Minister for the COVID-19 Response

Decision to use Novavax's COVID-19 vaccine (primary course)

16 August 2023

These documents have been proactively released by the Ministry of Health on behalf of the former Minister for the COVID-19 Response, Rt Hon Chris Hipkins.

Title of Cabinet paper:

Decision to use Novavax's COVID-19 vaccine (primary course)

Title of minute:

Decision to Use Novavax's COVID-19 Vaccine (Primary Course) (CAB-22-MIN-0046)

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S 9(2)(b) (ii): to protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information.

S 9(2)(f)(iv): to maintain the constitutional conventions for the time being which protect—the confidentiality of advice tendered by Ministers of the Crown and officials.

S 9(2)(i): to enable a Minister of the Crown or any public service agency or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities.

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CAB-22-MIN-0046

Cabinet

Minute of Decision

Decision to Use Novavax's COVID-19 Vaccine (Primary Course)

Portfolio **COVID-19 Response**

On 28 February 2022, Cabinet:

1 **noted** that the Novavax COVID-19 vaccine has been granted provisional consent from Medsafe for people aged 18 years and over as a primary course vaccine;

2 **noted** that the COVID-19 Vaccine Technical Advisory Group (CV-TAG) have endorsed the use of the Novavax vaccine in the COVID-19 Vaccine and Immunisation Programme as a second-line vaccine, with the Pfizer vaccine remaining the first line and preferred vaccine for a primary course;

3 **noted** that Novavax has advised that we can expect s 9(2)(b)(ii) by end of February 2022, which are currently expected to expire on 30 April 2022;

4 **noted** that Novavax intends to submit an application to Medsafe to extend the shelf life to nine months (if successful, these doses would expire 31 July 2022);

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

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

7 **agreed** to proceed with the use of the Novavax in the COVID-19 Vaccine and Immunisation Programme to initially increase uptake of the primary course, from Q1 2022;

8 **noted** that if Cabinet agrees to the use of the Novavax vaccine in the COVID-19 Vaccine and Immunisation Programme, the programme can bring it online from late March 2022;

9 **noted** that officials will revert to Vaccine Ministers with advice on optimising the Novavax supply going forward;

10 **noted** that a further decision to use Novavax will be triggered should Medsafe and/or CV-TAG recommend it for use as a booster.

Michael Webster
Secretary of the Cabinet

Commercially Sensitive

Office of the Minister for COVID-19 Response

Cabinet

Decision to use Novavax's COVID-19 vaccine (primary course)

Proposal

1 This paper seeks your agreement to proceed with the use of the Novavax vaccine in the COVID-19 Vaccine and Immunisation Programme (CVIP) to increase uptake of the primary course vaccine in the first instance.

Relation to government priorities

2 This proposal relates to the Government's priority of continuing to keep New Zealanders safe from COVID-19.

Context

3 New Zealand has secured access to COVID-19 vaccines from four different suppliers (Pfizer, AstraZeneca, Janssen, and Novavax) to ensure adequate supply to meet the priorities of the CVIP. Vaccines were acquired as part of the broader response to COVID-19 to manage the impact on New Zealanders and their wellbeing.

Table 1. Portfolio of COVID-19 vaccines (doses) by expected delivery schedules

	Q1 2022	Q2 2022	Q3 2022	Q4 2022	2023
Pfizer	s 9(2)(b)	[redacted]	[redacted]*	*	*
AstraZeneca	s 9(2)	[redacted]	-	-	-
Janssen	s 9(2)	-	-	-	-
Novavax	[redacted]	[redacted]	s 9(2)(b)	[redacted]	[redacted]

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

4 To date, the CVIP has been based primarily on Pfizer's vaccine, with a small volume of the AstraZeneca vaccine available for use. The portfolio provides the opportunity to increase overall rates of vaccine uptake by offering consumers a choice of vaccines. It also helps manage supply risk through diversification of suppliers.

5 The current priorities of the programme are:

5.1 continued improvements in vaccination uptake in the eligible population;

5.2 paediatric primary courses for 5-11 years; and

5.3 booster doses for the adult cohort (18 years and older).

6 In January 2022, Vaccine Ministers agreed that New Zealand will maintain a primarily mRNA-based immunisation programme [HR-2022-023 refers]. Officials continue to assess ongoing immunisation needs to support additional mRNA purchases.

7 In addition, the programme will continue to maintain access to a non-mRNA vaccine to enable continued vaccinations of those unable to receive mRNA vaccines and to potentially respond to future variants should they be more appropriate. New Zealand currently has access to three non-mRNA vaccines, specifically two viral vector vaccines (Janssen and AstraZeneca) and a protein subunit vaccine (Novavax).

8 The programme also needs to be responsive to further evolutions in the COVID-19 context. For instance, these changes could include:

8.1 expanded eligibility of adolescent (12 to 17 years) and paediatric (5 to 11 years) dose booster programmes as well as primary courses for younger children (under 5 years) and cohort effects as children age

8.2 increased virulence and severity of emerging COVID-19 variants and their impact on existing vaccine protection for another booster programme

8.3 introduction of updated variant vaccines or technology.

9 This means that the portfolio will need enough vaccine supply to maintain population coverage and respond to future vaccine needs in 2022.

Approval and use in other countries

10 Novavax has been approved for use as a primary course vaccine in 38 countries, including Australia, European Union member states, Singapore and the United Kingdom. While we understand that no regulator has yet approved the Novavax vaccine as a booster dose, Singapore's Expert Committee on Covid-19 Vaccination has also recommended the Novavax vaccine as their first non-mRNA booster dose.

11 Roll-out is currently underway in Indonesia and Australia, and South Korean authorities have indicated that they plan to commence administering the Novavax vaccine from 14 February 2022. Singapore is expecting their first batch of the Novavax vaccine to arrive in the next few months.

12 There have been reports of delivery delays to the Philippines and European Union and at this stage, we are not aware of any jurisdictions that have donated or publicly indicated they intend to donate the Novavax vaccine. s 9(2)(b)(ii) [redacted]

13 The COVAX Facility is reported to have an Advance Purchase Agreement (APA) for 13.1 billion doses of the Novavax vaccine s 9(2)(f)(iv) [redacted]

Decision to Use Framework

14 In February 2021, Cabinet endorsed the Decision to Use Framework to support best use of COVID-19 vaccines in our portfolio [CAB-21-MIN-0011 refers].

15 The Decision to Use Framework provides a robust process to inform decisions and optimise delivery for CVIP and flow on portfolio implications (see appendix 1).

A decision is required on the use of the Novavax COVID-19 vaccine

16 The Novavax vaccine is a two-dose recombinant spike protein nanoparticle vaccine containing the Matrix-M adjuvant, with the second dose administered three weeks after the first dose.

17 This vaccine can be stored and transported at standard cold chain temperatures of 2°C to 8°C and currently has a shelf life of six months in Australia and New Zealand. Other jurisdictions, including the European Union member states and the United Kingdom, have afforded Novavax a shelf life of six months. I understand that Novavax is currently in discussions with the Therapeutic Goods Administration and Medsafe regarding data requirements to extend the shelf life to nine months and have advised their intent to submit an application to Medsafe for a shelf-life extension on the week beginning 28 February 2022.

18 In general, the Novavax vaccine offers a high level of protection against symptomatic COVID-19 and severe disease. However, it is not known how effective the primary course is against variants of concern that have emerged recently, such as Delta and Omicron.

19 On 4 February 2022, Medsafe granted provisional approval of the two-dose Novavax Covid-19 vaccine, Nuvaxovid, for adults aged 18 and over.

20 Novavax has signalled an intention to apply to Medsafe in the coming weeks to expand the indications for its COVID-19 vaccine to include use as a booster. In parallel, our COVID-19 Vaccine Technical Advisory Group (CV-TAG) and the Australian Technical Advisory Group on Immunisation are considering the data currently available on boosters.

21 I also understand that Novavax intends to submit data to Medsafe to support an extension of its approval to include 12–17-year-olds as early as March 2022.

22 Novavax have informed officials that New Zealand has been allocated s 9(2)(b)(ii) [redacted]. As of last week, New Zealand was notified that these doses, which are currently in Australia, would arrive in New Zealand early March 2022. Our allocation currently expires 30 April 2022, and as the Novavax vaccine is currently only recommended as a primary series vaccine for those 18 years and over, we will likely have a significant oversupply of the Novavax vaccine in the first half of the year.

23 Following ongoing negotiations with the Ministry of Health, s 9(2)(j) [redacted]

24 I have considered the use of the Novavax COVID-19 vaccine:

24.1 in New Zealand as a primary vaccine to support our Immunisation Programme to maximise uptake in 2022, starting Q1 2022;

24.2 in New Zealand as a booster dose to support our Immunisation Programme to maximise uptake in 2022, subject to further advice; and

24.3 for donation to developing countries, where possible, to support increased vaccination and protect against the risk of COVID-19.

COVID-19 Vaccine Technical Advisory Group recommendations

25 CV-TAG met on 1 February 2022 and 8 February 2022 to discuss the use of a primary course of the Novavax COVID-19 vaccine. They have recommended that the Novavax vaccine be used as a second-line vaccine, with Pfizer remaining the first-line and preferred vaccine. This is consistent with the proposed use of the Novavax vaccine for those unable or hesitant to take an mRNA vaccine and will support the goal of maximising primary course uptake.

26 CV-TAG also noted that there is currently insufficient data on the Novavax vaccine to recommend it during pregnancy. Use in pregnancy should be based on an assessment of benefits and risks by the consumer and their healthcare professional.

27 With regard to timing, CV-TAG recommended:

27.1 that two doses of the Novavax vaccine, given 3 weeks apart, are required for a primary vaccination course;

27.2 that the Novavax vaccine can be administered as part of a heterologous primary schedule to people who have received another COVID-19 vaccine as their first dose, and this should occur at least 28 days after the first dose of the other COVID-19 vaccine, to account for recommended intervals for other vaccine brands;

27.3 there should be no upper limit on time since the first dose; and

27.4 the Novavax vaccine may be administered before, after, or at the same time as the influenza, MMR, HPV, diphtheria/tetanus/pertussis combination vaccine (Boostrix), and other vaccines. The only exception to this advice is for the live-attenuated shingles vaccine (Zostavax) where a 7-day interval, before or after administering the Novavax vaccine is advised.

28 UK phase III trial investigating coadministration of a licensed influenza vaccine with the Novavax vaccine found similar efficacies against symptomatic PCR-confirmed COVID-19 as the Novavax study. However, the sample size for this study was small. Based on first principles, there is the potential for a reduced immune response when two different types of vaccine are administered together or within several days of each other. However, there are no additional safety concerns associated with coadministration, over and above each vaccine's individual safety profile.

29 CV-TAG noted that there is a potential for the Novavax vaccine to be used as a

booster dose in the context of Omicron, however, at this stage, they will continue to monitor the evidence on the Novavax vaccine as a booster.

The potential role of Novavax in the COVID-19 Immunisation Programme

30 Novavax's role in the portfolio also supports the management of specific risks with our primarily Pfizer-based programme (e.g., supply shocks), or downstream risks in 2022 (e.g., variants of concern or second boosters). Importantly, our contract with Novavax affords us access to updated vaccines should Novavax develop them.

31 The general public, media, companies, and agencies have expressed interest in the Novavax vaccine being used as a primary course and booster vaccine. This includes people who have a contraindication to the Pfizer vaccine, those who may have a serious adverse reaction after the first Pfizer dose, or those who are hesitant about getting the Pfizer vaccine. It is difficult to estimate demand for the Novavax vaccine, however, I consider it prudent to have sufficient doses available so that everyone who is eligible has the option to access Novavax as needed.

32 Based on current levels of uptake, up to 360,000 doses of the Novavax vaccine could be utilised by people who are yet to complete a primary COVID-19 course. This would support the goal of maximising uptake as it provides sufficient volumes for people who are unable to be vaccinated with the Pfizer vaccine and those who are hesitant to receive a Pfizer (mRNA) vaccine, but still wish to be, or are required to be vaccinated.

33 I acknowledge it is likely that s 9(2)(b)(ii) may not be utilised by 30 April (when the product expires) as a primary course. However, I consider this risk partially mitigated given that Novavax is confident in its ability to extend the expiry of the product to nine months (the first shipment would expire 31 July) s 9(2)(b)(ii)

34 Ministry of Health officials s 9(2)(b)(ii) consider Novavax's proposal a reasonable and balanced offer relative to the current position of having a significant surplus of doses in Q1 2022.

35 s 9(2)(b)(ii) I consider the benefits associated with improving primary vaccination rates, including protecting individuals from severe illness, and reducing the risk of overwhelming healthcare systems, to outweigh the costs of taking receipt of this volume with a likely percentage of wastage. Therefore, I consider some wastage acceptable.

36 In addition, having s 9(2)(b)(ii) in New Zealand manages the risk of Novavax being approved as a booster earlier than expected. We also have access to more supply in April 2022 as we are scheduled to receive significant volumes of Novavax

throughout 2022/23. Officials are working with Novavax to confirm ongoing delivery schedules and vaccine characteristics.

Donating the Novavax vaccine to maximise utilisation is not an option at this stage

37 Following initial discussions with COVAX, I understand that they are not ready to accept Novavax donations in Q1 2022. However, they could be interested in Novavax donations in the future. This reflects that there are currently no contractual arrangements in place to enable Novavax donation to COVAX and the time it takes to generate demand for a new product.

38 Novavax has signalled that they will move forward with COVAX to set the foundation for future donations to enable countries to donate Novavax in future. Any decisions to donate Novavax doses in future will be supported by advice from officials to Vaccine Ministers in due course.

Recommendations for the use of Novavax

39 I am seeking your agreement to proceed with the use of the Novavax in the COVID-19 Immunisation Programme to initially increase uptake of the primary course, starting Q1 2022.

40 To support the goal of maximising uptake, I will seek a further decision to use on Novavax as a booster pending further advice.

Implementation

41 Planning is underway for the immunisation rollout so there will be minimal delay once decisions have been made on offering the Novavax vaccine. Rollout from late March 2022 allows sufficient time for:

41.1 confirming the delivery model and settings with District Health Boards (DHBs) and providers

41.2 workforce training;

41.3 technology development;

41.4 site onboarding; and

41.5 operational and public facing collateral development.

42 If Cabinet agree to use Novavax, it will be the first protein-based COVID-19 vaccine made available in New Zealand. I understand this may appeal to the unvaccinated population who have held concerns over mRNA based vaccines, and who have delayed vaccinations and remain non-compliant in DHBs.

43 I understand the storage of the product suits immunisation providers, as Novavax has similar characteristics to non-COVID-19 vaccines. For instance, Novavax has a maximum shelf life of 6 months and uses the traditional 2°C to 8°C cold chain storage infrastructure. Providers in the rural immunisation network and community-based

General Practitioners will experience greater flexibility to locally store vaccines and schedule vaccinations for their population.

44 Importantly, as a limited number of people are yet to complete a primary course of a COVID-19 vaccine, the number of delivery settings enabled by DHBs may initially be limited to reflect this demand pattern. The capacity and location of these settings would be re-visited following further advice on the Novavax vaccine as booster.

Financial Implications

45 The cost of purchasing the Novavax doses has already been confirmed and appropriated for and will not require additional funding. s 9(2)(b)(ii) [redacted]

46 Importantly, if a decision to donate Novavax is made, it may involve expenditure on top of vaccine costs if the donation is to low-income countries. These ancillary costs cover safe injectable equipment, freight and a no-fault compensation scheme levy. If New Zealand opts to pay for ancillary costs, which we should do as a good donor, these can be met from the Official Development Assistance budget. s 9(2)(i) [redacted]

47 s 9(2)(j) [redacted]

48 Should there be underutilisation of product, New Zealand will carry the responsibility of disposing all expired and unused product.

Legislative Implications

49 There are no legislative implications from the proposals in this paper.

Population Implications

50 Providing the Novavax vaccine as an option for people who are unable or hesitant to take a Pfizer or AstraZeneca vaccine may increase the proportion of people who have a level of protection from COVID-19, reducing the potential harm from COVID-19. Specifically providing Novavax has implications for key population groups:

50.1 Māori are partially or completely vaccinated at a rate of 0.93 compared to non-Māori non-Pacific peoples. Māori are also at significantly higher risk of severe disease and hospitalisation, across lower age groups than non-Māori non-Pacific. Providing vaccine options may result in increased uptake in COVID-19 immunisation among Māori, with overall reductions in risk to health of individuals, whanau, communities, and reduced risk of burden on healthcare systems.

50.2 Unvaccinated and partially vaccinated peoples are disproportionately represented in hospitalisations in New Zealand, illustrating increased risk of

severe disease and death from COVID-19. Providing vaccine options in the Programme may result in increased uptake in COVID-19 immunisation across New Zealand, with overall reduced risk of severe illness and hospitalisation, and a reduced risk of burden on healthcare systems.

Human Rights

51 There are no human rights implications from the proposals in this paper.

Consultation

52 The Ministry of Health has consulted with the Ministry of Foreign Affairs and Trade and Treasury. The Department of the Prime Minister and Cabinet has been informed.

Communications

53 It is anticipated that Vaccine Ministers will publicly announce the decision to use the Novavax vaccine as an alternative to the Pfizer vaccine.

54 The Ministry will provide Vaccine Ministers with a communication plan to support the announcement. Information will be provided about how and where to access the vaccine, along with information about dose intervals and anticipated side effects.

55 The Ministry of Health will continue to work closely with our partners in the community, including Māori and Pacific Health providers, so that those who are hesitant or unable to take the Pfizer vaccine can make an informed decision about vaccination options.

Proactive Release

56 This Cabinet paper will be released within 30 working days, with redactions as appropriate under the Official Information Act 1982.

Recommendations

The Minister for COVID-19 response recommends that the Cabinet:

1 note that the Novavax COVID-19 vaccine has been granted provisional consent from Medsafe for people aged 18 years and over as a primary course vaccine;

2 note that CV-TAG have endorsed the use of the Novavax vaccine in the COVID-19 Vaccine and Immunisation Programme as a second-line vaccine, with the Pfizer vaccine remaining the first line and preferred vaccine for a primary course;

3 note that Novavax have advised that we can expect s 9(2)(j) by end of February 2022 which are currently expected to expiry 30 April 2022;

4 note that Novavax intends to submit an application to Medsafe to extend the shelf life to 9 months (if successful, these doses would expire 31 July);

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

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

7 agree to proceed with the use of the Novavax in the COVID-19 Vaccine and Immunisation Programme to initially increase uptake of the primary course, from Q1 2022;

8 note that if you agree with the use of the Novavax vaccine in the COVID-19 Vaccine and Immunisation Programme, the programme can bring it online from late March 2022;

9 note that officials will revert to Vaccine Ministers with advice on optimising Novavax supply going forward;

10 note that a further decision to use Novavax will be triggered should Medsafe and/or CV-TAG recommend it for use as a booster.

Authorised for lodgement

Hon Chris Hipkins

Minister for COVID-19 Response

Appendix: Decision Framework