

Memo

Decision on definition of "fully vaccinated against COVID-19" and recognition of overseas administered vaccines for New Zealand contexts

To:	Dr Ashley Bloomfield, Director-General of Health	A
From:	Maree Roberts, Deputy Director-General, System Strategy and Policy	MR
Date:	10 November 2021	
For your:	Decision	

Purpose of report

- 1 Following yesterday's meeting of the COVID-19 Vaccine and Immunisation Programme Steering Group (CVIP Steering Group) where the recommendations of the COVID-19 Vaccine Technical Advisory Group (CV-TAG) were considered, your decision is now sought on:
 - a. which COVID-19 vaccines, administered overseas, should be recognised in New Zealand for the purposes of being "fully vaccinated"
 - b. the definition of being "fully vaccinated" against COVID-19 for use in settings in New Zealand.
- 2 Your decisions on these matters will have implications for:
 - a. eligibility to be issued with a New Zealand COVID-19 vaccination certificate (both the domestic certificate and the international certificate)
 - b. the operational policy for recording overseas administered vaccinations in the COVID-19 Immunisation Register (CIR)
 - c. operational guidance and targeted communications for vaccinators, health care providers and consumers on requirements for additional doses of vaccines
 - d. which vaccines will be suitable for vaccination mandates for particular workers (such as border, education, healthcare, and corrections workers)
 - e. future border entry pathways for vaccinated arrivals under the Reconnecting New Zealanders strategy.

Background and context

- 3 As international travel increases, we need to establish a position on which vaccines, administered overseas, will be recognised in the New Zealand context to inform a range of legal requirements, operational policies, clinical guidance, and business rules.

- 4 An agreed process for recording overseas administered COVID-19 vaccines is becoming increasingly pressing with the new vaccination mandates for some workers. In addition, we need to establish business rules for eligibility for the issuance of vaccination certificates for those who have been vaccinated overseas.
- 5 Without an agreed pathway to have overseas vaccinations recognised, many people who have been vaccinated overseas may face being excluded from employment or from accessing services, venues and facilities once vaccination mandates or certificate requirements are in place.

CV-TAG has previously provided advice on recognition of overseas vaccines

6. CV-TAG has previously provided recommendations for vaccination requirements for:
 - a. border workers, including how to approach incomplete and complete vaccination with non-recognised COVID-19 vaccines
 - b. entry to New Zealand, via managed isolation and quarantine (MIQ) for the 1 November requirement for non-New Zealand citizens
 - c. workers arriving in New Zealand under the recognised seasonal employer (RSE) scheme.
7. CV-TAG's new advice does not affect the recommendations for entry to New Zealand via MIQ (6b) or for RSE workers (6c). However, it does affect the list of accepted vaccines for border and other affected workers under mandatory vaccination orders.

CV-TAG has provided a new definition of 'fully vaccinated' for all New Zealand contexts

- 8 Further advice from CV-TAG was sought on the definition of fully vaccinated for use in the New Zealand context and which COVID-19 vaccines should be recognised for this definition. In assessing the vaccines, CV-TAG agreed the key consideration would be the extent of protection the vaccines provide against COVID-19.
- 9 I received the CV-TAG advice in a memo from Professor Ian Town, Chief Science Advisor and Chair of the CV-TAG, on 5 November 2021 (see appendix 1). On 9 November 2021, I brought this advice to the CVIP Steering Group for their consideration (see appendix 2).

CV-TAG key recommendations

- 10 Key amongst these recommendations is that a consistent definition be accepted for all settings in New Zealand, and that the list of accepted vaccines are all vaccines approved by the World Health Organization for Emergency Use Listing (WHO EUL) **PLUS** Gamaleya (Sputnik V).
- 11 Currently there are eight vaccines approved by the WHO EUL. These are:
 - Pfizer/BioNTech
 - Janssen (Johnson and Johnson)
 - AstraZeneca (Oxford)
 - AstraZeneca/Covishield (Serum Institute of India)
 - Moderna
 - Sinopharm

- Sinovac (CoronaVac)
 - Covaxin (Bharat Biotech)
- 12 These WHO EUL vaccines are by far the most common vaccines that arrivals into MIQ report having received. Recognising the WHO EUL vaccines is also in line with the most recent recommendation of the International Health Regulations (IHR) (2005) Emergency Committee regarding the COVID-19 pandemic. To be approved for WHO emergency use listing, vaccines are required to have an efficacy of 50% or above.
- 13 At its 9 November 2021 meeting the CMP Steering Group indicated its comfort with the CV-TAG recommendations. It was noted that basing the list on the WHO EUL was a pragmatic and inclusive approach.
- 14 Sputnik V has been approved for use in 73 countries. A significant proportion of seafarers who enter MIQ from Russia report being vaccinated with Sputnik V¹. In a recent media statement, the WHO report that they have received all the legal agreements necessary for EUL assessment of this vaccine and are now waiting to receive the full data for analysis for the EUL assessment process.

Ministry of Foreign Affairs and Trade has raised some matters with us about the inclusion of Sputnik V in this list

- 15 Subsequent to the paper I prepared for Steering Group, officials from the Ministry of Foreign Affairs and Trade raised with us some matters relating to the inclusion of Sputnik V in the list of vaccines New Zealand would recognise. Their concerns were discussed very
- 16 briefly at the Steering Group meeting. I have asked that MFAT prepare some written points for your consideration. These points are as follows:

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¹ Between 24 August 2021 and 2 November 2021 19,282 people arrived in MIQ. Of these 405 people reported having had 2 doses of Sputnik V and 14 more people had a first dose of Sputnik V. 168 of these are not formally "MIQ" guests but are entering MIQ for maritime crew-change purposes. There have been 6 cases of COVID-19 identified at the border among those who report having been vaccinated with Sputnik V (between 24 August and 2 November).

Other CV-TAG recommendations

The definition of fully vaccinated with recognised vaccines should be used in all contexts in New Zealand

- 17 CV-TAG recommends a uniform definition of what constitutes being fully vaccinated and that this applied to all situations in New Zealand, including but not limited to:
 - eligibility to be issued with a domestic COVID-19 vaccination certificate (CVC)
 - eligibility to be issued with an international COVID-19 vaccination certificate (as long as the final dose of vaccine has been administered in New Zealand)
 - vaccination mandates
 - establishing COVID-19 management pathways for those entering New Zealand.
- 18 This definition does not alter the policy for non-New Zealand citizens entering New Zealand via MIQ (which accepts all vaccines approved by at least one government or approval authority).

Period since last dose to be considered fully vaccinated should be seven days

- 19 Based on immunological principles and recent data, CV-TAG recommends that the definition of fully vaccinated against COVID-19 is seven or more days after the last dose of an accepted primary vaccination schedule.
- 20 Aware of this particular recommendation, at the COVID-19 Vaccine and Immunisation Programme Steering Group (CVIP SG) meeting on 2 November, Michael Dreyer (Group Manager, National Digital Services) advised you of the technical challenges of imposing a seven day wait-time until vaccination certificates can be issued. For the purposes of logistics and pragmatism, you agreed that a vaccination certificate, can be issued as soon as the last dose has been administered.

An incomplete primary course of any of these nine vaccines (WHO EUL and Sputnik V) will require an additional dose of Pfizer

- 21 If a person has received an incomplete primary course of these any of these vaccines then they will require an additional dose of a Medsafe approved vaccine to be considered fully vaccinated in the New Zealand context. This includes those who, having recovered from a COVID-19 infection, are only offered a single dose of a two-dose vaccine (as is the case in some European countries for example).

Vaccination with any other vaccines will require an additional dose of a Medsafe approved vaccine

- 22 People who have been vaccinated with COVID-19 vaccines outside of the list of nine vaccines will require an additional dose of Pfizer to be considered fully vaccinated in the New Zealand context.

Fully vaccinated is defined as seven days after the last dose of an accepted primary vaccination schedule

- 23 CV-TAG recommends the accepted primary vaccination schedules are:
 - the **approved number** of doses of **any Medsafe or WHO** approved vaccine
 - two doses of **any combination** of **any Medsafe or WHO** approved vaccines (heterologous schedules)

- two doses of the **Gamaleya Sputnik V** vaccine
- a **complete primary course of any of the COVID-19 vaccines** authorised by at least one government or authority **PLUS a single dose of a Medsafe approved vaccine** (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand)
- a **single dose of any of the COVID-19 vaccines** authorised by at least one government or authority **PLUS a single dose of a Medsafe approved vaccine** (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand).

24 Where an additional dose is given (as described in 22 (d) and 22 (e)), this dose should be given at least 28 days after the previous COVID-19 vaccine dose.

For people who have had the Janssen vaccine, an additional dose of a vaccine approved by Medsafe may be offered for additional protection

- 25 CV-TAG noted there is some evidence that a single dose of the Janssen vaccine may not be as effective against infection as other Medsafe approved vaccines. 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.
- 26 Although not required to meet the definition of fully vaccinated, CV-TAG recommends offering another dose of a vaccine approved by Medsafe to those who have had a single dose of the Janssen vaccine, particularly those at high risk of serious disease or occupational exposure.

Participants in COVID-19 vaccine trials should be provided with a temporary exemption from being fully vaccinated

- 27 CV-TAG recommends that those participating in a registered COVID-19 vaccine trial (<https://trialsearch.who.int>) should be provided with a temporary exemption from being fully vaccinated. Their subsequent pathway to becoming fully vaccinated should be based on the accepted primary schedules described in paragraph 25. For example, if an individual received a full course of a trial COVID-19 vaccine that was later approved by WHO then they would be considered fully vaccinated, whereas an individual in a control group who received no COVID-19 vaccine would require a full primary course of Pfizer.

CV-TAG has concerns about vaccination mandates for those under 18 years of age

- 28 CV TAG expressed concern about vaccine mandates requiring younger age groups (e.g., ≤ 18 years) to be fully vaccinated. They advise that consideration should be given to permitting younger people with one dose to work or undertake other activities covered by the mandate.

Maximum time since last dose and boosters are not included in this definition at this stage

- 29 CV-TAG recommended that the definition only consider an individual's status in relation to the primary course of COVID-19 vaccination, without stipulating a maximum time since last dose. As booster doses become more common, requirements for booster doses and maximum time since last vaccination could be added to future definitions.

As new evidence emerges, these recommendations will be updated

- 30 CV-TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available.

Next steps

- 31 Upon your agreement, what constitutes being "fully vaccinated" and which vaccines are recognised for this purpose will inform all relevant operational guidance, technical business rules, communications, policies and legislation. This includes advice to change the recognised vaccines for the mandatory vaccinations under the COVID-19 Public Health Response (Vaccinations) Order 2021 (schedule 3), operational guidance for recording overseas administered vaccines in the CIR and eligibility to be issued with a vaccination certificate.
- 32 Communications will be prepared to ensure key parties are aware of these decisions. You may also wish to advise the COVID-19 Vaccine Ministers of these decisions at their weekly meeting this Friday 12 November.

Recommendations

It is recommended that you:

- a) **Note** that on 9 November 2021 the COVID-19 Vaccine and Immunisation Programme Steering Group (CVIP Steering Group) considered the recommendations of the COVID-19 Vaccine Technical Advisory Group (CV-TAG) and they indicated they were generally comfortable with the proposed definition of "fully vaccinated" against COVID-19 for use in settings inside the New Zealand border.
- b) **Agree** that this definition of "fully vaccinated" is used for the following:
- (i) eligibility to be issued with a New Zealand COVID-19 vaccination certificate (both domestic certificate and the international certificates)
 - (ii) the business rules for recording overseas administered vaccinations in the COVID-19 Immunisation Register (CIR)
 - (iii) operational guidance and communications for vaccinators, health care providers and consumers
 - (iv) vaccination mandates for certain workers, such as border, education, healthcare, and corrections workers
 - (v) future border entry pathways for under the Reconnecting New Zealanders' strategy to be eligible for reduced isolation requirements.
- c) **Note** that this definition of "fully vaccinated" does not impact on the vaccination requirement for RSE workers from the Pacific or non-New Zealand citizen arrivals by air introduced on 1 November 2021, which recognises any COVID-19 vaccine approved by at least one government of authority (currently 23 vaccines).

Yes/No



*I propose this be called
"fully immunised" AB*

d) **Agree** that "~~fully vaccinated~~" is seven or more days after the last dose of an accepted vaccination schedule, as recommended by CV-TAG. **Yes/No** ☒

e) **Note** that you have previously agreed that COVID-19 vaccination certificates can be issued immediately after the last dose of an accepted vaccination schedule. *and that this be "fully vaccinated" AB* ✓

f) **Note** that CV-TAG recommends that all vaccines on the World Health Organization Emergency Use Listing (WHO EUL) **AND** Gamaleya Sputnik V are the recognised vaccines for New Zealand's "fully vaccinated" definition ✓

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h) **Agree** the recognised vaccines for New Zealand's definition of "fully vaccinated" are:

(i) all WHO EUL approved vaccines **AND** Gamaleya Sputnik V;

Yes/No ☒

OR

Can I have updated advice if/when WHO approves. A.

(ii) all WHO EUL approved vaccines.

Yes/No ☒

i) **Agree**, in line with CV-TAG recommendations, that New Zealand's definition of "fully vaccinated" against COVID-19 are where the accepted primary vaccination schedules are: **Yes/No**

(i) the approved number of doses of any **Medsafe or WHO EUL approved vaccine** (currently Pfizer, Janssen, AstraZeneca (Oxford and Covidshield/Serum Institute of India), Moderna, Sinopharm, Sinovac and Covaxin (Bharat Biotech) ✓

(ii) two doses of **any combination of the Medsafe or WHO approved vaccines** (heterologous schedules) ✓

(iii) two doses of the **Gamaleya Sputnik V** vaccine *No, as above AB*

(iv) a complete primary course of any other COVID-19 vaccines authorised by at least one government or authority **PLUS** a single dose of a Medsafe approved vaccine (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand) ✓

(v) a single dose of any of the COVID-19 vaccines authorised by at least one government or authority **PLUS** a single dose of a Medsafe approved vaccine (the Moderna COVID-19 vaccine is also acceptable as the additional dose in the case that it was administered outside of New Zealand). ✓

i) **Agree** that, where an additional dose is given (as described in i)(iv) and i)(v)), it should be given at least 28 days after the previous COVID-19 vaccine dose. **Yes/No** ☒

- k) **Note** that CV-TAG has expressed concerns about vaccination mandates for those under 18 years of age, and that it recommends that consideration be given to permitting younger people who have had one dose to be permitted to work or undertake other activities covered by the mandate. ✓
- l) **Agree** that those participating in a registered COVID-19 vaccine trial should be provided with a temporary exemption from being fully vaccinated. Yes/No
- m) **Note** that CV-TAG recommends offering another dose of a vaccine approved by Medsafe to those who have had a single dose of the Janssen vaccine, particularly those at high risk of serious disease or occupational exposure (but that this is not required to meet the definition of fully vaccinated). ✓
- n) **Agree** that the definition of fully vaccinated does not stipulate a maximum time since last dose. Yes/No
- o) **Note** that CV-TAG has advised that as booster doses become more common, requirements for booster doses and maximum time since last vaccination could be added to future definitions. ✓
- p) **Agree** that this definition of fully vaccinated be incorporated into the advice on pathways for inbound travellers for COVID-19 management (e.g., MIQ, self-isolation and testing requirements) under the Reconnecting New Zealanders strategy. Yes/No
- q) **Agree** that COVID-19 Vaccine Ministers are advised of these decisions in an oral item at their forthcoming meeting on Friday 12 November. Yes/No

Signature _____

Dr Ashley Bloomfield

Te Tumu Whakarae mō te Hauora

Director-General of Health

Date: 11/11/21

Appendix 1:

Memo from Dr Ian Town to Maree Roberts (5 November 2021) titled "New Zealand definition of fully vaccinated for use inside the New Zealand border".

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