

# Briefing

## Securing additional doses of Pfizer's COVID-19 vaccine in September

**Date due to MO:** 4 September 2021      **Action required by:** 5 September 2021

**Security level:** ~~Commercially Sensitive~~      **Health Report number:** HR20211964

**To:** Rt Hon Jacinda Ardern, Prime Minister  
 Hon Grant Robertson, Minister of Finance  
 Hon Chris Hipkins, Minister for COVID-19 Response

**Copy to:** Hon Nanaia Mahuta, Minister of Foreign Affairs

### Contact for telephone discussion

Name	Position	Telephone
<b>Dr Ashley Bloomfield</b>	Director-General of Health	s 9(2)(a)
<b>Jo Gibbs</b>	National Director, COVID-19 Vaccine and Immunisation Programme	s 9(2)(a)

### Minister's office to complete:

- |   |                                    |  |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved             | <input type="checkbox"/> Decline   | <input type="checkbox"/> Noted               |
| <input type="checkbox"/> Needs change         | <input type="checkbox"/> Seen      | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |  |

Comment:

# COVID-19 Vaccine Strategy – Securing additional doses of Pfizer vaccine in September

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**Security level:** ~~Commercially Sensitive~~      **Date:** 3 September 2021

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**To:** Rt Hon Jacinda Ardern, Prime Minister  
Hon Grant Robertson, Minister of Finance  
Hon Chris Hipkins, Minister for COVID-19 Response

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**Copy to:** Hon Nanaia Mahuta, Minister of Foreign Affairs

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## Purpose of report

1. To seek your agreement to enter into two bilateral agreements with Denmark and Spain for the purchase of up to 774,000 doses of Pfizer's COVID-19 vaccine to support the COVID-19 Vaccine Immunisation Programme (CVIP) in September 2021.

## Summary

2. There has been a significant increase in demand for COVID-19 vaccines over the last two weeks in response to the recent COVID-19 outbreak and subsequent Alert Level change and expanding vaccine eligibility within the programme to those aged 12 and over.
3. The vaccination rate has recently surpassed 535,000 vaccinations per week (77,000 per day). If vaccine uptake is maintained at the current rate, we risk disruption to the CVIP in mid-September as a result of a vaccine supply gap of approximately 750,000 doses.
4. New Zealand has an option to purchase up to 774,000 doses of Pfizer vaccine through bilateral agreements with Denmark and Spain, with 274,000 of those doses being delivered to New Zealand as early as 11 September 2021, with distribution to DHBs and vaccination centres to follow thereafter.
5. To ensure these doses can arrive within a timeframe that is beneficial to the CVIP, the Ministry has arranged its own transportation, and the doses will be imported by the Crown.
6. As such, the importation of these doses is subject to approval by the Director-General of Health under section 32A of the Medicines Act 1981 and the Crown will be responsible for meeting a number of requirements in relation to the provisional consent for the Pfizer vaccine and responding to any potential product quality issues.
7. A logistics plan is in place, which follows international best practices and procedures to ensure that the vaccine doses arrive in New Zealand safely.
8. The Minister of Finance has been asked to grant indemnities in favour of Spain and Denmark under the bilateral agreements, and two indemnities in favour of Pfizer and others under related documents.
9. We are recommending that Vaccine Ministers invite the Director-General of Health, on behalf of the Crown to sign bilateral agreements with Denmark and Spain.

## Recommendations

We recommend you:

- a) **Note** that we continue to face immediate vaccine supply pressure due to increased demand for vaccines following the current COVID-19 outbreak.
- b) **Note** that officials have explored several avenues to secure additional supply in September, ahead of the large shipments expected from Pfizer in October.
- c) **Note** that up to 774,000 doses of the Pfizer vaccine are available for resale from a combination of EU member states (Denmark and Spain) for delivery in New Zealand as early as 11 September 2021.
- d) **Note** that New Zealand is required to co-ordinate pick-up and transport of the vaccine from the selling countries to facilitate a timely delivery to support the COVID-19 Vaccine Immunisation Programme.
- e) **Note** that officials, with the support of external legal counsel Bell Gully, have finalised forms of bilateral agreements with each of the selling countries.
- f) **Note** that in August 2021, Cabinet [CAB-21-MIN-0350 refers]:
  - i. agreed to increase the tagged contingency "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" by an additional s 9(2)(b)(ii) to secure supply of an mRNA vaccine (including any additional purchases for 2021); and
  - i. authorised Vaccine Ministers to draw down on the tagged operating contingency funding.
- g) **Agree** that, if all outstanding regulatory matters are resolved, the Director-General of Health, on behalf of the Crown, will sign the bilateral agreements (with the exception of the provisions relating to indemnities) to secure an additional 750,000 doses of Pfizer vaccine. **Yes/No**
- h) s 9(2)(b)(ii) **Yes/No**
- i) **Agree** subject to your agreement to recommendation g) above, to draw down s 9(2)(b)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase up to an additional 774,000 doses of Pfizer's vaccine. **Yes/No**

- j) **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: **Yes/No**

<b>Vote Health</b>	<b>\$m – increase/(decrease)</b>				
	<b>Minister of Health</b>	2021/22	2022/23	2023/24	2024/25 & Outyears
<b>Multi-Category Expenses and Capital Expenditure:</b> Implementing the COVID-19 Vaccine Strategy MCA					
<b>Non-Departmental Output Expense:</b> Purchasing Potential and Proven COVID-19 Vaccines and Other Therapeutics					

- k) **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. **Yes/No**
- l) **Agree** that the expiry date for the “Minimising the health impacts of COVID-19” Tagged Operating Contingency be 1 February 2023. **Yes/No**
- m) **Note** that transport costs are additional to the price per dose in these bilateral agreements and have not yet been finalised (estimated to be around NZD **s 9(2)(b)(i)**). These costs will be covered by the by existing funding arrangements.
- n) **Note** that Treasury officials are separately seeking agreement from the Minister of Finance to the indemnities in favour of Spain and Denmark included in the bilateral purchase agreements and indemnities in favour of Pfizer and others included in related documents (Treasury Report 2021/2212 refers).
- o) **Note** that if the Minister of Finance agrees to grant all indemnities, then he will be invited to co-sign the bilateral agreements in respect of the indemnities in favour of Spain and Denmark, and sign related documents containing indemnities in favour of Pfizer and others.
- p) **Note** that importation and distribution of the vaccine by the Crown is subject to approval by the Director-General of Health under section 32A of the Medicines Act 1981; and New Zealand will not be in a position to enter the bilateral agreements unless and until that approval is granted.
- q) **Note** that the Crown (rather than Pfizer) will be importing these doses and accordingly the Crown will have obligations under the Medicines Act 1981 in relation to these doses.

- r) **s 9(2)(b)(i), s 6(b)(i)**  
[REDACTED]
- s) **Note** that subject to your agreement to recommendation g), the Director-General signing the bilateral agreements, and the Minister of Finance signing the bilateral agreements and related documents:
- i. they will be shared with Denmark and Spain for countersigning. As part of this process, the selling country must inform Pfizer of the resale deal which could take 48 hours;
  - ii. once the agreements have been executed, New Zealand can pick up the doses and transport them to New Zealand.
- t) **Note** that officials recommend a phased communications approach to reflect the amount of certainty at a given time:
- i. at this stage communicating we are in negotiations with a number of countries to secure additional doses
  - ii. signalling that we have secured additional doses from Spain and Denmark for September once bilateral arrangements have been executed
  - iii. making an announcement upon receipt of the initial doses.
- u) **Note** the purchase of these additional doses mean that from October we are likely to have an oversupply of vaccines and officials will provide further advice on the impacts of our delivery schedule in 2021, including options to minimise wastage.

Rt Hon Jacinda Ardern

**Prime Minister**

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Hon Chris Hipkins

**Minister for COVID-19 Response**

4/9/2021

...../...../.....

Hon Grant Robertson

**Minister of Finance**

...../...../.....



Jo Gibbs

**National Director, COVID Vaccine and Immunisation Programme**

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## Securing additional doses of Pfizer's COVID-19 vaccine in September

### Background

10. In total, we have agreed to purchase 10.1 million doses of Pfizer's COVID-19 vaccine for delivery in 2021, which has enabled the rollout of New Zealand's COVID-19 Vaccine Immunisation programme (CVIP) to date.
11. These doses are sufficient to fully vaccinate all eligible population groups this year (currently 4.2 million people). However, there has been a significant increase in demand for COVID-19 vaccines over the last two weeks in response to:
  - a. the recent COVID-19 outbreak and subsequent Alert Level change; and
  - b. expanding vaccine eligibility within the programme to those aged 12 and over.
12. The vaccination rate has recently surpassed 535,000 vaccinations per week (77,000 per day). If vaccine uptake is maintained at the current rate, we risk disruption to the CVIP in mid-September as a result of vaccine shortages. Incorporating a safety buffer, this may equate to a total gap in supply of approximately 750,000 doses in September.
13. **s 9(2)(b)(ii)**  
[Redacted]  
[Redacted]  
[Redacted]
14. The other COVID-19 vaccines in our portfolio that have already received regulatory consent from Medsafe (AstraZeneca and Janssen) **s 9(2)(b)(i)**  
[Redacted]
15. However, supported by the Prime Minister's engagement with her counterparts, the governments of Spain, and Denmark have confirmed that, between them, they can supply us with up to 774,000 doses of Pfizer vaccine in September. Further information is outlined below in table 1.

Table 1. Summary of Resale Offers

Source country	Vaccine	Volume (doses)	Availability	Location	Manufacturing source (site)
Spain	Pfizer	274,000	As early as 11 September	Madrid	Pruus, Belgium
Denmark	Pfizer	Up to 500,000	Across the weeks of 13 September and 20 September	Copenhagen	Pruus, Belgium

### Officials are finalising agreements with the selling countries

17. To confirm the purchase of these vaccines, New Zealand is required to enter into bilateral resale agreements with both Denmark and Spain.

18.

s 6(b)(i), s 9(2)(ba)(i)

19.

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21.

22.

### **These doses will be available for use in the programme from mid-September**

23. Officials are awaiting confirmation from Pfizer that all additional doses are identical to the doses secured under our advance purchase agreement with Pfizer, including labelling. If this confirmation is obtained, the additional doses will be within the scope of the existing Medsafe provisional consent. Provided that the Crown can verify on arrival in New Zealand that the doses remained within temperature profile specifications, and can provide independent batch certification for the additional doses, they can be incorporated seamlessly into the CVIP once they arrive in New Zealand. If there are any differences between the additional doses and the product approved by Medsafe, officials will seek advice from Medsafe regarding the implications.
24. There is sufficient Ultra Low Temperature storage, and adequate consumables (including needles, syringes, and diluent) available to support the immediate use of these additional doses in the programme.
25. Our estimated overall Pfizer vaccine delivery schedule, including these additional doses, is as follows:

s 9(2)(b)(ii)

26. Existing scheduled deliveries from Pfizer will continue to arrive weekly, with significant deliveries due to begin on 2 October.

## Risks and Assurances

*New Zealand has arranged transportation of these doses from the selling countries*

27. **s 9(2)(b)(ii)** [Redacted]
28. As a result, the Ministry has arranged transportation (including thermal shippers and data loggers) to deliver 274,000 doses from Spain as early as 11 September, and the remaining 500,000 doses from Denmark split across the week of 13 September and the week of 20 September.

**s 9(2)(b)(ii)** [Redacted]

29. **s 9(2)(b)(ii)** [Redacted]
30. As such, the importation is subject to the approval by the Director-General of Health under section 32A of the Medicines Act 1981 (the Act). This approval has the effect of exempting the Crown from compliance with certain provisions of the Act. The Crown will have some obligations under the Act in relation to these doses, including:
- a. ensuring that these doses are within the scope of the existing provisional consent
  - b. complying with requirements regarding containers and packaging; and
  - c. complying with record keeping obligations.

31. **s 9(2)(b)(ii)** [Redacted]

32. The Crown, as the importer of these doses, will need to respond to any actions requested by Medsafe if product quality issues arise in relation to these doses. A potential risk is that the Crown may not have the necessary information to respond to Medsafe, and the Crown has no contractual right to obtain the information from Pfizer.

**s 9(2)(b)(ii), s 9(2)(b)(i), s 6(b)(i)** [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



*A logistics plan is in place to ensure the vaccine arrives in New Zealand safely*

35. The vaccine doses will be shipped from Pfizer's manufacturing site to storage sites in the member states. These storage sites are the equivalents of Healthcare Logistics in New Zealand.
36. The vaccine doses will then be packed into approved boxes in line with Pfizer and international best practices and procedures to ensure that the vaccine remains within the acceptable temperature specifications. Data loggers will be used to monitor temperatures at all times during storage and transportation.
37. The Ministry of Health will obtain quality assurance documentation from each of the storage sites, which will be assessed by Medsafe to ensure the quality of the vaccine doses has been maintained.
38. Upon arrival, the vaccine doses will undergo the standard batch release process before being repacked and distributed for use in the CVIP.

*Officials recommend, on balance, that Vaccine Ministers should agree to the purchase of these additional vaccine doses*

39. The Ministry of Health has worked closely with the Ministry for Foreign Affairs and Trade, the Treasury, and been supported by legal advice from Bell Gully to ensure that the terms and conditions of this purchase are acceptable.
40. On 30 August, Cabinet agreed to progress negotiations with vaccine suppliers for additional vaccines to ensure that the portfolio continues to support immunisation needs in New Zealand and the Pacific. Cabinet delegated any future purchasing decisions to Vaccine Ministers [CAB-21-MIN-0350 refers].
41. We are recommending that Vaccine Ministers invite the Director-General of Health, on behalf of the Crown to sign (with the exception of the provisions relating to indemnities) the bilateral agreements with Denmark and Spain.
42. The Minister of Finance will co-sign the bilateral agreements alongside the Director-General of Health in respect of the indemnity provisions in favour of Spain and Denmark, and will sign related documents containing indemnities in favour of Pfizer and others.

### **Indemnities are required**

43. The bilateral agreements to purchase these doses require four indemnities to be granted by the Minister of Finance; indemnities in favour of Spain and Denmark under the bilateral agreements, and two indemnities in favour of Pfizer and others under related documents. The Minister of Finance has been asked to grant these indemnities under section 65ZD of the Public Finance Act 1989 [Treasury Report 2021/2212 refers].

s 9(2)(b)(ii)

## Equity

46. Ongoing access to COVID-19 vaccines is essential to maximise uptake, particularly in a period of increased interest in being vaccinated following the recent outbreak.
47. Eligibility within the programme has recently expanded to include under 30s, where there is a large proportion of Māori and Pacific people, so available supply is essential to enable high levels of uptake in this group.
48. Pacific populations have been most affected by the recent outbreak of COVID-19 in the community, making up a disproportionate percentage of cases and hospitalisations.
49. Ensuring that the CVIP can progress at as high a rate as possible during this time period is crucial to ensure that vulnerable populations can be protected from COVID-19.

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

50. Securing these doses not only enables the continuation of our domestic CVIP, but also provides greater certainty of supply to enable earlier donation of doses to Realm countries and the wider Pacific.

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

52. This collaboration with EU member states also supports their efforts to not waste vaccine, maximising the utility of every dose and supporting global coverage.

53. These additional doses mean that from October we are likely to have an oversupply of vaccines for those currently eligible. The focus of the CVIP will be on further increasing uptake and minimising wastage, and if evidence supports, a booster programme and increasing eligibility.

54. Further, officials will progress discussions to enable donation pathways as an option for minimising wastage and ensuring the New Zealand continues to play a role as a significant contributor to the global response to COVID-19.

55. Separate advice is being provided by officials on reprofiling Pfizer volumes for Q4 of 2021 (HR-20211981 refers).

56. s 9(2)(g)(i), s 6(a)

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

57. [REDACTED]
58. On 30 August Cabinet agreed to increase the tagged contingency “Minimising the health impacts of COVID-19 – Tagged Operating Contingency” by an additional [REDACTED] (including any additional purchases for 2021) [CAB-21-MIN-0350 refers], and authorised Vaccine Ministers to draw down on the tagged operating contingency funding.
59. [REDACTED]
60. The costs associated with transportation of the vaccines are additional to the price per dose in these bilateral agreements and have not yet been finalised. Current estimates are total costs will be approximately [REDACTED] which will be absorbed by current funding appropriated to the CVIP.
61. The tagged contingency is currently due to expire 1 February 2022. As Cabinet has delegated authority to Vaccine Ministers, officials recommend that the expiry date be extended to 1 February 2023 in the context of what we know currently about COVID-19 vaccine needs.

### **Communications**

62. Officials recommend that you take a phased communications approach to reflect the amount of certainty at a given time. While we are concluding resale deals with the EU and Pfizer, we can communicate that we are in negotiations with a number of countries to secure additional doses for NZ to ensure we can maintain current rates of vaccination.
63. Following execution of bilateral arrangements with Denmark and Spain, and acceptance of notification by Pfizer, you could signal that we have secured additional doses from Spain and Denmark, which will support roll out in September
64. Upon receipt of the initial doses we recommend making an announcement.
65. All communication is required to be carried out in coordination between New Zealand and the member state(s) under the terms of the bilateral agreements.

### **Next steps**

66. Before the bilateral agreements can be entered, we will need confirmation from Pfizer regarding product specification for the additional doses, and the approval of the Director-General of Health pursuant to section 32A of the Medicines Act 1981.
67. Subject to your agreement to the purchase of these additional vaccines, and the Minister of Finance’s agreement to provide the indemnities, the Director-General of Health and the Minister of Finance will be invited to sign, on behalf of the Crown, one bilateral

agreement with each selling country, and the Minister of Finance will be invited to sign the related documents containing indemnities in favour of Pfizer and others.

68. s 6(b)(i), s 9(2)(ba)(i)  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]
69. Following Pfizer's confirmation in writing, the doses are available to be transported to New Zealand.
70. Payments will be made within 15 calendar days of the member state issuing an invoice under the bilateral agreements.
71. Officials will provide further advice to Ministers on implications of potential oversupply in October and the impact on vaccine delivery in 2021.

ENDS.

PROACTIVELY RELEASED