Memo

Date:	6 September 2021
To:	Maree Roberts, Deputy Director General, System Strategy and Policy
Copy:	Alison Cossar, Manager, Public Health Policy, Systems Strategy and Policy Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme Niki Stefanogiannis, Deputy Director Public Health, Population Health and Prevention
From:	Dr Ian Town, Chief Science Advisor
Subject:	COVID-19 vaccines recognised for work at the Aotearoa New Zealand Border
For your:	Consideration

Purpose

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on COVID-19 vaccines that Aotearoa New Zealand recognises for those working at the international border ('the Border'), including advice on the criteria for deciding which vaccines should be recognised at the Border, and how to approach incomplete vaccination with recognised COVID-19 vaccines and vaccination with non-recognised COVID-19 vaccines among 'Border Workers'.

Context

2. The COVID-19 Public Health Response (Vaccinations) Order 2021 (the Vaccinations Order) requires certain work only be undertaken by vaccinated workers. This is due to the high risk of exposure to SARS-CoV-2 (the virus causing COVID-19) that these workers may experience in the course of their work and the risk of the workers becoming infected and transmitting SARS-CoV-2 to others. The current approach to COVID-19 vaccinations required for work at the Border does not accommodate New Zealanders who return from working overseas having received a COVID-19 vaccine other than 'Comirnaty', the Pfizer-BioNTech mRNA COVID-19 vaccine (the Pfizer vaccine).
3. The New Zealand Defence Force (NZDF) report having more than 250 personnel who have been vaccinated overseas with the Moderna, AstraZeneca, or Janssen vaccines. These personnel cannot be reassigned to work at managed quarantine and isolation facilities (MIQFs) because they do not meet the vaccination requirements in the Vaccinations Order. The NZDF has signalled that the inability to reassign personnel to work at the Border has created a workforce capacity issue that is becoming more acute over time.
4. In the longer-term, the Ministry of Health (the Ministry) is developing advice about which COVID-19 vaccines Aotearoa New Zealand will recognise to be considered for reduced testing or MIQF requirements for inbound travellers as part of the Reconnecting New Zealanders work. Any decisions made in the short-term about approved COVID-19 vaccines for work at the Border will

likely inform future decisions, however these fall outside of the scope of this memo and recommendations, which is restricted to discussing requirements for work at the Border.

5. The Ministry's Public Health Policy team sought advice from CV TAG on the short and longer-term options for COVID-19 vaccines recognised in New Zealand. On 22 June 2021 CV TAG met to consider the issue and recommended that individuals with a complete course of a vaccine approved by regulators in countries with similar regulatory systems to New Zealand could be eligible to work at the Border. However, CV TAG signalled that further discussion on the issue was required to clearly understand what the vaccines approved or provisionally approved by these agencies were. It was agreed that a list of COVID-19 vaccines with approval, provisional approval, or emergency use provisions from a Medsafe recognised authority would be brought to a future CV TAG meeting for discussion.

6. Medsafe considers that the authorities listed below have robust approval processes and conduct thorough assessments of applications for new medicines. They follow similar international standards and guidelines in their assessments to Medsafe. This allows Medsafe to rely on their assessments and approval to facilitate abridged evaluations of new medicine applications in New Zealand submitted via the abbreviated application pathway. The Medsafe recognised authorities are:[1]

    a) The Australian Therapeutic Goods Administration (TGA)

    b) The United States Food and Drug Administration (FDA)

    c) Health Products and Food Branch of Health Canada

    d) Medicines and Healthcare products Regulatory Agency (MHRA), in the United Kingdom

    e) European Medicines Agency (EMA) (centralised procedure only)

    f) EU member states (decentralised or mutual recognition procedure only)

7. The 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, however further data has been requested from the sponsor.[2]

8. As of 31 August 2021, COVID-19 vaccines that do not have Medsafe approval or provisional approval, but that do have approval, provisional approval, or emergency use provisions from Medsafe-recognised authorities are: **Moderna mRNA vaccine** (Spikevax) approved by the TGA, FDA, Health Canada, MHRA, and EMA; and **the AstraZeneca vaccine manufactured by the Serum Institute of India (Covishield)** has received separate approval from Health Canada.[3-7] Vaccines that are currently under rolling review by the EMA but have not yet been approved include CureVac, Gamalaya (Sputnik V), Sinovac (Coronavac) and Vidprevtyn from Sanofi-GSK. These are not currently recognised as part of these recommendations.

9. The vaccines provisionally approved by Medsafe and other regulatory bodies provide protection against COVID-19 and have good safety profiles, however, efficacy/effectiveness varies between the vaccines (see Table 1). A high level of protection against COVID-19 is needed for Border workers, not only for the direct individual benefits of protection against symptomatic infection and moderate-severe disease, but there is also a broader public health benefit through reducing viral infection and onward transmission.

Table 1: Vaccine efficacy/effectiveness of provisionally approved and recognised vaccines

	Pfizer	**AstraZeneca**	**Janssen**	**Moderna**
Against symptomati	*Efficacy*:	*Efficacy*:	*Efficacy*:	*Efficacy*:

c COVID-19 infection	95% (95%CI: 90.3-97.6) >7 days post 2nd dose.[8] *Effectiveness*: 94% (95%CI: 87-98.0) against symptomatic infection.[9] 85–95.3% >7 days post 2nd dose in Israel, UK and Italy.[9-13] UK: 70% (95%CI: 62-77) reduction in transmission post 2nd dose.[13] Israel: ~77% reduction among elderly post 2nd dose.[14]	63.1% (95%CI: 51.8-71.1) >14 days post 2nd dose.[15] US trial: 76% (95%CI: 68.0-82.0) from 15 days post 2nd dose when given four weeks apart.[16] 54.1% (95%CI: 44.7-61.9) >14 days post 2nd doses.[15] *Effectiveness*: Scotland: 88% (95%CI: 75-94) against hospitalisation 28-34 days post 1st dose.[17] UK: 80.4% (95%CI: 36.4-94.5) against hospitalisation post 1st dose in the elderly.[18]	74% (95%CI: 46.8-88.4) >28 days post vaccination.[19] *Effectiveness:* US: 76.7% (95%CI: 30.3-95.3) >14 days post vaccination.[20]	94.1% (95% CI:89.3–96.8) against infection including severe disease >14 days post 2nd dose.[21] *Effectiveness:* 98.2% (95%CI: 97.5-98.6) >7 days post 2nd dose.[22] 91.3% (95%CI: 79.3-96.3) against symptomatic infection and 68.3% (95%CI: 27.9-85.7) against asymptomatic infection >14 days post 2nd dose.[23]
Delta	*Effectiveness against symptomatic infection:* 88% (95%CI: 85.3-90.1) against symptomatic Delta infection.[24] 96% (95%CI: 86-99) against hospitalisation with Delta infection.[25] Scotland: 79% (95%CI 75-82) against infection[26] *Effectiveness against asymptomatic infection*: No data	*Effectiveness against symptomatic infection:* UK: 67% (95%CI: 61.3-71.8) against symptomatic Delta infection.[24] UK:92% (95%CI: 75-97) against hospitalisation with Delta infection.[25] *Effectiveness against asymptomatic infection:* No data	No data	*Effectiveness against symptomatic infection:* US: 66% (95%CI: 22-84) (pooled data with Pfizer).[27] US: 76% (95%CI: 58-87) >14 days post 2nd dose.[28] *Effectiveness against asymptomatic infection:* No data

10. There is some evidence that a single dose of the Janssen vaccine may not be as effective against infection and may pose a greater risk for work at the Border. A US study from General

Massachusetts Hospital compared immune responses in ambulatory adults vaccinated with Pfizer, Moderna or Janssen vaccines and found lower antibody concentrations and neutralisation titres for the Janssen vaccine. However, administering a second dose of either Pfizer or Moderna vaccines boosted the immune response.[29] Trials are underway to assess the efficacy after a second 'booster' dose and are showing promising preliminary results with a nine-fold increase in spike-binding antibodies (noting that this data has yet to be formally released, published in a journal, or evaluated by regulatory authorities).[30]

11. Recommendations are also needed for the following groups: individuals with incomplete vaccination with recommended vaccines; individuals with complete or incomplete vaccination with COVID-19 vaccines that are not recommended for use at the Border.

Recommendations

12. CV TAG met on 17 and 31 August 2021 to consider recommendations regarding which COVID-19 vaccines can be recognised for Border work, and how to approach incomplete and complete vaccination with non-recognised COVID-19 vaccines.

13. **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.[31-33]

    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 less 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.

14. **CV TAG recommends that:**

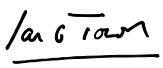
    a) A full course of vaccination with a COVID-19 vaccine recognised by Medsafe (or a Medsafe recognised authority) provides sufficient protection from COVID-19 for work at the Border, with the exception of the Janssen vaccine as a single dose schedule.

    b) 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.

    c) 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 non-Pfizer vaccine, or at least 28 days after the first dose if this was AstraZeneca or Moderna. There is no upper time limit on time for when that dose can be administered.

    d) Workers who have received a partial or complete course of vaccine with a non-recognised COVID-19 vaccine, should also receive one dose of the Pfizer vaccine.

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.



Dr Ian Town

Chief Science Advisor

Chair, CV TAG

References

1. 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.
2. 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.
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. Polack, F.P., et al., *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine.* New England Journal of Medicine, 2020. **383**(27): p. 2603-2615.
9. Dagan, N., et al., *BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting.* New England Journal of Medicine, 2021.
10. Hall, V.J., et al., *COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study.* The Lancet, 2021. **397**(10286): p. 1725-1735.
11. Haas, E.J., et al., *Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data.* The Lancet.
12. Fabiani, M., et al., *Effectiveness of the Comirnaty (BNT162b2, BioNTech/Pfizer) vaccine in preventing SARS-CoV-2 infection among healthcare workers, Treviso province, Veneto region, Italy, 27 December 2020 to 24 March 2021.* Eurosurveillance, 2021. **26**(17): p. 2100420.
13. Pritchard, E., et al., *Impact of vaccination on new SARS-CoV-2 infections in the United Kingdom.* Nature Medicine, 2021.
14. Rossman, H., et al., *COVID-19 dynamics after a national immunization program in Israel.* Nature Medicine, 2021. **27**(6): p. 1055-1061.
15. Voysey, M., et al., *Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials.* The Lancet, 2021. **397**(10277): p. 881-891.
16. AstraZenenca. *AZD1222 US Phase III primary analysis confirms safety and efficacy*. 2021; Available from: https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/azd1222-us-phase-iii-primary-analysis-confirms-safety-and-efficacy.html.
17. Vasileiou, E., et al., *Interim findings from first-dose mass COVID-19 vaccination roll-out and COVID-19 hospital admissions in Scotland: a national prospective cohort study.* The Lancet, 2021. **397**(10285): p. 1646-1657.
18. Hyams, C., et al., *Effectiveness of BNT162b2 and ChAdOx1 nCoV-19 COVID-19 vaccination at preventing hospitalisations in people aged at least 80 years: a test-negative, case-control study.* The Lancet Infectious Diseases, 2021.

19. Food and Drug Administration (FDA). *Vaccines and Related Biological Products Advisory Committee Meeting February 26, 2021, FDA Briefing Document, Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19*. 2021; Available from: https://www.fda.gov/media/146217/download.
20. Corchado-Garcia, J., et al., *Real-world effectiveness of Ad26.COV2.S adenoviral vector vaccine for COVID-19.* medRxiv, 2021: p. 2021.04.27.21256193.
21. Baden, L.R., et al., *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine.* New England Journal of Medicine, 2020. **384**(5): p. 403-416.
22. Butt, A.A., et al., *SARS-CoV-2 Vaccine Effectiveness in a High-Risk National Population in a Real-World Setting.* Annals of Internal Medicine, 2021.
23. Andrejko, K.L., et al., *Prevention of COVID-19 by mRNA-based vaccines within the general population of California.* Clinical Infectious Diseases, 2021.
24. Lopez Bernal, J., et al., *Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant.* New England Journal of Medicine, 2021.
25. Stowe, J., et al. *Effectiveness of COVID-19 vaccines against hospital admission with the Delta (B.1.617.2) variant*. 2021; Available from: https://khub.net/documents/135939561/479607266/Effectiveness+of+COVID-19+vaccines+against+hospital+admission+with+the+Delta+%28B.1.617.2%29+variant.pdf/1c213463-3997-ed16-2a6f-14e5deb0b997?t=1623689315431.
26. Sheikh, A., et al., *SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness.* Lancet, 2021. **397**(10293): p. 2461-2462.
27. Fowlkes, A., et al., *Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance - Eight U.S. Locations, December 2020–August 2021.* MMWR Morb Mortal Wkly Rep, 2021. **70**: p. 1167-1169.
28. Puranik, A., et al., *Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence.* medRxiv, 2021: p. 2021.08.06.21261707.
29. Naranbhai, V., et al., *Immunogenicity of mRNA-1273, BNT162b2 and Ad26.COV2.S COVID-19 vaccines.* medRxiv, 2021: p. 2021.07.18.21260732.
30. Johnson and Johnson. *Johnson & Johnson Announces Data to Support Boosting its Single-Shot COVID-19 Vaccine*. 2021 [cited 2021 27 August]; Available from: https://www.jnj.com/johnson-johnson-announces-data-to-support-boosting-its-single-shot-covid-19-vaccine.
31. 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.
32. 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.
33. 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.