Australian Government

COVID-19 VACCINATION

Primary Care Vaccine Roll-out

Provider Bulletin

13 September 2022

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

Key Messages

RECENT ATAGI CONSIDERATIONS

Moderna bivalent Original/Omicron vaccine

Following the Therapeutic Goods Administration (TGA) granting **provisional registration** for the Moderna Spikevax Bivalent Original/Omicron BA.1 (subsequently referred to as Moderna Bivalent) vaccine for use as a booster dose in people aged 18 years and older, the Australian Technical Advisory Group on Immunisation (ATAGI) has provided the following **recommendations**:

- The Moderna bivalent vaccine can be used as an alternative vaccine for **any booster dose in people aged 18 years or older**, according to the current **ATAGI recommendations for booster doses**.
- ATAGI have made no changes to the current booster recommendations and is not advising any extra booster doses beyond the second booster dose (fourth dose) in selected populations.
- The booster dose of COVID-19 vaccine should be given at least 3 months after the most recent COVID-19 vaccine dose or previous COVID-19 infection
- Co-administration of Moderna bivalent vaccine with other non-COVID vaccines is acceptable, as per current **ATAGI clinical guidance**.
- The bivalent Moderna vaccine is **not recommended for primary course** of vaccination (first two doses in most people or first three doses in severely immunocompromised people).
- ATAGI does not currently recommend use of the Moderna bivalent vaccine as a booster in anyone under 18 years as it is not registered for this age group.

The Australian Government has **accepted** advice from ATAGI and will include the Moderna Bivalent in the COVID-19 Vaccination Program for boosters in people aged 18 years or older from **10 October 2022**.

Important information on the COVID-19 Vaccination Program

CVAS

Moderna bivalent will be a new product in CVAS: 'Moderna bivalent 18+ blue/green'.

Remaining stocks of the Moderna monovalent vaccine (Moderna red) will gradually reduce over the coming months. As Moderna bivalent (Moderna blue/green) can only be administered for booster vaccinations, the Taskforce encourages sites to ensure they have adequate stocks of primary course vaccines, so as to enable primary courses of COVID vaccinations to still be administered as required.

Participation

All sites currently participating in the COVID-19 Vaccine Program will be onboarded for Moderna bivalent 18+ blue/green in tranches. Your PHN will advise you which tranche you will be onboarded in.

All primary care sites will receive an ongoing allocation of 100 doses of Moderna bivalent 18+ blue/green.

If sites do not complete the site declaration and place an order within 8 weeks, they will be deactivated for Moderna Bivalent in CVAS. Sites will be able to onboard again in the future via the standing EOI process through PHNs.

Site Declarations

Prior to submitting an order for the Moderna bivalent 18+ blue/green vaccine, sites will need to complete the Moderna Site Readiness Declaration and meet the requirements listed within this to administer the vaccine. If you have already completed the Site Declaration for Moderna you do not need to complete another declaration.

Moderna Training

The Moderna training modules will reflect current ATAGI advice. Clinicians will be required to complete the relevant training modules prior to administering the Moderna bivalent vaccine.

COVID-19 VACCINATION IN-REACH CLINICS EXTENDED

In-Reach clinic extension

The Department of Health and Aged Care is extending its Expression of Interest (EOI) process for COVID-19 in-reach vaccination clinics until 31 December 2022.

Residential Aged Care Homes that are unable to secure a primary care provider to administer COVID-19 doses, either with a GP or pharmacist or through their Primary Health Network, are still able to request an in-reach Commonwealth COVID-19 vaccination clinic.

The Department has written to residential aged care providers to inform them of the extension.

This will allow any residents who were unable to receive their COVID-19 vaccinations over winter to catch up with their COVID-19 vaccination schedule.

Please **read the letter to providers** for further details on the extension of these clinics.

STEPS TO FOLLOW FOR A POTENTIAL COLD CHAIN BREACH (CCB)

If your vaccines have been involved in a potential CCB, either within the clinical setting or during transit:

1. **Place** any affected vaccines in quarantine, secured within the *appropriate* cold chain storage requirements.
2. **Mark** stock as '*Do not use Do not discard*'
3. **Report** the potential CCB to the Vaccine Operations Centre (VOC) on 1800 318 208, providing as much information *and* temperature data as possible to aid in the assessment:
    - Date and time of breach.
    - Cause of breach, if known and actions taken to rectify it.
    - Temperature logger data.
    - Vaccine brand, batch number, expiry date and number of doses.
    - If anyone has been vaccinated with the vaccines involved in the CCB.
    - If any of the vaccines have previously been involved in a CCB.
4. **Wait** for the outcome of the assessment and advice on whether the vaccines are safe to use.

Outside of VOC operating hours, the required information for the potential CCB can be emailed to **covid19vaccineoperationscentre@health.gov.au** to be assessed as soon as possible (during business hours). If required, the VOC will be in contact for further clarification.

Notes:

- All staff involved in the monitoring or administration of COVID-19 vaccines should be familiar with and regularly review cold chain management processes.
- The National Vaccine Storage Guidelines 'Strive for 5', provides information and advice for vaccine storage management for Australian immunisation service providers: **www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5**
- It is critical that cold chain requirements are maintained, and the National Vaccine Storage Guidelines 'Strive for 5'are always followed. This ensures patients are receiving safe and effective vaccines.

SHELF LIFE EXTENSIONS

Pfizer 12 years+ (Purple)

The Therapeutic Goods Administration (TGA) has approved a shelf-life (manufacturer expiry) extension for **Comirnaty Pfizer 12 years+ (Purple)** vaccine from 12 months to 15 months from the manufacture date, provided that approved storage conditions have been maintained.

These vaccines can continue to be administered until the **USE BY DATE**, which is the **earliest** of the extended manufacturer expiry date and the thawed use-by date. The thawed use-by date is 31 days from the defrost date for the **Pfizer 12 years+ (Purple)** vaccine.

The shelf-life (manufacturer expiry) extension applies to the batches outlined in the **attached letter**. Please reference the table for existing stock and when receiving new orders. The packaging associated with the listed batches has not been amended to reflect the updated shelf-life (manufacturer expiry) extension. The new manufacture expiry date of each batch will also be shown in CVAS when completing delivery acceptance.

AstraZeneca

The TGA has also approved a shelf-life (manufacturer expiry) extension for **AstraZeneca (VAXZEVRIA)** vaccine from 6 months to 9 months from manufacture date, provided that approved storage conditions have been maintained.

The shelf-life extension (manufacturer expiry) applies to all future batches to the batches outlined in the **attached letter**.

Please be aware that the packaging associated with the above batches has not been amended to reflect the extended expiry dates. Please update the expiry date on any vials you have on site to reflect the new expiry date.

REMINDERS

Excess Stock Transfer

If a GP site contacts the VOC advising that they have excess stock to transfer, a Service Officer will ask the site if they have contacted their PHN or any sites nearby?

- If the site advises they **have** contacted their PHN and nearby sites then the Service Officer will create a VIMS case and the Excess Dose Service Officer will attempt to redirect them.
- If they advise they have not contacted their PHN or nearby sites, then the Service Officer will direct them to do so.

Changes to vaccine products being administered

Your PHN is your primary point of contact for any requests to change the vaccine type/s you wish to administer in the Program. We ask that you contact your PHN to notify your intention to withdraw or amend the vaccines you will be administering and your PHN will pass this information onto the Department of Health and Aged Care to enable accurate processing of the request.

People rely on the VCF to find and book COVID-19 vaccinations. It is crucial that it has accurate information. If you are changing the vaccine types you are administering, you must also log in to VCF Connect and update your service details. Keeping your details up to date is a mandatory requirement of the vaccine program.

Moderna Spikevax (6 months to 5 years)

Moderna 6 months to under 5 years vaccinations commenced Monday 5 September.
The Department of Health and Aged Care may reach out to additional providers to participate in the roll-out. If you are receiving a large number of calls and believe you would be able to vaccinate this cohort, let your PHN know.

If you are not administering Moderna 6 months to under 5 years and have patients approach you please direct them to the COVID-19 Vaccine Clinic Finder (**covid-vaccine.healthdirect.gov.au/booking/**) to secure an appointment.

Cancelling Orders

Remember when you cancel vaccine order in CVAS you need to also cancel the corresponding consumable order.

RESOURCES

Vaccine Comparison Poster

The COVID-19 Vaccine Comparison Poster has been updated to include information about the Moderna (SPIKEVAX) (Ages 6 months – 5 years), and the extension of indication of Novavax vaccine for individuals aged 12-17 years old: **COVID-19 Vaccines in Australia – A3 poster | Australian Government Department of Health and Aged Care**