



Primary Care Vaccine Roll-out

Provider Bulletin

30 July 2021

Bulletins provide you with regular updates and guidance on the COVID-19 Vaccine Program.

Key Messages

ATAGI advice

- **vaccination of those aged 12-15 years**

Following the TGA's provisional registration of Pfizer for 12-15 year olds, the Australian Technical Advisory Group on Immunisation (ATAGI) has reviewed the available data and evidence on vaccine safety and efficacy and released a statement recommending that the following groups **aged 12-15** be prioritised for vaccination with Pfizer:

- **children aged 12-15 with underlying medical conditions that increase their risk of severe COVID-19;**
- **Aboriginal and Torres Strait Islander children aged 12-15; and**
- **all children aged 12-15 in remote communities, as part of broader community out-reach vaccination programs.**

The Australian Government has accepted this recommendation and **will formally implement it from 9 August 2021**, including by updating the Eligibility Checker to allow this cohort to view vaccination clinics near them.

You can commence vaccinating patients in this cohort now if you have capacity and stock.

ATAGI will provide further advice on the broader 12-15 year age group in coming months.

You can find further information in the [ATAGI statement regarding vaccination of adolescents aged 12-15 years](#). A script to assist you in discussions with patients (and parents) has also been developed and is [attached](#).

- **COVID-19 vaccines in the setting of the Delta variant of concern**

The increased transmissibility and possible increased severity of the Delta variant of SARS-CoV-2 underscores the importance and immediate benefits of achieving the highest possible COVID-19 vaccine uptake, especially in outbreak areas.

ATAGI has released a statement on immunisation in the setting of transmission of the Delta variant of concern, including strategies to maximise first dose vaccine coverage (and the importance of second doses for durable protection).

You can find further information in the [ATAGI statement on vaccination in the transmission setting of the delta variant of concern](#)

PFIZER

Myocarditis and Pericarditis

ATAGI and the Cardiac Society of Australia and New Zealand (CSANZ) have released joint guidance on the risk of myocarditis and pericarditis following Pfizer vaccination following an observed risk observed in overseas studies, especially in males under 30 years of age after the second doses.

The Pfizer [Product Information](#) has been updated to reflect this, and a letter from Pfizer advising this change is attached for your information.

ATAGI and CSANZ emphasise that the overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of these conditions, and **Pfizer continues to be recommended for all people ≥ 16 years of age who do not have any contraindications to the vaccine**, in those aged 12-15 with specific medical conditions that increase their risk of severe illness from COVID-19, and in Aboriginal and Torres Strait Islander people aged 12-15.

During the consent process, all people who receive Comirnaty should be advised of the very rare risk of myocarditis and/or pericarditis after vaccination, and should be advised of possible symptoms, which include:

- chest pain, pressure or discomfort
- palpitations (irregular heartbeat, skipped beats or 'fluttering').
- syncope (fainting)
- shortness of breath
- pain with breathing.

Symptoms typically start within a few days after vaccination, and anyone experiencing symptoms should seek prompt medical attention.

You can find further information at the below links:

- [Joint ATAGI and CSANZ guidance](#)

ASTRAZENECA

Capillary Leakage Syndrome

The [Product Information \(PI\)](#) for the AstraZeneca vaccine has been updated to include Capillary Leak Syndrome (CLS) as a contraindication for the AstraZeneca vaccine.

CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia.

Providers should be aware of the information contained in the PI **and individuals with a known history of CLS should not be vaccinated with AstraZeneca**. A number of documents, including the consent form, are currently being updated to reflect this change and will be shared.

Updated documents and advice following these updates

A number of documents and links on the website have been updated following these three pieces of advice being received. They can be found at the links below:

CONSENT FORMS:

- Consent form: <https://www.health.gov.au/resources/publications/covid-19-vaccination-consent-form-for-covid-19-vaccination>

PATIENT INFORMATION SHEETS:

- Preparing for your COVID-19 vaccine: <https://www.health.gov.au/resources/publications/covid-19-vaccination-preparing-for-covid-19-vaccination>
- Information on AstraZeneca: <https://www.health.gov.au/resources/publications/covid-19-vaccination-information-on-covid-19-astrazeneca-vaccine>
- Information on Pfizer: <https://www.health.gov.au/resources/publications/covid-19-vaccination-information-on-covid-19-pfizer-comirnaty-vaccine>
- After your AstraZeneca: <https://www.health.gov.au/resources/publications/covid-19-vaccination-after-your-astrazeneca-vaccine>
- After your Pfizer: <https://www.health.gov.au/resources/publications/covid-19-vaccination-after-your-pfizer-comirnaty-vaccine>
- Provider information on consent: <https://www.health.gov.au/resources/publications/covid-19-vaccination-consent-information-for-providers-covid-19-vaccination-consent-and-faqs>

CLINICAL GUIDANCE and DECISION GUIDES:

- Clinical guidance <https://www.health.gov.au/resources/publications/covid-19-vaccination-ataqi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021>
- Selection of 2nd dose in specific circumstances – container page (not yet live): <https://health.gov.au/resources/publications/covid-19-vaccination-clinical-advice-on-the-use-of-a-different-covid-19-vaccine-as-the-second-dose>
- Shared decision making guide – pregnancy: <https://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy>
- Shared decision making guide – frail older people: <https://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-frail-older-people-including-those-in-residential-aged-care-facilities>
- Shared decision making guide – palliative care: <https://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-people-receiving-palliative-care-or-end-of-life-care>
- Shared decision making guide – immunocompromise: <https://www.health.gov.au/resources/publications/ataqi-covid-19-vaccination-shared-decision-making-guide-for-people-with-immunocompromise>
- Provider guide on immunocompromise: <https://www.health.gov.au/resources/publications/ataqi-provider-guide-to-covid-19-vaccination-of-people-with-immunocompromise>
- Primary care guide on TTS: <https://www.health.gov.au/resources/publications/covid-19-vaccination-primary-care-approach-to-thrombosis-with-thrombocytopenia-syndrome-after-covid-19-astrazeneca-vaccine>
- Provider information – TTS: <https://www.health.gov.au/resources/publications/covid-19-vaccination-information-for-immunisation-providers-on-thrombosis-with-thrombocytopenia-syndrome-tts-following-covid-19-vaccination>
- Patient information – TTS: <https://www.health.gov.au/resources/publications/patient-information-sheet-on-astrazeneca-covid-19-vaccine-and-thrombosis-with-thrombocytopenia-syndrome-tts>

Program Updates

Updated TGA Advertising Permissions

The TGA has updated the advertising permission in relation to COVID-19 vaccines.

The condition in the permission restricting reference to trade names has been amended as follows:

b. not contain any reference to trade names, or active ingredients, of the therapeutic goods, unless the advertisement is made by an approved COVID-19 vaccination provider

An approved COVID-19 vaccination provider means a provider who is:

- a recognised vaccination provider within the meaning of the Australian Immunisation Register Act 2015; and
- approved or authorised under relevant state or territory legislation to administer relevant COVID-19 vaccines; and
- approved by the Department to participate in the National COVID-19 Vaccination Program.

Links to the new permission and guidance are on the TGA website at:

- [Communicating about COVID-19 vaccines](#)
- [Therapeutic Goods \(Restricted Representations - COVID-19 Vaccines\) Permission \(No. 3\) 2021](#)

Optimal dosage interval for COVID-19 vaccines

General practices should note that there are circumstances where state and territory governments are making local decisions on the optimal waiting period between vaccine doses. The Commonwealth advises vaccination sites to administer doses in-line with existing evidence and ATAGI advice.

AstraZeneca: Recommended dosage interval is 4-12 weeks, with 12 weeks being considered the optimal and most efficacious interval outside of outbreak settings. ATAGI has advised that this interval should be reduced to 4-8 weeks in outbreak areas.

Pfizer: Recommended dosage interval is 3-6 weeks.

Excess Doses

We appreciate your support to effectively and efficiently manage your excess doses to minimise wastage. Excess doses are defined as those that remain at the end of a session that might expire before the next scheduled session.

Clinics should use the following strategies to prioritise others for vaccination to minimise vaccine wastage, including:

- managing bookings in line with vial sizes and available stock;
- keeping waiting lists of eligible patients; or
- directly approaching eligible patients or staff who are present in or near the practice at the end of a vaccination clinic.

If excess doses still remain, vaccination sites can vaccinate other patients or staff to maximise doses and minimise wastage. Practices should note and plan for second doses for any individuals receiving the excess doses. This guidance is available at the [Health.gov.au website](https://www.health.gov.au).