- f) Note that at this stage, there is not enough data to predict if or when any booster doses will be required to maintain high vaccine effectiveness and protection against COVID-19 for the general population.
- g) **Note** we have negotiated with Pfizer fo

- h) **Note** that this purchase enables us to support ongoing uptake in the population, and secures access to sufficient doses in the event that boosters are required.
 - i. in combination with doses expected to not to be utilised in 2021, this purchase would support booster doses at 9 months from the second dose, as well as paediatric doses from Q1 2022.
 - ii. this purchase also enables us to continue to support immunisation programmes in the Cook Islands, Niue and Tokelau, as well as Samoa, Tonga, Tuvalu and Fiji, in coordination with other donors, if required.
- i) **Note** the negotiations have been carried out by officials from the Ministries of Health and Foreign Affairs and Trade, and Pharmac, with the support of external legal counsel Bell Gully.
- j) Note that in August 2021, Cabinet [CAB-21-MIN-0350 refers]:
 - i. ^{s 9(2)(b)(ii)}
 - ii. authorised Vaccine Ministers to draw down on the tagged operating contingency funding.
- k) Agree subject to the agreement of the Minister of Finance to grant the indemnity in favour of Pfizer, the Director-General of Health, on behalf of the Crown, will sign the proposed amendment to the APA to purchase 4.7 million additional doses of Pfizer's COVID-19 vaccine to be delivered in 2022.
- l) <u>\$ 9(2)(b)(ii)</u> Yes/No
- m) Approve if you agree to the recommendation I) above, the following changes to the appropriations to provide for the decision, with a corresponding impact on the operating balance and net core Crown debt as follows:

Vote Health		\$m – increas	e/(decrease)	
Minister of Health	2021/22	2022/23	2023/24	2024/25 & Outyears
Multi-Category Expenses and Capital Expenditure:				
Implementing the COVID-19 Vaccine Strategy MCA	s 9(2)(b)(ii)			
Non-Departmental Output Expense:				

Purchasing Potential and Proven COVID-19 Vaccines and Other		
Therapeutics		

- Agree that the changes to appropriations for 2021/22 above be included in the 2021/22 Supplementary Estimates and that in the interim the increase be met from Imprest Supply.
- Note that Treasury officials are separately seeking agreement from the Minister of Finance to extend the indemnities in favour of Pfizer and others included in the APA to include these additional doses.
- p) Note that if the Minister of Finance agrees to extend the indemnities, then he will be invited to co-sign the amendment to the APA in respect of the indemnity obligations within the amendment in favour of Pfizer and others.
- q) Agree that, prior to any future purchases of Pfizer COVID-19 vaccines from Pfizer Yes/No or any other party (whether under this APA or otherwise) and any future donations of Pfizer COVID-19 vaccines, the Minister of Finance's prior approval must be obtained, in order for the Minister of Finance to consider the impact of that purchase/donation on those indemnity obligations.
- r) **Note** that officials recommend communicating this additional purchase once Pfizer have countersigned the amendment agreement.

Rt Hon Jacinda Ardern **Prime Minister**/...../..... Hon Chris Hipkins **Minister for COVID-19 Response**

Hon Grant Robertson
Minister of Finance

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Hon Andrew Little Minister of Health

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Hon Nanaia Mahuta

Minister of Foreign Affairs

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Hon Dr Megan Woods

Minister of Research, Science, and Innovation

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Hon Aupito William Sio
Minister for Pacific Peoples

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Hon Dr Ayesha Verrall
Associate Minister of Health

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Dr Ashley Bloomfield Director-General of Health

14/10/2021

Hon Peeni Henare

Associate Minister of Health

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Context

New Zealand has purchased a portfolio of vaccines and has sufficient volumes to deliver a Pfizer-based COVID-19 Immunisation Programme in 2021

- 1. New Zealand has purchased a portfolio of COVID-19 vaccines (Pfizer, AstraZeneca, Janssen, and Novavax) to manage risk and uncertainty, and is rolling out a Pfizer based COVID-19 Vaccine and Immunisation Programme (CVIP).
- 2. New Zealand has secured 10.88 million doses of the Pfizer vaccine for delivery in 2021, which is sufficient to fully vaccinate all eligible people this year (currently 4.2 million people), including with any extensions in eligibility (460,000 aged between 5 and 11). This means we will likely have a surplus of at least 2.2 million doses (assuming 95 percent uptake in people aged 12 and over). See table 1 below for Pfizer's indicative delivery schedule.

s 9(2)(b)(ii)	
5 5(Z)(D)(II)	

3. The shelf life of the Pfizer vaccine has increased from six to nine months which will mean that at least 1.6 million of the 2.2 million surplus doses from 2021 will be available for use up until June 2022.

There is almost certainly going to be a need for ongoing immunisation in 2022 and Cabinet has agreed to progress negotiations with Pfizer for supply in 2022

- 4. We anticipate that that there is likely to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (paediatric doses) and for a potential booster programme, if evidence determines this is required.
- 5. In 2022, CVIP should continue to prioritise maximising population coverage in eligible groups (in particular those who are yet to receive a vaccine), recognising that we anticipate that the last 20 percent of people to get vaccinated will be harder because they face more barriers to access and may be less motivated to get vaccinated.
- 6. Officials are working to ensure a small number of doses of AstraZeneca are available as a contingency in Q4 2021, ^{s 9(2)(b)(ii)}
- 7. Given efficacy data, and public perception of a highly safe and effective vaccine resulting from New Zealand's Pfizer-based approach to date, we expect to continue to need an mRNA vaccine over the longer term.

8.

<u>On 30 August, Cabinet agree</u>d ^{s 9(2)(b)(ii)}

and that officials progress negotiations with vaccine suppliers for additional vaccines where appropriate to ensure that the portfolio can continue to support immunisation needs in New Zealand and the Pacific [CAB-21-MIN-0350 refers]. Cabinet also delegated any future purchasing decisions to Vaccine Ministers.

We have an opportunity to purchase an additional 4.7 million doses of Pfizer for delivery in 2022

Purchasing these additional doses would enable ongoing uptake in 2022

- 9. Although supply in 2022 is expected to be less constrained than 2021 and should be able to match the desired CVIP more adequately, it is important to amend our APA now to allow for additional advance purchases for delivery in 2022 to avoid delayed access.
- 10. Officials have finalised negotiations with Pfizer New Zealand Ltd (Pfizer) to secure an additional 4.7 million Pfizer doses for delivery in 2022. This paper outlines the terms and conditions for the purchase of additional doses in 2022. Purchasing doses for 2022 ensures that we maintain a portfolio of vaccines, including a mRNA option.
- 11. s 9(2)(b)(ii)
- 12. Assuming a surplus of 2.2 million doses at the end of 2021, securing access to 4.7 million additional doses for delivery in 2022 would cover:
 - a. children aged 5 to11;
 - b. children who are 4 turning 5 who will become eligible;
 - c. all people who were eligible in 2021 but are not vaccinated (ie, 5 percent of eligible people are unvaccinated in 2022 based on a 95 percent uptake assumption for 2021;
 - d. eligible population who have received two doses receive a third dose if required;
 - e. children who are four turning five in Polynesia and if a third dose is required;
 - f. a 250,000-dose contingency to manage uncertainty around uptake and wastage assumptions and potential demand from people returning or entering New Zealand who are unvaccinated.

Further evidence is still needed to support a third dose

- 13. While we are proposing to purchase sufficient volumes of Pfizer to enable every eligible person a third dose, introducing a third dose in the CVIP should be firmly evidence-driven and targeted to the population groups in greatest need.
- 14. Evidence regarding the need for a third dose of the Pfizer vaccine is still very emergent. Further science and clinical advice would be required alongside approval from Medsafe before any third dose is able to be offered. This approval would also set a minimum interval between second and third doses (advice would be sought from the COVID-19 Vaccine Technical Advisory Group (CV TAG) on the optimal interval timing.
- 15. While there is currently insufficient evidence to support widespread need for a third dose, there is some evidence of waning immunity in those who received the vaccine in

April this year. We expect to have a clearer understanding of the need for third doses over coming months and we will continue to monitor the evidence as a priority.

16. Pfizer has indicated that it intends to make a submission to Medsafe ^{S 9(2)(b)(ii)} for the use of booster doses across all current eligible population groups. Regulators have taken varying approaches to date, with boosters approved for everyone above 16 in some jurisdictions (Israel), or only for elderly and immunocompromised in other jurisdictions (US).

17.	s 9(2)(b)(ii)	
18.	s 9(2)(b)(ii)	

A Medsafe decision is needed for any extensions in eligibility

- Officials anticipate that eligibility could be extended to include those aged 5 to 11 years early 2022, subject to Pfizer submitting data for Medsafe's assessment and approval. Purchasing additional vaccines for 2022 means we will have access to a paediatric vaccine for this age group.
- 20. Pfizer has noted in negotiations that a paediatric version of the vaccine for children 11 and under is under development, which would require establishment of a new global supply chain and would be subject to a new submission to Medsafe. (\$9(2)(b)(ii))

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22. Officials will provide advice following a recommendation from Medsafe on immunisation of 5 to 11 year olds. New Zealand and other countries may seek to vaccinate this age group using the current vaccine, at a lower dose. There are regulatory and administration issues that would need to be worked through before a decision on this could be made.

Although we are purchasing additional Pfizer doses, having access to a range of vaccines is essential

¹ a. The United Kingdom has purchased an additional 35 million doses for the second half of 2022.

b. Australia has purchased an additional 60 million doses for 2022 and 25 million doses for 2023.

c. The European Union has signed agreement to purchase 900 million doses with an option for a further 900 million.

23. While we are purchasing Pfizer to continue to supply the CVIP in 2022, our portfolio of vaccines remains important to manage supply and delivery schedule risks, and to diversify investment in a range of vaccines to support the CVIP needs. ^{S 9(2)(b)(ii)}

, including considering our future participation in COVAX.

(b) (ii)

24. Should there be a surplus of Pfizer vaccine as a result of lower than expected need or uptake, officials would attempt to reduce wastage \$9(2)(b)(fi)

or donation to support global vaccination efforts. ${}^{s}_{9(2)}$

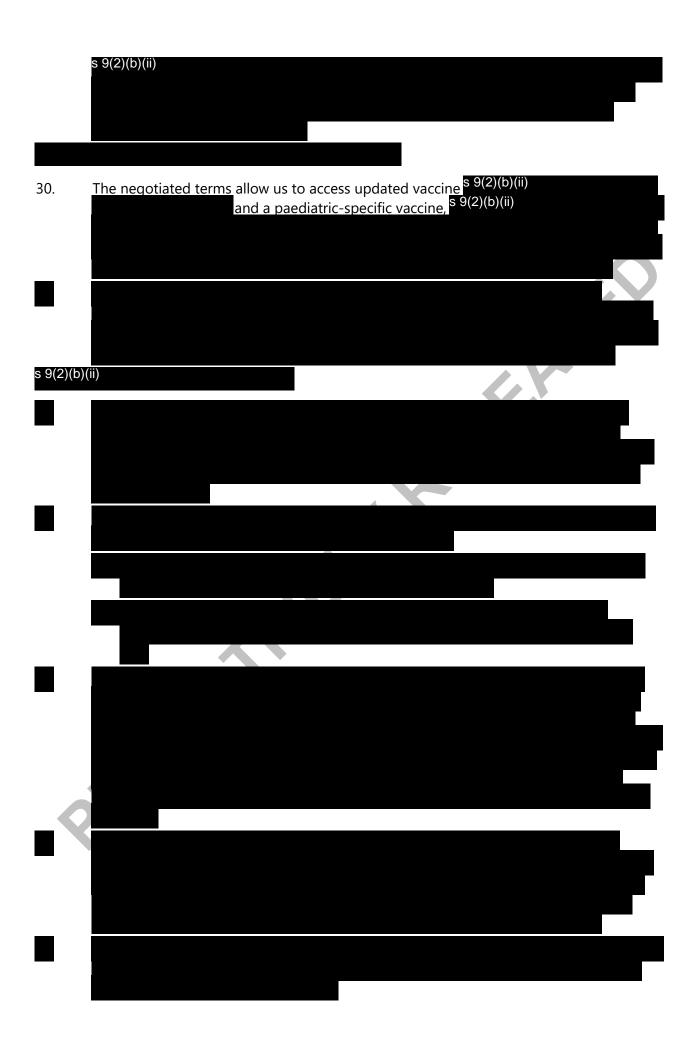
We recommend purchasing these additional doses of Pfizer's vaccine

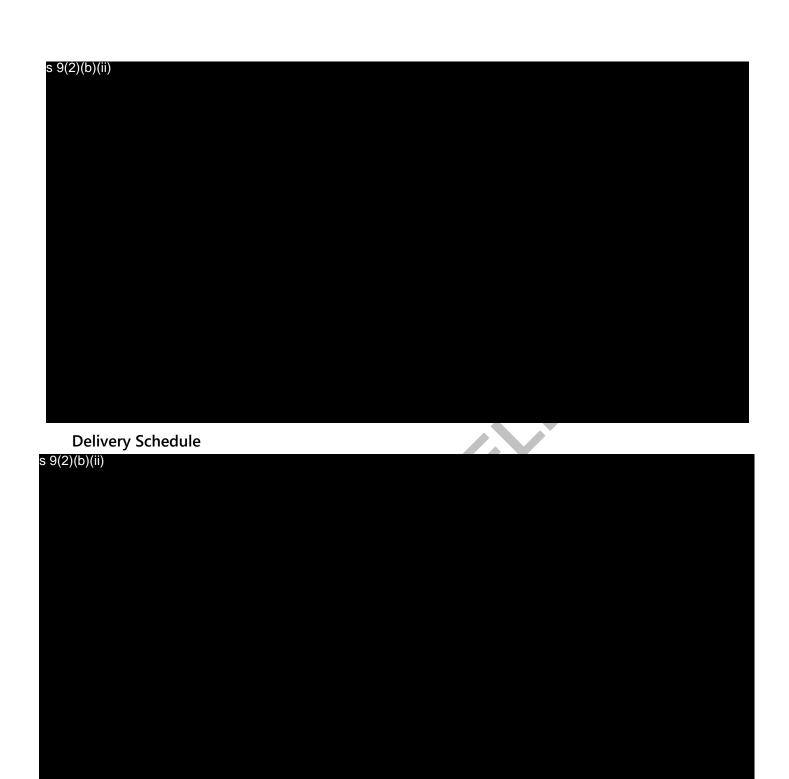
- 25. We are seeking your agreement to purchase 4.7 million doses of the Pfizer vaccine because:
 - a. this would provide continuation of supply of an mRNA vaccine (specifically Pfizer's vaccine) for the CVIP for those who do not access a vaccine in 2021 and who may require a third dose in 2022;
 - b. we have a strong working relationship with Pfizer already, have confidence in Pfizer's ability to manufacture and deliver a high-quality vaccine; and
 - c. we have worked closely with the Ministry for Foreign Affairs and Trade, Pharmac, and have been supported by legal advice from Bell Gully to ensure that the terms and conditions of this purchase are acceptable and are in line with global trends for COVID-19 vaccine advance purchase arrangements.
- 26. This purchase will be part of our COVID-19 vaccine portfolio, which continues to support ongoing supply of vaccines to support our immunisation needs, and manages downstream risks, including a sole reliance on Pfizer for COVID-19 vaccines.

Officials have negotiated updated terms and conditions with Pfizer

27. The negotiation priorities agreed by Vaccine Ministers on 13 August 2021 [HR-2021-1824 refers] have guided the negotiations with Pfizer for doses in 2022. This section provides commentary on the updated terms and conditions in the amendment to the APA against our negotiation priorities.

s 9(2)(b)(ii)			
5 3(Z)(D)(II)			





- 44. Assuming a surplus of 2.2 million doses at the end of 2021, this delivery schedule would enable a rollout of booster doses for all eligible groups at 9 months from the second dose, as well as paediatric doses from Q1 2022.
- 45. Should there be a surplus of the Pfizer vaccine as a result of lower than expected need or uptake, officials would attempt to reduce wastage or donation to support global vaccination efforts.

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Planning is now underway to ensure these doses can be utilised

- 47. The Ministry of Health is working on the future COVID-19 immunisation strategy. This will include not only consideration of future COVID-19 vaccine needs but also other vaccine requirements, particularly those who need to continue high levels of protection for New Zealanders such as influenza and measles. It will also look at the delivery of an overall integrated immunisation schedule. This work will cover, policy, purchasing and delivery options.
- 48. It is also expected that the roles and responsibilities for future purchasing will look different following Cabinet's decision on the implementation of the Health and Disability System Review.
- 49. The Ministry will continue to seek advice from the CV TAG on the evidence to support future immunisation needs, specifically for children and with respect to booster vaccinations.
- 50. In parallel to planning for 2022, the CVIP is in the process of securing sufficient consumables (including needles, syringes, and diluent) to support the use of these additional doses from Q1 2022.

s 9(2)(b)(ii), s 9(2)(g)(i)

Process for extending eligibility or introducing a third dose or updated vaccine

- 52. Before Cabinet can consider extending eligibility, or introduce a third dose or updated vaccine into the programme, Pfizer must submit an application to Medsafe to seek approval. Any application will be prioritised by Medsafe and Pfizer has indicated its intention to submit an application for paediatric doses (5-11) $\frac{S 9(2)(b)(ii)}{S 9(2)(b)(ii)}$, with an application for booster doses $\frac{S 9(2)(b)(ii)}{S 9(2)(b)(ii)}$
- 53. If the Pfizer vaccine is approved by Medsafe for use in a broader capacity, we would seek agreement from Cabinet to use the vaccine with supporting advice from the CV TAG.

This purchase will continue to support New Zealand's role as a contributor to the global response to the pandemic

- 54. On 30 August, Cabinet agreed to continuing to support the Cook Islands, Niue, and Tokelau to access sufficient vaccines to cover their ongoing immunisation needs in 2022 [CAB-21-MIN-0350 refers] and to work with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022.
- 55. Purchasing additional Pfizer vaccine will enable us to continue to support Polynesia and Fiji to access vaccine for their eligible population.

56. It would also be possible to donate surplus vaccine to the COVAX Advance Market Commitment (AMC) for distribution to developing countries more widely. However, as above, we expect global vaccine supply will improve next year and dose donation will therefore become a less critical supply source for developing countries.

Equity

- 57. Ongoing access to COVID-19 vaccines is essential to maximise uptake, it also ensures that we have sufficient supply for those who have not accessed a vaccine in 2021 such as children.
- 58. Ensuring that the CVIP can progress at as high a rate as possible is crucial to ensure that vulnerable populations can be protected from COVID-19.
- 59. Availability of vaccines to support booster doses if needed will ensure the most vulnerable will have access to the best protection available to prevent against severe health outcomes from COVID-19.



We recommend drawing down funding from the tagged contingency to meet the cost of the purchase



63. A draw down from the tagged contingency in the 2021/22 financial year is required to cover the costs of these vaccine doses.

Communications

- 64. Officials recommend that you announce up to 4.7 million doses have been secured to support the COVID-19 Immunisation Programme following execution of the amendment agreement. S 9(2)(b)(ii)
- 65. All communication is required to be carried out in coordination between New Zealand and Pfizer.

Next steps

66. Subject to your agreement to the proposed amendment to our APA with Pfizer, and the Minister of Finance's agreement to grant the indemnity, the Director-General of Health

and the Minister of Finance will be invited execute the amendment on behalf of New Zealand

Annexes

1.	s 9(2)(b)(ii)
2.	s 9(2)(b)(ii)

ENDS.

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