Appendix X

COVID-19 Vaccine Portfolio Update – 12 November 2021

Date:	11 November 2021
To:	Prime Minister Jacinda Ardern and COVID-19 Vaccine Ministers
From:	Maree Roberts, Deputy Director-General, System Strategy and Policy
Subject:	COVID-19 Vaccine Portfolio Update

Purpose of report

1. This memo provides an update on the COVID-19 Vaccine Portfolio and seeks your agreement to:
   a. the preferred delivery schedule for Pfizer's booster and paed atric doses
   b. the preferred option for an alternative vaccine candida e for managing downstream risk in the portfolio in 2022.

Background

2. COVID-19 vaccine purchasing decisions o date have been made under the COVID-19 Vaccine Strategy (Vaccine Strategy) agreed by Cabin t in May 2020. The objective of the Vaccine Strategy was to secure access to uff ient quantities of safe and effective COVID-19 vaccines, in order to implement a preferr d immunisation programme at the earliest possible time [CAB-20-MIN-0229 refers].

3. New Zealand purchased a portfolio of vaccines to manage the risk of vaccine development or supply failure. To date the COVID-19 Immunisation Programme (the Programme) has been based solely around Pfizer's vaccine, however the portfolio continues to play a significant role in managing ris nd potentially increasing rates of overall vaccine uptake.

Current Portfolio situation

Table 1. Current expected vaccine portfolio delivery schedule (in doses)

s 9(2) b)(ii)

[redacted]

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4. Pfizer's vaccine continues to be primary vaccine in the Programme; however, 100,000 doses of AstraZeneca's vaccine will be available from late November for those unable or unwilling to receive Pfizer's mRNA vaccine. Further doses be may available through this route if uptake is high.

5. As at 8 November 2021, 89% of eligible New Zealanders (aged 12 and up) have received a single dose of Pfizer's vaccine and 78% are fully vaccinated. A small number of immunocompromised people are now able to access a third dose to improve their immune response.

6. The focus of the Programme is now shifting to further immunisation needs in late 2021 and 2022, and the role of the vaccine portfolio is to support those needs. Key areas of fo us include:

   a. ongoing improvements in uptake across New Zealand

   b. booster doses for eligible groups people (aged 18 and above)

   c. paediatric doses for eligible groups (aged 5-11), subject to Medsafe approval and clinical advice

   d. ongoing support to enable Polynesia and the Realm to imp ement their vaccination programmes (which may include booster doses and paediatric vaccinations).

Pfizer's delivery schedule

7. On 8 November, Medsafe approved the use of fizer's vaccine as a third 'booster' dose at least 6 months following the second dose in individual aged 18 and over. The COVID-19 Vaccine Technical Advisory Group (CV TAG) has p ovided clinical advice which will support a decision by Cabinet on 15 November 2021.

8. Medsafe is also currently reviewing an application from Pfizer for the use of a new version of its vaccine developed specifically f r use in paediatrics (5-11 years of age). The timeline for this decision is unknown, and will depend on how comprehensive the application by Pfizer is.

9. While decisions have not yet been made regarding booster doses and paediatric doses, officials are working with Pfizer to ensure doses will be available to support the approach taken by the Programme. Early mod lling has been generated to forecast demand and supply needs.

10. The current m delling assumes (for New Zealand, the Realm, and Polynesia):

    a. immunis tion of all 5-11s in Q1 2022

    b priority access to booster doses for high risk groups in late Q4 2021 and Q1 2022

    c. booster doses for the eligible population (aged 18 and above) before the end of Q2 2022.

11. Based on the current modelling, changes to the expected delivery schedule will need to be agreed between Pfizer and officials to enable the proposed rollout. A total of 1.25 million doses of paediatric vaccine would be required in Q1 2022, s 9(2)(b)(ii) [redacted] However, fewer doses for the 5-11 year olds may be needed, depending on the clinical recommendations and data provided.

12. s 9(2)(b)(ii) [redacted]

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s 9(2)(b)(ii) [redacted]

13. s 9(2)(b)(ii) [redacted]

Table 2. Projected vaccine utilisation in 2022 (in doses)

	Q1 2022	Q2 2022
Booster doses (NZ)	380,000	3.4 million
Booster doses (Realm & Polynesia)	-	300,000
Paediatric doses (NZ)	1 million	-
Paediatric doses (Realm & Polynesia)	130,000	-

Table 3. Projected vaccine supply needs in 2022 (in doses)

s 9(2)(b)(ii) [redacted]

	Required delivery schedule		
	Supply available end of 2021	Q1 2022	Q2 2022
Adult doses	2.6 million	-	1.6 million
Paediatric doses	-	1.25 million	-

14. s 9(2)(b)(ii) [redacted]

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Pfizer is also introducing an updated 'ready-to-use' version of its vaccine

15. Pfizer's updated formulation, s 9(2)(b)(ii) , will not require the use of a diluent and will reduce the administrative burden for vaccinators. However, at this stage, our preference will be for the original product, which has a longer shelf life and to reduces the complexity of managing multiple vaccine types in the Programme.

s 9(2)(b)(ii)

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

s 9(2)(b)(ii)

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

AstraZeneca and Janssen are unlikely to support paediatric or booster doses

18. AstraZeneca's vaccine is being used in Q4 2021 to support ongoing improved uptake in New Zealand, and Janssen's vaccine may be uti ise similarly in Q1 2022 or as a contingency to manage downstream risks.

19. There may be additional utility of AstraZeneca's vaccine to support ongoing uptake in New Zealand and immunisation efforts in the Pacific, however it is not expected that either AstraZeneca or Janssen's vaccines will play a significant role for use as a booster vaccine or for paediatric use in New Zealand.

20. Separate advice on how to utilise the remaining doses of AstraZeneca and Janssen's vaccines in our portfolio being provided to Cabinet later this month.

There may be a need for a second option in the portfolio as an alternative to Pfizer

21. Whi the Programme to date has been successfully rolled out using Pfizer's vaccine, and there will be sufficient vaccine across 2022 to support our needs, there may be a need for an additional vaccine:

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

    b. as an alternative option for people unable or unwilling to receive Pfizer's vaccine

    c. to manage the risk of a supply shock of Pfizer's vaccine and to s 9(2)(g)(i) .

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22. With limited ongoing utility of AstraZeneca and Janssen's vaccines, it may be desirable to access Novavax's vaccine through our current portfolio, or to introduce an additional vaccine to the portfolio s 9(2)(b)(ii)

Novavax's vaccine could be used as an alternative in 2022

23. Novavax's application for provisional consent is under review by Medsafe. The timelines for a decision will depend on how comprehensive the application is and how quickly Novavax is able to respond to any questions. It is not expected that Novavx's vaccine will be approved b fo e Q1 2022.

24. s 9(2)(b)(ii) [redacted]

25. s 9(2)(b)(ii) [redacted]

26. The benefits of Novavax's vaccine remain somewhat unknown, as it is yet to be used outside of clinical trials. Early data indicates a similar level of effectiveness in clinical trials to other vaccines at reducing symptomatic infection and the risk of severe disease. ndonesia is the only country to date to approve Novavax's vaccine for use under an Em rgency Use Authorisation, and key regulators such as the MHRA in the UK and the EM in Europe are reviewing the application in parallel with Medsafe.

27. Novavax may be more acceptable to some f the population that have been put off by known potential adverse effects of Pfizer, Janssen and As raZeneca's vaccines. Novavax's vaccine is expected to have a 9 month shelf life and can be stored using typical vaccine cold chain processes (at 2-8°C).

28. Novavax has not yet confirmed a time ine for regulatory applications for booster doses or paediatric doses, though trials for use of Novavax's vaccine as a heterologous booster (ie, for people that have already received a primary course of Pfizer's vaccine) are underway.

There is value in continuing to include Novavax in the vaccine portfolio longer term

29. We already have access to Novavax's vaccine s 9(2)(b)(ii) . As the vaccine portfolio stands, retain g access allows us to manage future risks and potential need (for example, future booster doses, updated versions of Novavax's vaccine, and in response to emerging evidence on safety and ef ectiveness across the portfolio).

30. s 9(2))(ii) [redacted]

31. 9(2)(b)(ii) [redacted]

32. s 9(2)(b)(ii) [redacted]

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s 9(2)(b)(ii)

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

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

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

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

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

Options for supporting the Programme in 2022

s 9(2)(b)(ii)

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

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

s 9(2)(b)(ii

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

41. s 9(2)(b)(ii) The most likely benefit of Novavax's vaccine would be to support ongoing improvements in uptake, particularly in individuals unwilling to receive Pfizer's mRNA vaccine. Novavax's vaccine is expected to be available for use as a booster and for paediatrics however the timelines are not yet certain.

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42. Further advice can be provided on optimal delivery schedules for your decision next week.

s 9(2)(b)(ii) [redacted]

43. s 9(2)(b)(ii) [redacted]

Next steps

44. If you agree, s 9(2)(b)(ii) [redacted]

45. Officials will also work with Novavax s 9(2)(b)(ii) [redacted] to progress ne t steps, based on your preferences.

Recommendations

It is recommended that you:

1.	note	that to date the COVID-19 Immunisation Programme has been based solely around Pfizer's vaccine, however the portfolio continues to play a significant role in managing risk, and potentially increasing rates of overall vaccine uptake.
2.	note	that on 8 November, Medsafe approved the use of Pfizer's vaccine as a third 'booster' dose at least 6 months following the second dose in individuals aged 18 and over. The COVID-19 Vaccine Technical Advisory Group (CV TAG) has provided clinical advice which will support a decision by Cabinet on 15 November 2021.
3.	note	that Medsafe is also currently reviewing an application from Pfizer for the use of a new version of its vaccine developed specifically for use in paediatrics (5-11 years of age). The timeline for this decision is unknown, and will depend on how comprehensive the application by Pfizer is.
4.	note	s 9(2)(b)(ii) [redacted]

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5.	agree	s 9(2)(b)(ii) [redacted]
6.	agree	s 9(2)(b)(ii), s 6(b)(i) [redacted]
7.	agree	s 9(2)(b)(ii) [redacted] officials work to secure access to Novavax's vaccine s 9(2)(b)(ii) [redacted], subject to Medsafe approval to su po t ongoing improvements in uptake, particularly in individuals unwilling to rece ve Pfizer's mRNA vaccine, for potential future use as a booster
8.	agree	s 9(2)(b)(ii) [redacted]

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