

Briefing

Purchasing additional Pfizer vaccine from Spain, ^{s 6(a)} and Denmark

Date due to MO: 31 August 2021

Action required by: 1
September 2021

Security level: IN CONFIDENCE

Health Report number: 20211936

To: Rt Hon Jacinda Ardern, Prime Minister
Hon Chris Hipkins, Minister for COVID-19 Response

Contact for telephone discussion

| Name | Position | Telephone |
|-----------------|---|-----------|
| Maree Roberts | Deputy Director-General, System Strategy and Policy | s 9(2)(a) |
| Allison Bennett | Manager, System Enablers, Public Health System Policy | 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 Withdrawn | |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:

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Security level: IN CONFIDENCE **Date:** 31 August 2021

To: Rt Hon Jacinda Ardern, Prime Minister
Hon Chris Hipkins, Minister for COVID-19 Response

Purpose of report

1. This paper provides an update on options to secure a total of 750,000 additional Pfizer doses to bolster supply and allow the COVID-19 Vaccine and Immunisation Programme (CVIP) to maximise uptake through September. It refers specifically on opportunities to purchase doses from Spain, ^{s 6(a)} and Denmark, facilitated by the European Union (EU).

Key Points

2. New Zealand is facing a potential supply shortfall of up to 750,000 doses of the Pfizer vaccine through September due to the significant increase in vaccine uptake following New Zealand's shift to Alert Level 4 in response to an outbreak of the Delta variant in the community.
3. The vaccination rate has surpassed 535,000 vaccinations per week, an increase of more than 180 percent from the week ending 15 August. If vaccine uptake is maintained at the current rate, we risk supply disruptions to the COVID-19 Immunisation Programme in mid-September.
4. Supported by the Prime Minister's engagement with her counterparts, the governments of Spain, Denmark ^{s 6(a)} have confirmed that, between them, they can supply 750,000 doses in September to support our potential supply shortfall.
5. This is the preferred option for securing additional doses at this stage as ^{s 9(2)(b)(ii)}
^{s 9(2)(b)(ii)}
6. We recommend that New Zealand confirm with the EU and Pfizer that New Zealand would like to purchase these 750,000 doses from a combination of Spain, Denmark ^{s 6(a)} ^{s 6(a)} and proceed to finalise legal arrangements as soon as possible.
7. To secure these doses in early September, New Zealand will need to arrange transport from the selling countries. This presents some legal, regulatory and logistical challenges that need to be worked through, in parallel to finalising legal documentation with selling countries this week.

8. If you agree, Officials will revert to Vaccine Ministers later this week to seek approval for the Director-General of Health to sign the final contracts on behalf of the Crown. Officials will also seek approval from the Minister of Finance to grant the required indemnities.

Recommendations

- | | | |
|----|--|--------|
| a) | Note that we continue to face immediate vaccine supply pressure due to increased vaccination rates following the current COVID-19 outbreak. | Yes/No |
| b) | Note that officials have been exploring all possible avenues to secure additional supply in September, ahead of the large shipments expected from Pfizer in Q4. | Yes/No |
| c) | Note that 750,000 doses of the Pfizer vaccine are available for resale from a combination of Spain, Denmark s 6(a) for delivery starting the week of 6 September. | Yes/No |
| d) | Note that Pfizer can either delivery the product direct from the Manufacutring flow to New Zealand (expected from late September) , or we can co-ordinate the trapsort direct from the selling countries (potential to receive circa 500,000 doses in week commencing 6 September). | Yes/No |
| e) | Note that securing these doses brings our expected delivery in September to approximately 2 million doses, and an expected total of 10.85 million doses over 2021. | Yes/No |
| g) | Agree that officials should work with Pfizer, the EU, Spain, Denmark, s 6(a) s 6(a) to secure additional doses with the fastest delivery route and progress with agreements. | Yes/No |
| h) | Note that officials will come back to Vaccine Ministers later this week to seek approval for the Director-General of Health to sign the final agreements on behalf of the Crown. | Yes/No |
| i) | Note that officials are working through regulatory issues with Medsafe and legal to assure we are operating inside the boundaries of the legislations and appropriate steps are in place to enable purchase and delivery | Yes/No |
| j) | Note that officials expect an indemnity will be required from the Minister of Finance to Pfizer on the same or similar terms as the indemnities offered by the EU and New Zealand to Pfizer in their respective Advance Purchase Agreements. | Yes/No |
| k) | s 6(a), s 6(b)(i) | Yes/No |
| l) | Note that officials will provide further advice to the Minister of Finance on granting the required indemnities. | Yes/No |

- m) **Note** that officials are working with Pfizer and the EU on a range of issues including delivery timeframes, logistics, regulatory assurance, indemnities, and costs.

Yes/No

- n) s 6(a), s 6(b)(i)

Yes/No



Rt Hon Jacinda Ardern

Prime Minister

Date: 31/8/21

Hon Chris Hipkins

Minister for COVID-19 Response

Date:



Maree Roberts

Deputy Director-General

System Strategy and Policy

Date: 31/08/2021

Purchasing additional Pfizer vaccine from Spain, ^{s 6(a)} [REDACTED] and Denmark

Background

9. There has been a significant increase in demand for COVID-19 vaccines over the last two weeks, since the Delta outbreak began in New Zealand. The vaccination rate has surpassed 535,000 vaccinations per week (77,000 vaccinations per day), an increase of more than 180 percent from the week ending 15 August. This is in part due to high vaccine uptake in response to the recent COVID-19 outbreak and subsequent Alert Level change as well as increasing vaccine eligibility.
10. In total, we have procured 10.1 million doses of Pfizer's COVID-19 vaccine, which is sufficient to fully vaccinate all eligible people this year (currently 4.2 million people). However, if vaccine uptake is maintained at the current rate, we risk running out of vaccine supply in mid-September. Planned Pfizer deliveries will continue on a weekly basis through September, see Table 1 below.

s 9(2)(b)(ii)

[REDACTED]

11. Including provisions for safety stock, this equates to a potential supply gap of up to 750,000 doses in the month of September. Insufficient supply risks reducing vaccine uptake to plan which may discourage uptake in the longer term.

s 9(2)(b)(ii)

[REDACTED]

12. Officials have been exploring three pathways to securing additional doses to meet the supply shortfall in September:

s 9(2)(b)(ii)

[REDACTED]

b. purchasing doses from (or swapping doses with) another country; or

s 9(2)(b)(ii)

[REDACTED]

13. [REDACTED]

s 9(2)(b)(ii)

[REDACTED]

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

Update on securing doses through opportunities for resale

15. As directed, officials have sought opportunities to purchase doses of the Pfizer vaccine from other countries. An interagency process is now under way, led by the Ministry of Health (MoH) and supported by the Ministry of Foreign Affairs and Trade (MFAT) and the Treasury. Independent legal advice is being provided by Bell Gully.

16. As directed, officials approached a range of countries about possible purchase of additional doses of Pfizer vaccine with September delivery. s 6(a), s 6(b)(i)

s 6(a), s 6(b)(i)

17. A summary of offers for securing additional doses through resale is provided below:

Table 1. Summary of Resale Offers

s 6(a), s 6(b)(i)

EU-led resale

18. Supported by the Prime Minister's engagement with her counterparts, the governments of Spain, Denmark s 6(a) have confirmed that, between them, they can supply 750,000 doses.

19. Pfizer has presented two options to secure deliveries from Spain, Denmark s 6(a) which have important implications for timeliness of delivery. Pfizer can either deliver the product direct from the manufacturing flow to New Zealand, or we can co-ordinate the transport and pick-up ourselves from the selling countries.

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

s 9(2)(b)(ii)

21. If New Zealand arranges collection of the doses ourselves from s 6(a) re-selling countries, then we can expect:
- a. 500,000 additional doses delivered in the week of 6 September, and
 - b. 250,000 additional doses in the week beginning 13 September
22. Following discussions with Pfizer and the EU, officials have concluded that co-ordinating transport from the selling countries is our only option to secure delivery in early September.
23. If New Zealand proceeds with the option to collect doses from central warehouses in the relevant Member States, New Zealand will need to co-ordinate transport direct from the selling countries (this creates the possibility of receiving up to 500,000 doses in the week commencing 6 September).
24. This option offers the benefit of receiving larger volumes of doses earlier in September. Doses purchased through this pathway will have the similar expiry dates as those sourced from the manufacturing flow.
25. This pathway also requires more co-ordination from New Zealand because we would be responsible to arrange collection of the doses from countries and transport to New Zealand. New Zealand would also need to arrange quality assured transport and logistics to maintain product effectiveness and safety. s 9(2)(b)(ii)
- s 9(2)(b)(ii)
26. There are a number of legal and regulatory challenges officials are exploring to assure product quality and safety:
- a. verify whether the EU member states Pfizer doses are identical to those regulated under our APA
 - b. provisions in the Medicine Act to enable import in this context
 - c. ensure that the EU member states have the appropriate provisions in place to safely store product.

Other offers

27. s 6(a), s 6(b)(i)

28.

29.

30. s 6(a)

Officials recommend pursuing EU-led resale

31. To date, officials have prioritised engagement with the EU Commission to explore the opportunity for purchase from Spain, Denmark s 6(a) This is an attractive option due to complementary attributes such as product source, location of doses, availability, and volume of doses on offer.
32. Following further engagement with the EU over the last few days, officials are now more confident in their ability to secure supply from Spain, Denmark s 6(a) in September. This is subject to satisfactory conclusion of legal arrangements by all parties within the necessary timeframes, suitable logistics arrangements, and satisfaction of New Zealand's legal and regulatory requirements.
33. We recommend that officials confirm to the EU and Pfizer that New Zealand would like to purchase 750,000 doses from a combination of Spain, Denmark s 6(a) and proceed to finalise legal arrangements as soon as possible.

34. s 6(a)

Implications for September delivery schedule

35. In engagement with the EU, officials have communicated that New Zealand will need to receive additional supply by or before the week of 13 September in order to bridge the supply gap.
36. Under the EU-led resale option (and subject to finalisation of the details), we could expect to receive 500,000 additional doses delivered in the week of 6 September, and an 250,000 additional doses in the week beginning 13 September. Timings are also contingent on contractual agreement between New Zealand, and the selling countries. Receiving as many of these doses as soon as possible will increase our ability to offer high vaccination rates per week throughout September without having to reduce capacity.

Purchasing additional Pfizer doses in September will support the CVIP roll out, although output management would still be required

37. We continue to face immediate pressure on supply due to the increased rate of vaccine administration following New Zealand's shift to Alert Level 4 in response to an outbreak of the Delta variant in the community.
38. We have seen the weekly rate of vaccine administration increase in the last two weeks by over 180%. The additional supply requested will allow us to deliver at a continual rate of 545k per week whilst also maintaining the contingency of central supply.
39. Our increased rate of vaccination will exhaust supply without interventions to moderate the volume from the CVIP. It is important that the CVIP actively manages vaccine administration rates in September, even with additional deliveries potentially available from the week commencing 6 September.

40. The CVIP will endeavour to maintain a level of central stock of vaccine for contingency while also maintaining efforts to target those populations most at risk of exposure and/or risk of poor outcomes. The CVIP will also continue to focus efforts on the supply to sites and models that drive the largest volume, while minimising disruption as much as possible for those people who have an existing booking.

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

42.

43. This means that from October we are likely to have an oversupply of vaccines. The programme's focus will be on further increasing uptake and minimising wastage, and if evidence supports, a booster programme and increasing eligibility.

44. Further, we will be well placed to operationalise Cabinet's decision to donate doses to Polynesia, and Fiji. Officials anticipate that 370,000 doses will be required to support vaccination of their population aged 12 years and over. Officials will provide further advice to Ministers on implications for Vaccine delivery in 2021.

Legal and regulatory considerations

45. The EU have an advanced purchased agreement (APA) with Pfizer, s 6(b)(i)

46. This means that for New Zealand to purchase doses for collection from Member States, we will be required to enter into s 6(a) bilateral resale agreements with Denmark, Spain, s 6(a) We understand that these bilateral agreements will refer to our own APA with Pfizer, including for the terms of indemnity.

47. The EU will share these agreements with us on 1 September, and we will subsequently share with Bell Gully for rapid legal review.

48. s 9(2)(ba)(i)

49. Officials are preparing a request to the Minister of Finance to grant the required indemnities and will revert with this advice later this week.

50. The Ministry is consulting with Medsafe and have engaged Crown Law to manage risks associated with product quality assurance and import responsibilities to ensure we are operating inside the boundaries of the legislation.

Next steps

51. Officials will liaise with Medsafe to co-ordinate engagement across countries' regulators to ensure there can be efficient information exchange, and that the appropriate level of assurance can be provided regarding product quality and other regulatory standards.
52. Officials are continuing to liaise with Pfizer to seek confirmation of product specifications and other requirements as per the agreement.
53. Upon receipt, officials with the support of Bell Gully will rapidly review the draft bilateral resale agreements with Denmark, Spain, s 6(a) with a view to finalising these documents as soon as possible this week.
54. Officials will initiate engagement with transport companies to communicate and organise logistical arrangements to pick the doses up from Member States and transport to New Zealand.
55. Officials will revert to Vaccine Ministers later this week to seek approval for the Director General of Health to sign the final contracts on behalf of the Crown. Officials will also seek approval from the Minister of Finance to grant the required indemnities.
56. This advice will also include an update on delivery timeframes, indemnities, regulation and logistical considerations as well as costs.
57. In the meantime, the CVIP will look at options to manage vaccine administration rates in line with supply.

ENDS.