

Briefing

Proposed approach to COVID-19 vaccines that New Zealand recognises for work at the Border

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Security level: IN CONFIDENCE **Health Report number:** HR20212018

To: Hon Chris Hipkins, Minister for COVID-19 Response

Copy to: Rt Hon Jacinda Ardern, Prime Minister
 Hon Andrew Little, Minister of Health
 Hon Dr Ayesha Verrall, Associate Minister of Health
 Hon Peeni Henare, Associate Minister of Health
 Hon Aupito William Sio, Associate Minister of Health
 Hon Michael Wood, Minister of Transport and Minister for Workplace Relations & Safety

Contact for telephone discussion

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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 Withdrawn | |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:

Proposed approach to COVID-19 vaccines that New Zealand recognises for work at the Border

Security level: IN CONFIDENCE **Date:** 27 September 2021

To: Hon Chris Hipkins, Minister for COVID-19 Response

Purpose of report

1. This report:
 - a) seeks your agreement to key policy decisions for the second amendment to the COVID-19 Public Health Response (Vaccinations) Order 2021 (Vaccinations Order), specifically the proposed approach to COVID-19 vaccines that New Zealand recognises for work at the Border
 - b) provides advice on the process for the catalogue of COVID-19 vaccine standards agreed for certain purposes (e.g. Border work or people arriving into New Zealand).
2. This report discloses all relevant information and implications known at the time.

Summary

3. The Vaccinations Order requires certain work at the New Zealand Border to only be undertaken by vaccinated workers due to the risk that these workers, in the course of their work activities, may be exposed to and transmit the COVID-19 virus.
4. As part of the wider context for potential changes to the Vaccinations Order, two judicial review proceedings have been instigated in the High Court in relation to the lawfulness of requirements within the Order, which may require urgent actions and/or amendment to address any findings.
5. The Vaccinations Order is contributing to workforce capacity issues because it does not recognise people vaccinated overseas with a partial or full course of COVID-19 vaccines other than the Pfizer/BioNTech vaccine.
6. The COVID-19 Vaccine Science and Technical Advisory Group (CV-TAG) has reviewed COVID-19 vaccines currently recognised by Medsafe and/or a Medsafe recognised authority (i.e. Pfizer, Moderna, AstraZeneca and Janssen). Generally, these COVID-19 vaccines appear to have sufficiently high efficacy and effectiveness against symptomatic infection after the full course, except for the single-dose Janssen.
7. To broaden the group of COVID-19 vaccines allowable for work at the Border, we propose an overall approach that includes COVID-19 vaccines recognised by Medsafe and/or a Medsafe recognised authority. Additionally, we propose a further dose of the Pfizer/BioNTech vaccine for Border workers who have not received a full course of a recognised COVID-19 vaccine to ensure they have a sufficient level of immunity for high-risk work.

8. CV-TAG recommends a further dose of the Pfizer/BioNTech vaccine for Border workers who have received one dose of the Janssen vaccine. This recommendation addresses concerns about whether the Janssen vaccine would provide sufficient protection for high-risk work at the Border, especially given the lack of data in relation to the Delta variant.
9. However, certain unvaccinated Border workers (pilots and port workers) have expressed concerns about the primary vaccine available and propose receiving an alternative COVID-19 vaccine in order to fulfil their obligations under the Vaccinations Order. These hesitant Border workers would be unlikely to accept the further dose of the Pfizer/BioNTech vaccine recommended by CV-TAG.
10. We expect some hesitant Border workers may remain otherwise unvaccinated if not given the option to receive the Janssen vaccine. If so, there are several risks to consider related to workforce capacity issues and the potential for COVID-19 transmission at and within the New Zealand Border. These risks should be considered alongside the risks signalled by CV-TAG in relation to the suitability of the Janssen vaccine for protection at the Border.
11. We propose an option to also recognise the Janssen vaccine for specified Border workers who are hesitant to receive the primary vaccine available, which would enable them to fulfil obligations under the Vaccinations Order. This option would require these workers to have a single dose of the Janssen vaccine, and then later a second dose of this same vaccine, if recommended by CV-TAG for them to be compliant with the Vaccinations Order.
12. If you agree to the proposed recommendations within this paper, further work will be necessary to enable recognition of COVID-19 vaccines administered overseas. The Ministry will also record any vaccine standards you agree in a centralised compendium for easy access and investigate the most suitable way to manage and make use of the list.

Recommendations

We recommend you:

- a) **Agree** that the overall approach underpinning the COVID-19 Public Health Response (Vaccinations) Order 2021 recognises COVID-19 vaccines that are: Yes/No
 - fully approved or provisionally approved by Medsafe; and/or
 - fully approved, provisionally approved and/or authorised for emergency use by Medsafe recognised authorities
- b) **Agree** to the COVID-19 Vaccine Science and Technical Advisory Group's further recommendations that an additional dose of Comirnaty (Pfizer/BioNTech) vaccine is necessary if a Border worker has:
 - i. an incomplete vaccination with a vaccine recognised by Medsafe or a Medsafe recognised authority Yes/No
 - or**
 - ii. received a partial or complete course of vaccination with a COVID-19 vaccine not recognised by Medsafe or a Medsafe recognised authority Yes/No

- c) **Agree** that if you agree to recommendation (a), then the following COVID-19 vaccines would be recognised for work at the Border: Yes/No
- Comirnaty (Pfizer/BioNTech)
 - AstraZeneca
 - Moderna
 - Janssen.
- d) **Note** that trials are presently underway to assess the efficacy of the Janssen vaccine after a second dose
- e) **Agree** to recognise the single-dose Janssen vaccine for specified Border workers who are hesitant to receive the primary vaccine available, followed by a second dose of the Janssen vaccine if recommended by the COVID-19 Vaccine Science and Technical Advisory Group, which would be a requirement for them to fulfil obligations under the COVID-19 Public Health Response (Vaccinations) Order 2021 Yes/No
- f) **Permit** the interagency engagement group to communicate with key stakeholders about the changes in relation to COVID-19 vaccines that New Zealand recognises for Border work.



Dr Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health

Date:



Hon Chris Hipkins
Minister for COVID-19 Response

Date: 2/10/2021

The timeframes being discussed here are too long. Given the impact on employment etc, I would like to sign-off an amendment to the Order within the next 2 weeks (1 week if possible). CH

Next amendment to the COVID-19 Public Health Response (Vaccinations) Order 2021

Background

13. On 1 May 2021, the Vaccinations Order came into force, which requires certain work at the New Zealand Border (the Border) to only be undertaken by vaccinated workers. This is due to the risk that these workers, in the course of their work activities, may be exposed to and transmit the COVID-19 virus.
14. A person conducting a business or undertakings (PCBUs) and groups of workers were covered by the Vaccinations Order in two separate tranches, with the most recent tranche commencing on 15 July 2021. The groups required to be vaccinated include workers:
 - a. at managed isolation and quarantine facilities (MIQFs)
 - b. at airside area of affected airports and some other high-risk areas at airports
 - c. at affected ports
 - d. at accommodation services where specified aircrew members are self-isolating
 - e. who handle items removed from the affected places listed above and touch affected items while undertaking work for a relevant PCBU that is contracted to provide regular services for MIQFs, an affected aircraft, or an affected ship (for example, cleaning, laundering, or refuse disposal services).

Judicial review proceeding underway in relation to the Vaccinations Order

15. As part of the wider context for potential changes to the Vaccinations Order, two judicial review proceedings have been instigated in the High Court. One of these proceedings will be heard together under urgency on 22 September 2021. Both proceedings raise a number of allegations challenging the lawfulness of the Vaccinations Orders¹.
16. If the hearing on 22 September occurs, it is likely a judgment will be made before the end of the month. It is possible, though we consider unlikely, that the Court will find the Vaccination Order unlawful. Also, it may be that new issues with the Vaccination Order may come to light at the hearing or out of the judgment. If either of these possibilities happen, then urgent action and/or amendment for the Vaccination Order may be necessary. The second proceeding does not yet have a hearing date.

¹ Two of these allegations relate to whether it was irrational (and therefore unlawful) for the Minister to be satisfied that the Vaccination Order: a) is a justified limit on the rights and freedoms of affected workers under the New Zealand Bill of Rights Act 1990; and b) is appropriate to achieve the purpose of the COVID-19 Public Health Response Act 2020. The second proceeding raises allegations around the safety and effectiveness of the Pfizer COVID-19 vaccine. It is likely if other COVID-19 vaccines are recognised within the Vaccination Order that the second proceeding will expand to challenge the safety and effectiveness of those other COVID-19 vaccines.

The Vaccinations Order is limited in the COVID-19 vaccines recognised for Border work, which is contributing to workforce capacity issues

17. In relation to COVID-19 vaccines, the Vaccinations Order states:
 - a. the person must have received 2 injections of the Comirnaty (Pfizer/BioNTech) vaccine, allowing a transition period for PCBUs and Border workers, and
 - b. the time period in which the person must be vaccinated by, for example, 1 injection before becoming an affected person and 2 injections 35 days after becoming an affected person.
18. The current approach to COVID-19 vaccines required for work at the Border does not accommodate New Zealanders who return from working overseas and who have received a full course of a COVID-19 vaccine other than Pfizer/BioNTech vaccine. The Vaccinations Order does not recognise any other COVID-19 vaccines now or in the future that could provide a sufficient level of protection for work at or close to the Border.
19. We understand that the limitation of only recognising the Pfizer/BioNTech vaccine has produced workforce capacity issues for employers and PCBUs responsible for people who undertake work at the Border.
20. In particular, 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. Some personnel currently working at MIQFs have not been able to rotate out for a year or more.
21. The Vaccinations Order also does not accommodate cases where workers are partially vaccinated overseas with a COVID-19 vaccine other than Pfizer/BioNTech vaccine and return to work at the New Zealand Border. There is currently no pathway for these workers to become 'fully vaccinated' as defined in the Vaccinations Order. There are concerns about whether it is safe to administer two doses of the Pfizer/BioNTech vaccine to people who have had a full course of another COVID-19 vaccine.

We propose you amend the Vaccinations Order to recognise a wider group of COVID-19 vaccines

Proposals

22. CV-TAG has provided advice after reviewing COVID-19 vaccines recognised by Medsafe and/or a Medsafe recognised authority. This advice forms the basis of several proposals we seek your agreement to.

We propose an overall approach that includes COVID-19 vaccines recognised by Medsafe or a Medsafe recognised authority

23. We propose you amend the Vaccinations Order to reflect an overall approach that recognises COVID-19 vaccines fully approved or provisionally approved by Medsafe; and/or fully approved, provisionally approved and/or authorised for emergency use by

Medsafe-recognised authorities². These authorities include medicines regulators with similarly stringent approaches to approvals (e.g. European Medicines Authority). The list of COVID-19 vaccines recognised currently includes Pfizer/BioNTech, Moderna, AstraZeneca and Janssen.

We propose a further dose of the Pfizer/BioNTech vaccine for Border workers in certain circumstances

24. In addition, CV-TAG recommends that a further dose of the Pfizer/BioNTech vaccine is necessary if a Border worker has:
- a) an incomplete vaccination with a vaccine recognised by Medsafe or a Medsafe recognised authority, or
 - b) received a partial or complete course of vaccination with a COVID-19 vaccine not recognised by recognised by Medsafe or a Medsafe recognised authority.
25. CV-TAG also recommends a further dose of the Pfizer/BioNTech vaccine is necessary if a Border worker has a full course of vaccination with the Janssen vaccine, which is largely due to concerns about the effectiveness against infection given the high-risk environment at the Border. We provide greater discussion of the issue in paras 35 to 40.

We propose to offer the Janssen vaccine for specified Borders workers who are hesitant to receive the primary vaccine available

26. We understand that certain unvaccinated Border workers (approximately 30 pilots and port workers) have expressed concerns about the primary vaccine available and propose receiving an alternative COVID-19 vaccine, specifically the Janssen vaccine, in order to fulfil their obligation under the Vaccinations Order.
27. We propose to recognise the single-dose Janssen vaccine for specified Border workers who are hesitant to receive the primary vaccine available, which would be followed by a second dose of the Janssen vaccine if recommended by CV-TAG in the future.

Analysis of proposals

COVID-19 vaccines recognised by Medsafe or a Medsafe recognised authority

28. It is necessary that any recognised COVID-19 vaccine for Border work should provide a level of protection that is proportionate to the high risk of exposure to and transmission of the COVID-19 virus, especially given the spread of the Delta variant. Consequently, it is critical to draw on the most robust evaluations of efficacy, safety and quality that are currently available. However, relevant information, data and evidence is still emerging.
29. Medsafe is New Zealand's medicines regulator and is responsible for approving suitable COVID-19 vaccines for use in New Zealand. As such, we consider that Medsafe's

² Medsafe recognised authorities are the Australian Therapeutic Goods Administration (TGA), 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, European Medicines Agency (EMA) (centralised procedure only), and EU member states (decentralised or mutual recognition procedure only). For practicality, we suggest not including EU member states (decentralised or mutual recognition procedure only) because all new vaccines approved in EU only go through centralised process.

assessments provide a minimum standard in New Zealand for the level of expected efficacy, safety and quality for COVID-19 vaccines.

30. Medsafe considers that a number of other authorities have robust approval processes and conduct thorough assessments of applications for new medicines. They follow similar international standards and guidelines in their assessments to Medsafe³.
31. We consider that the optimal balance across wellbeing, equity and legacy objectives is achievable through broadening the group of COVID-19 vaccines to those recognised by Medsafe and/or a Medsafe recognised authority and requiring a further dose of the Pfizer/BioNTech vaccine for Border workers in certain circumstances. These objectives include supporting the legitimacy and trust in the overall COVID-19 response. Appendix One provides further detail on all options considered, including the recommended option (Option 2b).
32. The proposed list of COVID-19 vaccines has been reviewed by the CV-TAG with consideration of the level of efficacy and effectiveness necessary for work at the Border, including effectiveness against the Delta variant.
33. At this stage, most proposed COVID-19 vaccines (i.e. Pfizer/BioNTech, AstraZeneca and Moderna vaccines) appear to have high efficacy and effectiveness against symptomatic infection and moderate-to-serious disease after the full course, except for the single-dose Janssen vaccine. CV-TAG's full advice is attached in Appendix Two.

A further dose of Pfizer/BioNTech

34. CV-TAG advises that mixing vaccine doses is unlikely to result in adverse effects and could provide an improved immune response. A further dose of Pfizer/BioNTech would ensure Border workers who have not received a full course of a recognised COVID-19 vaccine have a sufficient level of immunity for high-risk work at the Border.

Offering the Janssen vaccine

35. s 9(2)(g)(i) [Redacted]
36. s 9(2)(g)(i) [Redacted]
37. As some hesitant Border workers may remain otherwise unvaccinated if not given the option to receive the Janssen vaccine, there are several risks to consider:

³ We acknowledge that the World Health Organization (WHO) provides a list of COVID-19 vaccines for emergency use, which allows countries to expedite their own regulatory approval to import and administer COVID-19 vaccines. However, WHO's focus differs in that it aims to protect global health through rapid access to medicines, vaccines and diagnostics in an emergency rather than providing sufficient protection for high-risk work at the Border.

- a) Government continues to focus on maximising uptake of COVID-19 vaccines in New Zealand to prevent transmission of the COVID-19 virus, supporting the COVID-19 Elimination Strategy. If these specific Border workers remain unvaccinated, then this could to some degree affect whether New Zealand will be able to prevent transmission of COVID-19 within the country's border.
- b) If these workers remain unvaccinated, then this could contribute to workforce capacity issues at the Border. These Border workers may need to take leave or cease working if employers and/or PCBUs cannot redeploy them to undertake lower risk work.
- c) Some of these unvaccinated Border workers may continue to undertake high-risk work if they have received an economic exemption. Unvaccinated Border workers could affect whether transmission of COVID-19 permeates the New Zealand Border.

38. Risks associated with Border workers who may remain unvaccinated should be considered alongside the risks signalled by CV-TAG in relation to the suitability of the single-dose Janssen vaccine for protection at the Border.

39. s 9(2)(j)
 [Redacted text block]

40. CV-TAG continues to monitor all relevant information for COVID-19 vaccines and can provide further recommendations about a second dose of the Janssen vaccine as further evidence becomes available.

New Zealand Bill of Rights Act 1990 implications

- 41. We do not consider that the impact of the proposed changes will have any implications in relation to obligations under the New Zealand Bill of Rights Act 1990. This is mainly due to the fact that the proposed changes do not change the coverage of Border workers included within the Vaccinations Order.
- 42. There is the potential that some Border workers may benefit from, where possible, greater choice of COVID-19 vaccines that will allow them to meet their obligations under the Vaccinations Order.

Implementation

Record of overseas vaccinations

- 43. If a COVID-19 vaccine is administered overseas, there is a way to manually load these records into the COVID-19 Immunisation Register (CIR) and then link the records to the workers records in the Border Workforce Testing Register (BWTR). PCBUs can access the register to update worker details and confirm whether the worker is vaccinated.
- 44. However, there are a few challenges still to work through to enable implementation, specifically:

- a) clear guidance to District Health Boards on how to undertake the manual process
 - b) there is no established way in New Zealand to verify the authenticity of overseas COVID-19 vaccination documents.
45. Any process to validate COVID-19 vaccinations from overseas would likely need to consider how to prove that the vaccination occurred, and that the COVID-19 vaccine is authentic. Both these issues would require further work.
46. As part of the Reconnecting New Zealand strategy, several agencies are investigating how to develop a system to recognise traveller health declarations, but the system will not be in place until later this year. Until international standards for COVID-19 vaccination certificates are adopted more widely, variability will present significant challenges for checking and verifying vaccination statuses of international travellers into New Zealand (DPMC-2021/22-251 refers).
47. However, we note that NZDF is able to verify the vaccines types and courses that their personnel have had administered overseas, since vaccination details are recorded in the patients clinical record (which is internal within NZDF's health system). The Chief Medical Officer has confidence in NZDF's system for advising and recording immunisation of personnel.
48. If you agree to recognise COVID-19 vaccines administered overseas, further work will be necessary with Border worker agencies to enable this to occur in practice. This would likely take a minimum of three weeks, especially given the lack of an established way to validate the authenticity of evidence provided by Border workers to prove vaccination status.

Process for the catalogue of COVID-19 vaccine standards agreed for certain purposes

49. The Ministry will record any vaccine standards you agree in a centralised compendium for easy access, and this will include information about:
- a) the purpose associated with the vaccine standard (e.g. ensure sufficient protection for Border workers)
 - b) the relevant list COVID-19 vaccines.
50. We will investigate the most suitable way manage and make use of the list in practice.

Pfizer/BioNTech vaccine use beyond Medsafe approved advices

51. To fulfil CV-TAG's recommendations (see paras 24 and 25), COVID-19 vaccinators would require the authority to legally administer a further dose of the Pfizer/BioNTech vaccine for Border workers in certain circumstances.
52. COVID-19 vaccinators administering a further dose of the Pfizer/BioNTech vaccine would go beyond the Medsafe approved dosing advice. Section 25 of the Medicines Act 1981 would enable some COVID-19 vaccinators, known as authorised prescribers, to legally administer a further dose of the Pfizer/BioNTech vaccine. However, the use of authorised prescribers narrows the group of COVID-19 vaccinators for this purpose t (e.g. nurse practitioners; other health practitioners and designated prescribers).
53. Actions would be necessary to ensure a coordinated approach to providing further doses of the Pfizer/BioNTech vaccine to Border workers in certain circumstances.

Equity

54. The proposed amendments do not broaden the groups of persons affected by the current Vaccination Order but do make the vaccination requirements more specific.
55. Generally the proposed approach for COVID-19 vaccines recognised for Border work does not increase health or other inequities domestically and globally due to differential access to COVID-19 vaccines.
56. Border workers, including people working at MIQFs, are at the frontline of the pandemic and therefore at the highest risk of being infected. For workers who are not yet vaccinated, proposed amendments would broaden the group of COVID-19 recognised for work at the Border and potentially encourage uptake overall. This impact may lower the risk of infection for these workers and the risk of transmission to communities of people that these workers ordinarily interact with including place, ethnicity, faith and age-based communities. In April 2021 the COVID-19 Science and Insights Group estimated the current border workforce demographics using testing and vaccination data. This indicates that:
- a) there was a high proportion of people identified as Asian and Pacific Peoples working in managed isolation facilities and affected airports
 - b) there are fewer people identified as Māori than in the general population in the border workforce
 - c) most MIQF workers are aged between the ages of 20 and 24, while airport workers' age is distributed more flatly
 - d) since the beginning of the pandemic, the proportion of border workers who live in more socioeconomically deprived areas has been trending upwards
57. These estimated workforce demographics do not include port workers.
58. There may be inequities for workers who do not want to be vaccinated with the Pfizer/BioNTech vaccine and/or are less able to successfully negotiate a redeployment may be worse off. Generally, workers who do not have equitable access to the required vaccines may be worse off. However, these workers will be able to immediately access COVID-19 vaccines as part of Group 1 of the COVID-19 Sequencing Framework.

Next steps

59. The proposed tentative timeline for drafting and introduction of the second amendment to the Vaccinations Order covering all affected groups of workers is set out below. Please note the timeframes consider the time necessary for implementation and may be delayed depending on the outcome of current judicial proceedings underway.

Stage	Indicative timeframe	Owner
Minister agrees policy decisions	Friday 1 October	Minister's Office
Drafting instructions to PCO	Wednesday 6 October	MoH Legal
PCO provide finalised draft amendment	Wednesday 13 October	PCO

Briefing internal sign-out	Wednesday 13 October	MoH Policy
Briefing and draft amendment Order to Minister's Office to support ministerial consultation	Thursday 14 October – Wednesday 20 October (5 days for consultation)	Minister's Office
PCO finalise Order for Ministerial signing	Thursday 21 Oct - Tuesday 26 October (3 days – Labour Day)	PCO
Internal sign out of Briefing and Order	Tuesday 26 October	MoH Policy
Final Amendment Order and Briefing sent to the Minister	Wednesday 27 October	MoH Policy
Minister of COVID-19 Response signs Order	Thursday 28 October	Minister's Office
PCO gazette Order	Friday 29 October by 5pm	PCO
Amendment comes into force	Sunday 31 October at 11:59pm	

60. It will be necessary to communicate with key stakeholders about the requirements that will come into effect to prepare for implementation of changes in the second amendment.
61. We seek your permission for the interagency engagement group to communicate the changes to vaccination requirements at a high-level with key stakeholders. This action will enable us to circulate key messages to manage expectations about the changes.

Appendix One: Options considered for COVID-19 vaccines recognised for work at the Aotearoa/New Zealand Border

Option	Description	Practical implications ⁴	Wellbeing	Equity	Legacy
One	Vaccinations Order only recognises Medsafe fully approved or provisionally approved COVID-19 vaccines.	At present includes Pfizer/BioNTech, Janssen and AstraZeneca vaccine. Novavax currently under assessment by Medsafe.	<p>Pros</p> <p>Informed by evidence and/or advice about harms and benefits as assessed by New Zealand standards.</p> <p>Minimises the risk of health, social, and economic harm, especially for employers, PCBUs, workers and broader society.</p> <p>Supports uptake of a wider group of COVID-19 vaccines.</p> <p>Cons</p> <p>Limits group of COVID-19 vaccines to those with submitted applications in New Zealand, which may impact uptake generally.</p>	<p>Pros</p> <p>Supports the promotion of equitable health outcomes across public and private employers, PCBUs and workers.</p> <p>Cons</p> <p>May increase health or other inequities domestically and globally due to differential access to COVID-19 vaccines:</p> <ul style="list-style-type: none"> Some PCBUs may be more likely to need to recruit workers from overseas who have received an excluded COVID-19 vaccine Some workers vaccinated overseas may not be able to undertake work at the Border because they received an excluded COVID-19 vaccine. 	<p>Pros</p> <p>Supports the recovery from the COVID-19 pandemic, including the Delta variant.</p> <p>Supports legitimacy by acting in the best interests of New Zealanders.</p> <p>Promotes continued trust in the COVID-19 response efforts.</p> <p>Cons</p> <p>Legitimacy and trust in the COVID-19 response may be compromised because:</p> <ul style="list-style-type: none"> s 9(2)(i) it does not provide flexibility to adapt to changing domestic and international circumstances, such as: <ul style="list-style-type: none"> the need to fill domestic roles at the Border with people vaccinated overseas with an excluded COVID-19 vaccine. that sufficient COVID-19 vaccines with no application submitted in New Zealand would not be recognised.
Two	Vaccinations Order recognises COVID-19 vaccines: <p>a) fully approved or provisionally approved by Medsafe; and/or fully approved, provisionally approved and/or authorised for emergency use by Medsafe recognised authorities</p> <p>b) fully approved or provisionally approved by Medsafe; and/or fully approved, provisionally approved and/or authorised for emergency use by Medsafe recognised authorities - with qualifications for single-dose Janssen and non-recognised COVID-19 vaccines and incomplete vaccinations (recommended).</p>	In addition to Option One, at present it now includes Moderna. Novavax, Sinovac, CureVac and Sputnik are currently under rolling review by EMA.	<p>Pros</p> <p>Informed by evidence and/or advice about harms and benefits as assessed by New Zealand and/or similar standards (for both options 2a and 2b).</p> <p>Minimises the risk of health, social, and economic harm, especially for employers, PCBUs, workers and broader society (for both options 2a and 2b).</p> <p>Supports uptake of a wider group of COVID-19 vaccines (for both options 2a and 2b).</p> <p>Cons</p> <p>Limits group of COVID-19 vaccines to those with submitted applications in New Zealand or to certain other regulatory authorities, which may impact uptake generally (for both options 2a and 2b).</p>	<p>Pros</p> <p>Supports the promotion of equitable health outcomes across public and private employers, PCBUs and workers (for both options 2a and 2b).</p> <p>Generally, does not increase health or other inequities domestically and globally due to differential access to COVID-19 vaccines (for both options 2a and 2b).</p> <p>Cons</p> <p>May increase health or other inequities domestically and globally due to differential access to COVID-19 vaccines (for option 2a only):</p> <ul style="list-style-type: none"> Some PCBUs may be more likely to need to recruit workers from overseas who have received an excluded COVID-19 vaccine. Some workers vaccinated overseas may not be able to undertake work at the Border because they received an excluded COVID-19 vaccine. 	<p>Pros</p> <p>Supports the recovery from the COVID-19 pandemic, including the Delta variant (for both options 2a and 2b).</p> <p>Supports legitimacy by acting in the best interests of New Zealanders and promotes continued trust in the COVID-19 response efforts (for both options 2a and 2b).</p> <p>Cons</p> <p>Legitimacy and trust in the COVID-19 response may be compromised (for option 2a only) because:</p> <ul style="list-style-type: none"> s 9(2)(i) it does not fully provide flexibility to adapt to changing domestic and international circumstances, such as: <ul style="list-style-type: none"> the need to fill domestic roles at the Border with people vaccinated overseas with an excluded COVID-19 vaccine. there is no pathway to be deemed "vaccinated" for COVID-19 vaccines with no application submitted in New Zealand or to certain regulatory authorities.

⁴ Note: There are different regulatory versions of COVID-19 vaccines depending on the site of manufacture, which means approval of a COVID-19 vaccine is not exactly equivalent across regulatory authorities.

Three	<p>Vaccinations Order does not recognise COVID-19 vaccines other than:</p> <p>(a) a full course of the Pfizer/BioNTech vaccine; or</p> <p>(b) one additional dose of the Pfizer/BioNTech vaccine.</p>	<p>It would:</p> <p>a) only recognise two doses of the Pfizer/BioNTech vaccine</p> <p>b) only recognises at least one dose of the Pfizer/BioNTech vaccine.</p>	<p>Pros</p> <p>Partly informed by evidence and/or advice about harms and benefits as assessed by New Zealand standards (for both options 3a and 3b).</p> <p>Partly minimises the risk of health, social, and economic harm, especially for employers, PCBUs, workers and broader society (for both options 3a and 3b).</p> <p>Cons</p> <p>Not fully informed by evidence and/or advice about the harms and benefits as assessed by New Zealand standards and/or similar standards (for both options 3a and 3b).</p> <p>Significantly limits group of COVID-19 vaccines, which may impact uptake generally (for both options 3a and 3b).</p>	<p>Cons</p> <p>May not support the promotion of equitable health outcomes across public and private employers, PCBUs and workers (for both options 3a and 3b).</p> <p>May increase health or other inequities domestically and globally due to differential access to COVID-19 vaccines (for both options 3a and 3b):</p> <ul style="list-style-type: none"> Some PCBUs may be more likely to need to recruit workers from overseas who have received an excluded COVID-19 vaccine. Some workers vaccinated overseas may not be able to undertake work at the Border because they received an excluded COVID-19 vaccine. 	<p>Pros</p> <p>Partly supports the recovery from the COVID-19 pandemic, including the Delta variant (for both options 3a and 3b).</p> <p>Cons</p> <p>Legitimacy and trust in the COVID-19 response may be compromised (for both options 3a and 3b) because:</p> <ul style="list-style-type: none"> § 9(2)(i) it does not provide flexibility to adapt to changing domestic and international circumstances, such as: <ul style="list-style-type: none"> the need to fill domestic roles at the Border with people vaccinated overseas with an excluded COVID-19 vaccine there is no pathway to be deemed “vaccinated” for excluded COVID-19 vaccines.
Four	<p>Vaccinations Order does not specifically reference COVID-19 vaccines other than the Pfizer/BioNTech vaccine.</p> <p>Instead, it recognises internal government agency processes used to advise government personnel on sufficient COVID-19 vaccines (only applies to government workers).</p>	<p>At present, includes primarily Pfizer/BioNTech, Janssen, AstraZeneca and Moderna. However, there is the possibility other COVID-19 vaccines where accessibility is limited.</p>	<p>Pros</p> <p>Partly informed by evidence and/or advice about benefits as assessed by New Zealand standards and/or similar standards.</p> <p>Minimises the risk of health, social, and economic harm, especially for employers, PCBUs, workers and broader society.</p> <p>Supports uptake of a wider group of COVID-19 vaccines.</p> <p>Cons</p> <p>Not fully informed by evidence and/or advice about the harms and benefits as assessed by New Zealand standards and/or similar standards.</p>	<p>Pros</p> <p>Supports the promotion of equitable health outcomes only across public service employers, PCBUs and workers.</p> <p>Cons</p> <p>Does not support the promotion of equitable health outcomes across both public and private employers, PCBUs and workers.</p> <p>May increase health or other inequities domestically and globally for private employers, PCBUs and workers due to differential access to COVID-19 vaccines, noting:</p> <ul style="list-style-type: none"> private PCBUs may be more likely to need to recruit workers from overseas who have received an excluded COVID-19 vaccine. private workers vaccinated overseas may not be able to undertake work at the Border because they received an excluded COVID-19 vaccine. 	<p>Pros</p> <p>Supports the recovery from the COVID-19 pandemic, including the Delta variant.</p> <p>Supports legitimacy by acting in the best interests of New Zealanders.</p> <p>Promotes continued trust in the COVID-19 response efforts.</p> <p>Cons</p> <p>Legitimacy and trust in the COVID-19 response may be compromised because:</p> <ul style="list-style-type: none"> § 9(2)(i) there may not be evidence that some recognised COVID-19 vaccines provide sufficient protection for Border work. it does not provide flexibility to adapt to changing domestic and international circumstances for private employer, PCBUs and workers. there may inconsistency in COVID-19 vaccines recognised across the public employers, PCBUs and workers.

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Appendix Two: COVID-19 Vaccine Technical Advisory Group Advice - COVID-19 vaccines recognised for work at the Aotearoa/New Zealand Border

62. 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)
63. The COVID-19 vaccines currently provisionally approved by Medsafe for use in New Zealand are **Pfizer/BioNTech, Janssen, and AstraZeneca**. An application for the **Novavax COVID-19 vaccine** has been received, however further data has been requested from the sponsor [2].
64. 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, Gamaleya (Sputnik V), Sinovac (Coronavac) and Vidprevtyn from Sanofi-GSK. These are not currently recognised as part of these recommendations.
65. 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/BioNTech	AstraZeneca	Janssen	Moderna
Against symptomatic COVID-19 infection	<i>Efficacy</i>			
	95% (95%CI: 90.3-97.6) >7 days post 2 nd dose [8].	63.1% (95%CI: 51.8-71.1) >14 days post dose [15]. US trial: 76% (95%CI: 68.0-82.0) from 15 days post 2 nd dose when given four weeks apart [16]. 54.1% (95%CI: 44.7-61.9) >14 days post 2 nd doses [15].	74% (95%CI: 46.8-88.4) >28 days post vaccination [19].	94.1% (95% CI:89.3-96.8) against infection including severe disease >14 days post 2 nd dose [21].
	<i>Effectiveness</i>			
	94% (95%CI: 87-98.0) against symptomatic infection [9]. 85-95.3% >7 days post 2 nd dose in Israel, UK and Italy [9-13]. UK: 70% (95%CI: 62-77) reduction in transmission post 2 nd dose [13]. Israel: ~77% reduction among elderly post 2 nd dose [14].	Scotland: 88% (95%CI: 75-94) against hospitalisation 28-34 days post 1 st dose [17]. UK: 80.4% (95%CI: 36.4-94.5) against hospitalisation post 1 st dose in the elderly [18].	US: 76.7% (95%CI: 30.3-95.3) >14 days post vaccination [20].	98.2% (95%CI: 97.5-98.6) >7 days post 2 nd 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 2 nd dose [23].
Delta	<i>Effectiveness against symptomatic infection:</i>			
	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].	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].	No data	US: 66% (95%CI: 22-84) (pooled data with Pfizer) [27]. US: 76% (95%CI: 58-87) >14 days post 2 nd dose [28].
	<i>Effectiveness against asymptomatic infection:</i>			
	No data	No data	No data	No data

66. s 9(2)(j) [REDACTED]

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

Recommendations

68. 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.

69. **CV-TAG noted that:**

- a) Data is 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/BioNTech, 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 is 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.

70. **CV-TAG recommends 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) an additional dose of the Pfizer/BioNTech 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/BioNTech vaccine. This should occur at least 21 days after the first dose of the non- Pfizer/BioNTech 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.
 - f) workers who have received a partial or complete course of a non-recognised COVID-19 vaccine, should also receive one dose of the Pfizer/BioNTech vaccine.
71. 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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