Australian Government

COVID-19 VACCINATION

COMIRNATY (PFIZER) 5 TO 11 YEARS (ORANGE) FACT SHEET

Version 2 – July 2023

This fact sheet is for Primary Care sites who are participating in this roll-out as part of the COVID-19 Vaccination Program. It provides information and guidance about the administration and storage of the Pfizer 5 to 11 years (**Orange**) which is approved for use as a vaccine for children aged 5 to 11 years.

Eligible population

The Australian Technical Advisory Group on Immunisation (ATAGI) **recommends** the Pfizer 5 to 11 years (**Orange**) for use as a primary course vaccine for people aged 5 to 11 years.

COMIRNATY (PFIZER 5 YEARS TO 11 YEARS)

The Pfizer 5-11 years (Orange) vaccine is a mRNA vaccine. The ATAGI recommends a dosing schedule that is 2 doses, 8 weeks apart.

The dose interval can be shortened in special circumstances to a minimum of 3 weeks, for higher-risk groups (such as those with medical risk factors for severe illness) or before international travel. The benefits of earlier protection should be weighed against the benefits of the longer dose interval, such as a slightly lower risk of adverse events and a longer duration of protection.

A third primary dose is recommended for children aged 5 to 11 years with severe immunocompromise, see **ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised**. The third dose should be given from **2 months** after the second vaccine dose.

The Pfizer 5-11 years (Orange) vaccine comes in an orange-capped multidose vial containing 10 doses and requires dilution with 1.3mL of saline.

General practices and pharmacies will receive the Pfizer vaccine **thawed**. ACCHS will receive stock as either **frozen** or **thawed**, dependent on how they currently receive Pfizer vaccines.

An unopened thawed vial can be stored refrigerated at 2°C to 8°C for a maximum 70 days (10 weeks) from thaw date within the 18-month shelf life. The thaw use-by date is the allowable timeframe for vaccines to be in a thawed state (refrigerated at 2-8°C) and applies to all mRNA vaccines.

Administrators should be conscious of both the batch (manufacturer) expiry date and the thaw use-by date, taking the earlier of the two dates as the final date the vaccines can be used. **Once diluted, the vaccine must be used within 6 hours (when stored between 2°C and 30°C),** following which the remaining solution should be discarded. Do not shake the vial.

Please refer to the **TGA,** the mandatory **Pfizer (5 to 11 years) training module,** the **Product Information** or **ATAGI's Clinical Guidance** for the most up to date information.

Pfizer 5 to 11 years (ORANGE cap) Pack Dimensions

Each box contains 10 vials. Box Dimensions
(L x W x H) are:
85 x 37 x 37 (mm) to 89 x 39 x 47 (mm)

Pfizer 5 to 11 years (ORANGE cap) Orders

Pfizer vaccine (5 to 11 years) can be ordered in multiples of 100 doses, up to your maximum allocation.

Pfizer (5 to 11 years) Consumables

The Pfizer (5 to 11 years) consumables that will be delivered separately to your vaccine include the below (or similar):

- Sodium Chloride 0.9% 10mL ampoules (pack of 50);
- 1mL Syringe with fixed needle 25 gauge 25mm (pack of 100);
- 3mL Luer lock syringe (pack of 100);
- 1 mL Luer lock syringe (pack of 100);
- 25 gauge 25 mm low dead space needle (pack of 100);
- 21 gauge 38mm low dead space needle (pack of 100).

Disposal of Vaccines

Vaccines that are considered wastage (either due to expiry, damage, cold chain breach) must be disposed of in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheets for the COVID-19 vaccine type being disposed of.

Vaccines cannot be disposed of in the sink, toilet, or through the regular garbage disposal processes.

Booster Dose

ATAGI **recommends** that children aged 5-11 years who have medical comorbidities that increase their risk of severe COVID-19, or disability with significant or complex health needs, should **consider** a 2023 booster dose.

A booster dose can be given to **eligible** children if their last COVID-19 vaccine dose or confirmed infection (whichever is the most recent) was 6 months ago or longer, regardless of the number of prior doses received, based on an individual risk benefit assessment with their immunisation provider.

ATAGI **does not** currently recommend a booster dose for children and adolescents aged under 18 years **who do not have** any risk factors for severe COVID-19.

Site declaration

Sites who would like to participate in this roll-out, and who have previously completed the **Pfizer Site Readiness Declaration**, do not need to complete another declaration before being able to order Pfizer 5 to 11 years (**Orange**) vaccine. Any selected sites who have not yet completed a Pfizer Site Readiness Declaration **will be required** to complete this in the COVID-19 Vaccine Administrative System (CVAS) before being able to order the Pfizer 5 to 11 years (**Orange**) vaccine.

Training

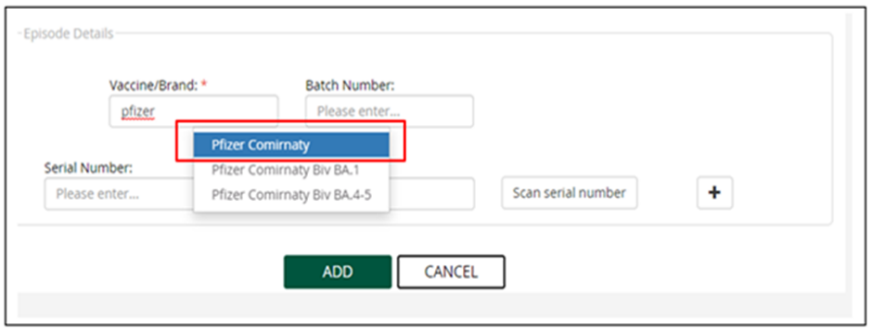
All clinical staff must complete the **COVID-19 Vaccination Training Program** (CVTP) before administering Pfizer 5 to 11 years (**Orange**) vaccine. The Module is called **Additional Module 4: Pfizer (COMIRNATY) (5 to less than 12 years).**

Non-clinical staff, especially those who receive or handle vaccines, should also complete the CVTP. The training modules are updated regularly to reflect the latest advice on COVID-19 vaccines.

Read more on the COVID19 vaccination training page **COVID-19 vaccination training program | Australian Government Department of Health and Aged Care**.

Reporting a Pfizer 5 to 11 years (Orange) vaccination to the Australian Immunisation Register

When reporting the administration of a Pfizer 5 to 11 years (**Orange**) vaccine to the AIR, vaccination providers should use the vaccine code **COMIRN**. The Pfizer 5 to 11 years (**Orange**) vaccine is available to report to the AIR using Practice Management Software (PMS), however if this vaccine is not displayed, we recommend vaccination providers contact their software provider in the first instance. Alternatively, vaccination providers can report the vaccine to the AIR using the **AIR site**. Please see an example below:



It is mandatory under the *Australian Immunisation Register Act 2015,* for vaccination providers to report all COVID 19 vaccinations administrated on or after 20 February 2021.Vaccination providers should use the latest version of their PMS to make sure they meet reporting requirements.

It is the responsibility of the vaccination provider to upload the COVID-19 vaccination into the patients AIR either within **24 hours** and no later than 10 working days after vaccination.

Please note: There are multiple Pfizer Comirnaty vaccines available in Australia and it is important that vaccination providers enter the **correct vaccine and batch number** when reporting information to the AIR. Healthcare providers **should check each patient's immunisation history and Medicare reference numbers before administering any COVID-19 vaccine.**

Consent

Informed consent is required before administering any COVID-19 vaccine dose and providers are required to document consent in a patient's medical record. Verbal or written consent is acceptable. Vaccination providers can access interpreters from Translating and Interpreting Service (TIS National) on 131 450 to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

An example form for vaccination providers to obtain patient consent prior to COVID-19 vaccination can be found **here**. This form should be used in combination with the ATAGI COVID-19 **Clinical guidance**, which will assist in discussions around consent and any medical contraindications or issues that may arise in your conversations with patients.

Reporting in COVID-19 Vaccine Administrative System (CVAS)

A reminder that it is **mandatory** to complete a **CVAS *Delivery Acceptance Report*** on the day of vaccine delivery and the ***Vaccine Stock Management Report*** for all vaccine stock held in the clinic is due by 9pm on Friday local time each week.

You will need to complete a Stock Management report for each vaccine your site is approved to administer, **even if you do not receive any deliveries or administer any doses in that week.** Any wastage involving 10 or more vials in one incident should be reported immediately after the wastage event via the Wastage reporting tab in CVAS.

USEFUL LINKS

The **ATAGI** website contains:

- **ATAGI's recommendation for Pfizer 5 to 11 years vaccine**
- **ATAGI Clinical Guidance**

The **TGA** website contains the:

- **Information about the Pfizer vaccines**
- **Pfizer (5 to 11 years) Product Information**
- **Consumer Medicine Information**

The **Department of Health and Aged Care** website contains the:

- **COVID-19 Vaccines in Australia – A3 poster**
- **ATAGI recommended COVID-19 doses and vaccines Poster**