

Memo

COVID-19 vaccines for arrivals to Aotearoa New Zealand: COVID-19 Vaccine Technical Advisory Group (CV TAG) Recommendations

Date:	1 October 2021
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From:	Dr Ian Town, Chief Science Advisor
For your:	Information

Purpose of report

1. This memo summarises the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on COVID-19 vaccination requirements for people arriving to the country under the Recognised Seasonal Employer (RSE) scheme. These recommendations are made as a part of the next step in the phased introduction of vaccination requirements at the border.

Background and context

2. CV TAG has previously provided recommendations on COVID-19 vaccination requirements for Border Workers, recognising that enhanced protection against infection was needed due to their individual occupational risk profile but also the broader public health benefit through reducing viral infection and onward transmission. Details of recommendation are provided in Appendix 1.
3. Recommendations have also been provided on vaccination requirements for entering managed isolation and quarantine (MIQ). These recommendations specify that a full primary course of vaccination with any COVID-19 vaccine would be acceptable for entering MIQ. For those who have had a full primary course of a vaccine NOT approved, provisionally approved, or authorised for emergency use by a Medsafe-recognised authority, they should be offered an additional dose of Pfizer vaccine. Further details of recommendation are provided in Appendix 2.

4. COVID-19 vaccines currently provisionally approved by Medsafe for use in New Zealand are Pfizer, Janssen, and AstraZeneca. An application for the Novavax COVID-19 vaccine has been received, but the timeframe for completion depends on further data from the sponsor.[1]
5. Medsafe considers that the following authorities follow similar international standards and guidelines to Medsafe. This allows Medsafe to facilitate abridged evaluations of new medicine applications in New Zealand via the abbreviated application pathway. The Medsafe recognised authorities are: The Australian Therapeutic Goods Administration (TGA), The United States Food and Drug Administration (FDA), Health Products and Food Branch of Health Canada, Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, the European Medicines Agency (EMA) (centralised procedure only) and EU member states (decentralised or mutual recognition procedure only).[2]
6. COVID-19 vaccines that do not have Medsafe approval or provisional approval, but comply with requirements of Medsafe-recognised authorities are: Moderna mRNA vaccine (Spikevax) - TGA, FDA, Health Canada, MHRA, and EMA; and the AstraZeneca vaccine manufactured by the Serum Institute of India (Covishield) - Health Canada.[3-7] Vaccines that are currently under rolling review by the EMA but not yet approved include CureVac, Gamalaya (Sputnik V), Sinovac (Coronavac) and Vidprevtyn from Sanofi-GSK.
7. As part of the continual improvement approach to reduce the risk of COVID-19 entering the community, the Government has signalled it wants to look at vaccination requirements for arrivals to New Zealand. In the short term, imposing a vaccination requirement on inbound RSE workers has been proposed as a next step in the phased introduction of vaccination requirements at the border.
8. The Government have announced that a one-way quarantine-free travel scheme will be open for RSE workers from Samoa, Tonga and Vanuatu. This begins from 4 October for RSE workers from Vanuatu, and 12 October for RSE workers from Samoa and Tonga. This scheme will allow up to 14,400 workers from those Pacific nations to enter without 14 days in MIQ.
9. Current requirements as part of this scheme specify that RSE workers must have had at least one dose of vaccination pre-departure, undertake Day 0 and Day 5 tests, and complete a 7-day self-isolation period in employer-arranged accommodation. They will be released to work after a negative Day 5 result.
10. RSE workers are expected to arrive having received either the AstraZeneca vaccine (Samoa, Tonga and Vanuatu) or the Sinopharm vaccine (Vanuatu). The Government has been informed that most RSE workers will be fully vaccinated, however some may arrive having only had one dose. The issue of people arriving with 1 dose will be time-restricted in that by late 2021 all incoming RSE workers should be fully vaccinated.
11. The Ministry of Health's Global Health Polynesian Health Corridors team and Polynesian Pandemic Preparedness Worksteam has requested advice about the vaccination requirements for RSE workers:
 - a. who have received a full primary course of vaccination with the AstraZeneca vaccine;
 - b. who have received a full primary course of vaccination with the Sinopharm vaccine;
 - c. who have received an incomplete primary course of one dose of the AstraZeneca vaccine;
 - d. who have received an incomplete primary course of one dose of the Sinopharm vaccine.

Recommendations

12. CV TAG met on 21 September 2021 to consider recommendations regarding COVID-19 vaccines for arrivals to Aotearoa New Zealand.
13. CV TAG noted that:
 - a. There have been no cases of COVID-19 in Samoa, Tonga, and Vanuatu in the last 6 months. Therefore, the purpose of these entry requirements for RSE workers is to ensure they are protected from COVID-19 while in New Zealand with a similar level of protection as others in New Zealand.
 - b. Data are still emerging on the efficacy of heterologous vaccine schedules from approved and recognised vaccines in New Zealand's portfolio. Initial results show that mixing doses of mRNA and adenovirus-vectored vaccines is associated with an acceptable reactogenicity profile and generates levels of anti-spike neutralising antibody titres shown to provide high levels of protection in primary efficacy trials.[8-10]
 - c. Because receiving vaccines for COVID-19 are free to all within New Zealand, no cost will be associated with administration of any additional doses to RSE workers.
14. CV TAG recommends that:

For RSE workers who have received	Recommendation
a. 2 doses of the AstraZeneca vaccine	This is a full primary course of vaccination approved by Medsafe. Considered 'fully vaccinated'.
b. 2 doses of the Sinopharm vaccine	This vaccine is NOT approved by Medsafe and/or Medsafe recognised authorities. These RSE workers should receive one dose of the Pfizer vaccine.
c. 1 dose of the AstraZeneca vaccine	These RSE workers should receive one dose of the Pfizer vaccine.
d. 1 dose of the Sinopharm vaccine	

- e. Regarding timing, administration of any additional doses should occur:
 - i. At least 28 days after the most recent dose of COVID-19 vaccine, with no upper limit on time since the last dose.
 - ii. If the interval since the most recent dose allows, the Pfizer dose should be offered to people on entry, while in self-isolation or at the latest as they leave self-isolation.

- iii. If the interval since the most recent dose does not allow vaccination before leaving self-isolation, a vaccination booking at the earliest available opportunity will be made before leaving self-isolation.
15. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

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Dr Ian Town

Chief Science Advisor and Chair of the COVID-19 Vaccine Technical Advisory Group

References

1. Medsafe. *Approval status of COVID vaccines applications received by Medsafe*. 2021 [cited 2021 27 August]; Available from: <https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp>.
2. Medsafe, *New Zealand Regulatory Guidelines for Medicines*, in *Part A: When is an application for approval of a new or changed medicine required?*, Medsafe, Editor. 2014, Medsafe: Medsafe. p. 132.
3. The Australian Therapeutics Goods Administration. *COVID-19 vaccine: Provisional registrations*. 2021; Available from: <https://www.tga.gov.au/covid-19-vaccine-provisional-registrations>.
4. European Medicines Agency. *COVID-19 vaccines: authorised*. 2021 [cited 2021 27 August]; Available from: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised#authorised-covid-19-vaccines-section>.
5. Government of Canada. *Drug and vaccine authorizations for COVID-19: List of applications received*. 2021; Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html>.
6. National Health Service. *Coronavirus (COVID-19) vaccines*. 2021 [cited 2021 27 August]; Available from: <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/>.
7. US Food and Drug Administration. *COVID-19 Vaccines*. 2021 [cited 2021 27 August]; Available from: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.
8. Gross, R., et al., *Heterologous ChAdOx1 nCoV-19 and BNT162b2 prime-boost vaccination elicits potent neutralizing antibody responses and T cell reactivity*. medRxiv, 2021: p. 2021.05.30.21257971.
9. Borobia, A.M., et al., *Reactogenicity and Immunogenicity of BNT162b2 in Subjects Having Received a First Dose of ChAdOx1s: Initial Results of a Randomised, Adaptive, Phase 2 Trial (CombiVacS)*. SSRN, 2021.
10. Liu, X., et al., *Safety and immunogenicity of heterologous versus homologous prime-boost schedules with an adenoviral vectored and mRNA COVID-19 vaccine (Com-COV): a single-blind, randomised, non-inferiority trial*. *The Lancet*, 2021.

Appendix 1: Previous CV TAG recommendations for Border Workers

CV TAG has previously provided advice on COVID-19 vaccination requirements for Border Workers, recognising that enhanced protection against infection was needed due to their individual occupational risk profile but also the broader public health benefit through reducing viral infection and onward transmission. CV TAG noted that:

- a. Data are still emerging on the efficacy of heterologous vaccine schedules from approved and recognised vaccines in New Zealand's portfolio, however initial results show that mixing vaccine doses is associated with a low incidence of adverse effects and could provide an improved immune response through increased anti-spike antibody titres and neutralising antibodies.[8-10]
- b. Protection against symptomatic infection is of enhanced importance for work at the Border. Extensive data has emerged showing high efficacy and effectiveness against symptomatic infection after two doses of the Pfizer, AstraZeneca, or Moderna vaccines in Phase 3 clinical trials and large post-marketing studies. There is strong evidence that the Janssen vaccine (the single-dose, adenovirus vector vaccine) provides a high degree of protection against moderate and severe disease from COVID-19, however there are fewer data on the efficacy or effectiveness against symptomatic infection, especially in the context of the Delta variant of SARS-CoV-2, and the immune response appears to be lower.

On this basis, CV TAG recommended for Border Workers that:

- c. A full course of vaccination with a COVID-19 vaccine recognised by Medsafe or a Medsafe recognised authority provides sufficient protection from COVID-19 for work at the Border, with the exception of the Janssen vaccine as a single dose schedule.
- d. A 'booster' dose of the Pfizer vaccine should be administered for Border workers who have only received a single dose of the Janssen vaccine, due to the higher risk of SARS-CoV-2 infection for Border work, and the need for enhanced protection against infection among Border Workers
- e. If a worker is in New Zealand and has an incomplete vaccination with a vaccine recognised by Medsafe or a Medsafe recognised authority, they should complete their vaccination by receiving one dose of the Pfizer vaccine. This should occur at least 21 days after the first dose of the Pfizer vaccine, or at least 28 days after the first dose of AstraZeneca or Moderna. There is no upper time limit on time for when that dose can be administered.
- f. Border workers who have received a partial or complete course of vaccine with a COVID-19 vaccine not approved by Medsafe or a Medsafe recognised authority, should also receive one dose of the Pfizer vaccine.

Appendix 2: Previous CV TAG recommendations for entry to MIQ

CV TAG have previously provided advice on COVID-19 vaccination requirements for entering MIQ. CV TAG noted that:

- a. officials are preparing a proposal for the Minister for COVID-19 Response to take to Cabinet that would impose a pre-entry requirement from 1 November 2021, that all (non-New Zealand citizen) arrivals by air are fully vaccinated.
- b. under this proposal all arrivals would still undergo testing and 14 days MIQ, which will continue to be the key line of defence.
- c. this is being proposed as an additional precautionary measure to further reduce the risk of COVID-19 entering the New Zealand community (and until New Zealand achieves high vaccination coverage).
- d. are significant ethical and equity issues given that most people have no choice about which vaccine they receive, and many countries still have poor access to vaccines and low vaccination rates.
- e. while the effectiveness varies across the different vaccine products, any vaccine is better than no vaccine.
- f. new recommendations will be needed if requirements around MIQ on entry to Aotearoa New Zealand change. This is due to different considerations around requirements of vaccines without MIQ as the key line of defence.
- g. updated recommendations will likely be needed if there are changes to the approved COVID-19 vaccination schedules in New Zealand.

On this basis, CV TAG recommended for arrivals to MIQ:

- a. a full primary course of vaccination with any of the 22 COVID-19 vaccines approved by at least one government or authority (or an approved combination of those vaccines in their origin country) with the last dose at least 14 days before arrival would be acceptable for entering MIQ for 14 days, given that testing and MIQ would provide the key line of defence. Vaccination should be documented in the manner that the origin country provides.
- b. an exemption process should be put in place for those who require an exemption on humanitarian grounds, because they are below the approved age for COVID-19 vaccination in their origin country, or for other similar reasons.
- c. those aged 12 years or over who enter the country with a full primary course of vaccination, but with a vaccine that is NOT one of those approved by a Medsafe-recognised authority should be offered an additional dose of Pfizer vaccine as soon as possible after entry to New Zealand (and at the latest as they leave MIQ). This should occur at least 28 days after the last dose, with no upper limit on time since the last dose.
- d. those who enter the country, are aged 12 years or over, and have received no doses of any of the 22 COVID-19 vaccines, should be offered a full course of Pfizer vaccine as soon as possible after entry to New Zealand (and at the latest receiving the first dose as they leave MIQ).

- e. those who enter the country, are aged 12 years or over and have received an incomplete primary course of any of the 22 COVID-19 vaccines (whether approved by a Medsafe-recognised authority or not), should be offered an additional dose of Pfizer vaccine as soon as possible after entry to New Zealand.
 - ii. this should occur at least 28 days after the most recent dose of COVID-19 vaccine, with no upper limit on time since the last dose.
 - iii. if the interval since the most recent dose allows, vaccination with Pfizer should be offered to people while in MIQ or at the latest as they leave MIQ.
 - iv. if the interval since most recent dose does not allow vaccination on or before leaving MIQ, a future vaccination booking should be offered as they leave MIQ at the latest.