



ATAGI advice on the definition of fully vaccinated

14 December 2021

The Australian Technical Advisory Group on Immunisation (ATAGI) have advised that for the purposes of people returning from overseas travel, those individuals who are considered fully vaccinated against COVID-19 are those who:

- have received two doses of any Therapeutic Goods Administration (TGA) approved or TGA-recognised COVID-19 vaccine at least 14 days apart, and
- are at least 7 days post their second dose, with the exception of the Janssen (Johnson and Johnson) COVID-19 vaccine, where they are regarded as fully vaccinated 7 days after the single dose

This definition includes homologous (two doses of the same vaccine) and heterologous (two doses of different TGA-approved or recognised vaccines) schedules.

This definition may be updated over time based on emerging evidence.

ATAGI notes that the definition of fully vaccinated with COVID-19 vaccines approved for use in Australia is described in the [Clinical guidance on use of COVID-19 vaccine in Australia in 2021](#) (the Clinical Guidance). The Clinical Guidance is developed for COVID-19 immunisation providers and program staff and is updated based on currently available data. It provides recommendations on the use of the following COVID-19 vaccines approved and available for use in Australia: Pfizer (Comirnaty), AstraZeneca (Vaxzevria) and Spikevax (Moderna).

For information regarding the use of this definition for the purposes of travel, please visit:

- australia.gov.au
- <https://covid19.homeaffairs.gov.au>

TGA approved and recognised vaccines

The TGA has provisionally approved several COVID-19 vaccines for use in Australia.

COVID-19 vaccines additional to those approved in Australia are also being reviewed by the TGA for evidence of safety, quality and efficacy for the purposes of being recognised for inclusion in internationally recognised health credentials, such as the proposed International Civil Aviation Organization (ICAO) travel pass.

ATAGI notes that the TGA has announced the following vaccines as approved or recognised and therefore this definition will apply to:

TGA approved vaccines	TGA recognised vaccines
Pfizer Australia Pty Ltd (Comirnaty)	Coronavac (Sinovac)
AstraZeneca Pty Ltd (Vaxzevria)	Covishield (AstraZeneca/Serum Institute of India)
Janssen-Cilag Pty Ltd (COVID-19 Vaccine Janssen)	Covaxin (manufactured by Bharat Biotech, India)
Moderna Australia Pty Ltd (Spikevax)	BBIBP-CorV (manufactured by Sinopharm, China)

Further information concerning TGA-recognised vaccines is available from the TGA website at: [International COVID-19 vaccines recognised by Australia | Therapeutic Goods Administration \(TGA\)](#).

Special considerations for the definition of fully vaccinated

Adolescents (12-17 years)

ATAGI recommends that the same definition of fully vaccinated is used in all those 12 years and older.

ATAGI acknowledges that adolescent vaccine programs in some countries consider a primary course to require only a single dose of vaccine. ATAGI considers that one dose of a TGA-approved or TGA-recognised vaccine provides partial protection for adolescents.

Adolescents (12-17 years) who are not fully vaccinated (for example due to having had no COVID-19 vaccine, having had receipt of a single dose of a COVID-19 vaccine, or having had receipt of a vaccine that is not TGA-approved or TGA-recognised) are considered to have a lower risk of transmitting SARS-CoV-2 than unvaccinated adults aged 18 years and older.

However, their risk of acquiring and transmitting COVID-19 is higher than that if they were fully vaccinated as per the above definition. Children aged under 12 years (currently unable to be vaccinated) also are considered to have a lower risk of transmitting SARS-CoV-2 than unvaccinated adults.

Within this group, factors other than full vaccination status also determines risk, including:

- vaccination status of their parents or accompanying guardians;
- partial vaccination (single dose confers some protection);
- age (younger individuals are at lower risk of transmission);
- the epidemiology of COVID-19 in the country of origin; and
- other risk mitigations (e.g. pre-flight testing, other COVID safe behaviours before and during transit).

Whether modified quarantine recommendations are required on arrival for those under 18 years of age is a matter for jurisdictions to consider and manage.

For more information see: www.health.gov.au/news/returning-australian-children

Mixed vaccination schedules

For the purposes of this definition, ATAGI considers alternative vaccine schedules (including heterologous schedules) to be acceptable where they are TGA-approved or TGA-recognised.

Boosters

Boosters are not required to meet the definition of fully vaccinated, as the standard primary course of two doses (with the exception of the Janssen vaccine, which only requires one dose) are sufficient to meet the definition of fully vaccinated.

3rd primary dose for severely immunocompromised individuals

Some severely immunocompromised individuals are recommended to receive a third COVID-19 vaccination as part of their primary course. This third dose is not required to be considered fully vaccinated for the purposes of this definition, but may be recommended to address the risk of sub-optimal or non-response to the standard two dose schedule. More information can be found in [ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised](#).

Past SARS-CoV-2 infection

ATAGI notes that natural immunity from past infection is recognised as fully-vaccinated in several European countries. ATAGI also notes the challenge of confirming past infection and uncertainty with regards to the duration of protection.

While evidence suggests that past infection reduces the risk of reinfection for at least six months (and therefore may be regarded as a temporary exemption for vaccination for a maximum of six months), ATAGI recommends that two doses of a TGA-approved or TGA-recognised COVID-19 vaccine according to the recommended schedule is still required in order to be considered fully vaccinated. Past infection with SARS-CoV-2 is not a contraindication to vaccination.

ATAGI will continue to review and consider the evidence base regarding natural immunity following recovery from COVID-19 noting these recommendations are based on immunological principals due to a lack of data.

Recommendations for people who arrive in Australia and are not considered fully vaccinated

One dose of a TGA-approved or recognised vaccine

People who have received a first dose of a COVID-19 vaccine that is TGA-approved or TGA-recognised and are due for or required to have a second dose in Australia should be offered a TGA approved vaccine brand available in Australia to complete the primary vaccination course.

ATAGI has provided advice on special circumstances where the administration of an alternative vaccine brand for the second dose of a two-dose course of COVID-19 vaccination in Australia may be warranted. See: [ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances](#).

The recommended interval for administration of a second COVID-19 vaccine dose is 4 to 12 weeks after the first dose. This advice applies to adults and adolescents aged 12-17 years.

A longer interval is acceptable if the second dose cannot be administered during this time window. The minimum interval for administration of a second dose is 14 days. Receipt of this second TGA-approved or TGA-recognised vaccine would meet the definition of fully vaccinated.

Vaccines that are not TGA approved or recognised

People who have received either a first dose or a full course of a COVID-19 vaccine that is not TGA-approved or TGA-recognised should be offered two doses of an alternative TGA-approved vaccine brand available in Australia to be considered fully vaccinated. People should begin their full course of a TGA-approved or recognised COVID-19 vaccination at an interval of 4 to 12 weeks after their most recent COVID-19 vaccine dose. A longer interval is acceptable if the vaccine course cannot be started during this time frame. The minimum interval for administration of a second dose is 14 days. Receipt of this TGA-approved or TGA-recognised vaccine course would meet the definition of fully vaccinated.

Invalid doses

The Clinical Guidance notes that a second dose of a COVID-19 vaccine administered less than 14 days after the first dose is considered an invalid dose. In this instance, it is recommended that an additional COVID-19 vaccine dose should be administered as a replacement dose, in order to attain a level of immune response that is comparable to that expected following completion of a two-dose primary course of a COVID-19 vaccine according to the recommended dosage and schedule.

The interval between the invalid second dose and the replacement dose is flexible, and is recommended at 4 to 12 weeks after the invalid second dose.

The same COVID-19 vaccine brand should be used for the replacement dose to complete the primary vaccination course, unless there are special circumstances for indicating the use of an alternative vaccine. Noting that there are no direct clinical trial data on vaccines used in Australia regarding a second dose being administered at less than 14 days after the first dose, this replacement dose recommendation is based on immunologic principles.

For further information, refer to the Clinical Guidance and the [ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances](#).

Past SARS-CoV-2 infection

COVID-19 vaccination in people who have had PCR-confirmed SARS-CoV-2 infection can be deferred for a maximum of six months after the acute illness, as a temporary exemption due to acute major medical illness.

However, people with laboratory confirmation of past infection can start their vaccination course, or complete the second dose, if they have already had a first dose prior to being infected by SARS-CoV-2 as soon as they have recovered from the symptomatic infection. The minimum interval requirement between the two doses must still be met.

Individuals who have prolonged symptoms from COVID-19 beyond six months after acute infection can be vaccinated on a case-by-case basis, in line with the information above (i.e. it is generally recommended to be fully recovered from past SARS-CoV-2 infection, however some circumstances may warrant individual assessment).

ATAGI notes serological testing or other testing to detect current or previous infection with SARS-CoV-2 before vaccination is neither necessary nor recommended before vaccination.

Scenario	Example (manufacturer &/or name of vaccine)	Number of doses received	Doses required to be considered fully vaccinated per ATAGI advice	Clinical recommendation
TGA-approved (excluding Janssen-Cilag)	Pfizer (Cominaty) AstraZeneca (Vaxzevria) Spikevax (Moderna)	One dose*	One dose of a TGA-approved vaccine, at least 14 days after the first dose	One dose of the same vaccine, at an interval appropriate for the vaccine type Second and third dose if immunosuppressed, two-six months after the second dose
		Two doses	Not applicable	Third dose if immunosuppressed, two-six months after the second dose
TGA-approved (Janssen-Cilag)	Janssen (Johnson & Johnson)	One dose	Not applicable	Second dose if immunosuppressed, two-six months after the first dose
TGA-recognised	Coronovac (Sinovac) Sinopharm (under 60 years) Covaxin (Bharat Biotech India) Covishield (AstraZeneca / Serum Institute of India)	One dose	One dose of a TGA-approved vaccine, at least 14 days after the first dose	One dose of a TGA-approved vaccine, four weeks after the first dose Second and third dose if immunosuppressed, two-six months after the second dose
		Two doses	Not applicable	Third dose if immunosuppressed, two-six months after the first dose
Not TGA-approved and not TGA-recognised	Gamaleya National Center (Sputnik V) Sinopharm (over 60 years)	One or two doses	Two doses of a TGA-approved vaccine, at the recommended interval (at least 14 days apart)	Two doses of a TGA-approved vaccine (at an interval appropriate for the vaccine type) Three doses if immunosuppressed (two-six months after the first dose)
Previous infection	Not applicable	None or one dose not TGA approved/ recognised	Two doses of a TGA-approved vaccine, at least 14 days apart	Valid exemption for up to six months.# Vaccination can commence once recovered from acute illness.
		One dose TGA approved or recognised	One dose of a TGA-approved vaccine, at least 14 days after the first dose	Valid exemption for up to six months.# Vaccination can recommence once recovered from acute illness.

* includes adolescents who may have received a single dose of TGA approved/recognised vaccine according to some overseas schedules.

More information can be found in [ATAGI Expanded guidance on temporary medical exemptions for COVID-19 vaccines](#).