COVID-19 Vaccine Roll-out through Community Pharmacies

ONBOARDING PACK
Part 1 of 3
March 2022 Version 6

This Onboarding Pack provides information and advice specific to the administration of the Vaxzevria (AstraZeneca), the Spikevax (Moderna), the Nuvaxovid (Novavax), the Comirnaty (Pfizer) for 12+ years (purple cap) vaccine and the Comirnaty (Pfizer) for 5-11 years (orange cap) vaccine in a community pharmacy.

This version replaces previous versions

health.gov.au/covid19-vaccines
Dear COVID-19 vaccination partners,

Rolling out the COVID-19 vaccine is one of the greatest logistical challenges in Australia’s history.

To ensure everyone in Australia has access to COVID-19 vaccines, Australia's COVID-19 Vaccine National Roll-out Strategy is underpinned by multiple parts of the health system working together to contribute to the vaccination effort.

Community pharmacies will play a crucial role in partnering with the Australian, State and Territory Governments to ensure access to the COVID-19 vaccine across Australia, with the success of the national roll-out strengthened by the commitment of pharmacies supporting the national vaccination effort and their local communities.

This Onboarding Pack is intended to provide clear guidance on the operational and functional arrangements in place for the Australian COVID-19 Vaccine Roll-out Program (the Program). It contains:

- the next steps to be undertaken to finalise your acceptance into the Program
- what you can do to prepare your pharmacy to commence vaccinating your local community
- details on Program processes and reporting requirements.

Whilst this pack is intended to provide as much detail as possible, processes and resources may be updated from time to time. Any changes will be passed on to you.

Thank you again

Dr Brendan Murphy
Secretary
Commonwealth Department of Health
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AEFI</td>
<td>Adverse Event Following Immunisation</td>
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<td>AIR</td>
<td>Australian Immunisation Register</td>
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<tr>
<td>ARGATG</td>
<td>Australian Regulatory Guidelines for Advertising Therapeutic Goods</td>
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<td>ATAGI</td>
<td>Australian Technical Advisory Group on Immunisation</td>
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<tr>
<td>CBP</td>
<td>Commonwealth Booking Platform</td>
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<tr>
<td>COVID-19</td>
<td>Coronavirus Disease 2019</td>
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<tr>
<td>COVID-19 Vaccine</td>
<td>Collective references to the Spikevax (Moderna), the Comirnaty (Pfizer) for 12+ years (purple cap), Comirnaty (Pfizer) for 5-11 years (orange cap), the Vaxzevria (AstraZeneca) and Nuvaxovid (Novavax) vaccines</td>
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<tr>
<td>CVAS</td>
<td>COVID-19 Vaccine Administrative System</td>
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<td>CVCP</td>
<td>COVID-19 Vaccination in Community Pharmacies</td>
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<td>CVIP</td>
<td>Clinician Vaccine Integrated Platform</td>
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<tr>
<td>EDM</td>
<td>Electronic Direct Mail</td>
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<tr>
<td>EOI</td>
<td>Expression of Interest</td>
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<tr>
<td>GMO</td>
<td>Genetically Modified Organism</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<td>HPOS</td>
<td>Health Professional Online Services</td>
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<td>IHS</td>
<td>Immunisation History Statement</td>
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<td>MAP</td>
<td>Main Authorised Person</td>
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<tr>
<td>MDV</td>
<td>Multi-Dose Vial</td>
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<td>MMM</td>
<td>Modified Monash Model</td>
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<tr>
<td>NHSD</td>
<td>National Health Services Directory</td>
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<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>PPA</td>
<td>Pharmacy Programs Administrator</td>
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<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>PRODA</td>
<td>Provider Digital Access</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>VCF</td>
<td>Vaccine Clinic Finder</td>
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<tr>
<td>VOC</td>
<td>Vaccine Operations Centre</td>
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</table>

health.gov.au/covid19-vaccines
1. PROGRAM OVERVIEW

COVID-19 VACCINE ROLL-OUT

As part of the National COVID-19 Vaccination Roll-out, the Australian Government is supporting community pharmacies as they administer COVID-19 vaccinations in their local community. Pharmacies commenced vaccinations in June 2021 and have since administered over 1 million vaccinations.

States and territories have legislative responsibility for who can vaccinate, with what vaccines and when vaccinations can begin, following initial assessment by the Australian Government Department of Health.

From 14 February 2022, community pharmacies participating in the COVID-19 Vaccination in Community Pharmacy (CVCP Program) can administer the Nuvaxovid (Novavax) vaccine.

From 12 December 2021, community pharmacies participating in the CVCP Program can administer the Spikevax (Moderna) vaccine as a COVID-19 booster vaccine and continue to administer the Comirnaty (Pfizer) 12+ years (purple cap) vaccine as a booster. Community pharmacies participating in the CVCP Program continue to be able to administer the Comirnaty (Pfizer) vaccine 12+ years (purple cap), Comirnaty (Pfizer) vaccine 5-11 years (orange cap), Spikevax (Moderna) vaccine and the Vaxzevria (AstraZeneca) vaccine as first and second doses.

Community pharmacies participating in the CVCP Program must ensure the administration of the COVID-19 vaccine is carried out in the setting declared in the Expression of Interest (EOI) process by appropriately COVID-19 vaccine trained health professionals, in accordance with their state/territory regulations and about the vaccines in use.

PLEASE NOTE

Information may change as the roll-out progresses, please refer to the Department of Health website for the most up to date information.

For ease of reading, henceforth the:

- Vaxzevria (AstraZeneca) vaccine will be referred to as AstraZeneca
- Spikevax (Moderna) as Moderna
- Nuvaxovid (Novavax) as Novavax
- Comirnaty (Pfizer) for 12+ years as Pfizer 12+ years (purple cap); and
- Comirnaty (Pfizer) vaccine for ages 5-11 years as Pfizer 5-11 years (orange cap).

health.gov.au/covid19-vaccines
2. ONBOARDING CHECKLIST

GETTING READY TO PROVIDE VACCINATIONS

Below is a checklist to help you prepare for the delivery of vaccinations to your community. Further detail on each will be provided in the following sections.

<table>
<thead>
<tr>
<th>Complete?</th>
<th>Task</th>
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<tbody>
<tr>
<td>☐</td>
<td>Have you registered the Pharmacy for the Australian Immunisation Register (AIR)?</td>
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<tr>
<td></td>
<td>Have you undertaken the steps required to ensure your pharmacy is ready to report to AIR through either your professional services software, the Australian Digital Health Agency’s Clinician Vaccine Integrated Platform (CVIP) or directly via Health Professional Online Services (HPOS)?</td>
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<td>☐</td>
<td>Do you have an appointment system in place, and can you accept on-line bookings?</td>
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<td>☐</td>
<td>Have you and your staff completed the COVID-19 Vaccination Training Program and reviewed all updates?</td>
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<td></td>
<td>Have you and your staff completed the COVID-19 Vaccine Training Modules, including the vaccine specific training for every vaccine type your pharmacy is planning to administer?</td>
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<td>Have you familiarised yourself with the type of assistance the Vaccine Operation Centre (VOC) can provide?</td>
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<tr>
<td>☐</td>
<td>Have you completed your registration in the COVID-19 Vaccine Administrative System (CVAS)?</td>
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<td></td>
<td>Have you reviewed the ordering and stock management timeframes and requirements and prepared relevant policies and procedures to receive, store and handle vaccines?</td>
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<tr>
<td>☐</td>
<td>Have you ordered vaccine stock and any consumables you will require?</td>
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<tr>
<td>☐</td>
<td>Do you have your anaphylaxis kit ready?</td>
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<td></td>
<td>Do you plan on advertising to your community? If so, have you used the communications provided in this onboarding kit to ensure compliance with the Therapeutic Goods Administration (TGA) Advertising Act?</td>
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<tr>
<td>☐</td>
<td>Have you reviewed the ‘COVID-19 Pre-Vaccination Checklist’ provided in Part II of the Onboarding Pack, to be used for all vaccinations?</td>
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<tr>
<td>☐</td>
<td>Have you prepared the ‘Patient Consent’ forms for all vaccinations? (including, where applicable, the special consent form for parents/guardians of children aged 5 to 11 years)?</td>
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<tr>
<td>☐</td>
<td>Have you reviewed the ‘Post-Vaccination Checklist’ for use after vaccine administration?</td>
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<tr>
<td>☐</td>
<td>Have you reviewed the COVID-19 Vaccination in Community Pharmacies (CVCP) Program Rules?</td>
</tr>
<tr>
<td>☐</td>
<td>Have you registered for the CVCP Program via the Pharmacy Programs Administrator (PPA) Portal in order to submit claims for payment?</td>
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</tbody>
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health.gov.au/covid19-vaccines
3. ONLINE SERVICES

GUIDANCE

Report to Australian Immunisation Register

It is mandatory under the Australian Immunisation Register Act 2015 to report all COVID-vaccine encounters to the Australian Immunisation Register (AIR). Healthcare providers should check a patient’s immunisation history before administering a COVID-19 vaccine. This is an expectation of all health care professionals prior to vaccinating patients.

COVID-19 vaccine encounters should be uploaded into AIR within 24 hours from vaccine administration (including the patient’s individual Medicare reference number), to ensure consumer immunisation information is up to date. Every upload must include:

- brand name
- dose number
- batch number
- date of administration
- country of administration (if received overseas).

Patient data collected through AIR must be managed in a manner consistent with the Privacy Act 1988, and the AIR. Further information is available on the Department’s website.

Pharmacies may use either of the following to report to the AIR.

- **Professional services software** – this is the preferred option. Several products are integrated with the AIR. Community pharmacies will need to complete an Online Claiming Provider Agreement form to register their software for reporting vaccinations to the AIR.
- **Health Professional Online Services (HPOS)** – this is a secure way for healthcare providers to interact electronically with Services Australia, including to submit immunisation encounters to AIR.

Vaccination Information can be viewed within 24 to 48 hours through the AIR or My Health Record.

Uploading to AIR for Patients without Medicare

The AIR can record vaccination information for individuals in Australia even if they are not eligible for Medicare. This is done using existing practice software in different ways. If a vaccination provider’s software does not allow them to record this through their system, it can be entered using the AIR Secure Site.

For patients who are ineligible for Medicare, first check if an existing record is in AIR before creating a new record. You can search by name, adding date of birth and postcode to narrow the search.

If there is no existing record, create a new record by selecting Record Encounter and provide the individual’s full name and date of birth. Further information on how to do this can be found here.

Health professionals are encouraged to add as much detail as possible to allow for future matching including: First and last names (if known); Address; Date of birth; and Postcode.

These individuals will be recorded on the AIR, and their record will be available for subsequent immunisation encounters or until a Medicare registration is completed.

health.gov.au/covid19-vaccines
Importantly: **Do not use the ‘Urgent Clinical Need’ Medicare number for manual AIR reporting.**

Services Australia has a dedicated AIR hotline that can provide further assistance on 1800 653 809. Health professionals can also access education modules on using the AIR Site on the Services Australia website.

**Check Immunisation History**

Please remember **to check each patient’s medical history before administering a vaccine, including through your clinical software, the AIR, My Health Record and/or CVIP.**

ATAGI recommends that patients receiving a COVID-19 vaccination should receive their primary course (i.e. Dose 1 and Dose 2) of the same COVID-19 vaccine.

Pregnant women who have received their first dose of AstraZeneca are encouraged to speak to their Doctor about the best choice of vaccine for their second dose.

COVID-19 vaccines can be co-administered (that is, given on the same day) with an influenza vaccine. Studies demonstrate the safety and immunogenicity of co-administration of COVID-19 and influenza vaccines.

COVID-19 vaccines can also be co-administered with other vaccines if required.

This includes routine childhood and adolescent vaccines. The benefits of ensuring timely vaccination and maintaining high vaccine uptake outweigh any potential risks associated with immunogenicity, local adverse reactions or fever.

Further information on timing of administration of other vaccines can be found on the Department of Health website.

It is expected that healthcare providers check each patient’s medical and immunisation history before administering every COVID-19 vaccine dose.

Vaccination information can be viewed within 24 to 48 hours of vaccine administration through your professional services software, the AIR and/or My Health Record.

C/…
GUIDANCE

PRODA (or Provider Digital Access)

Most digital services that report to AIR, including some software providers and HPOS, will require you to have a PRODA account if you don't already have one. Pharmacy staff reporting COVID-19 vaccinations to the AIR via these platforms should also have their own individual PRODA account.

PRODA is an authentication tool used by Services Australia to allow individuals and community pharmacies to interact with their system. You should check with your software provider to confirm whether you will require a PRODA account or if there are any other steps required to enable integration.

Healthcare providers working at multiple pharmacies reporting vaccinations to the AIR must ensure they are correctly linked to the Pharmacy where they will be providing vaccinations in PRODA. Pharmacy staff should be reminded not to share their PRODA account details with other staff. Talk to your software provider or Services Australia about PRODA requirements.

Recording of overseas COVID-19 vaccinations

Recognised vaccination providers in Australia can report overseas vaccinations to the AIR if both of the following apply:

- the vaccine is approved for use in Australia, or recognised, by the Therapeutic Goods Administration (TGA), and
- if an individual received the vaccination on or after 1 October 2020.

The individual must be present and provide documents translated in English that show what vaccinations were administered.

Mixed doses of approved or recognised vaccines, can be reported to the AIR.

Updating your details with Medicare

Your Medicare provider number is used to claim, bill, refer or request Medicare services.

You will need more than one provider number if you:

- deliver health services in different locations; and/or
- are registered in more than one health profession.

The address used to order COVID-19 vaccines to your clinic needs to match the Medicare provider number address to ensure proper linkage within the COVID-19 vaccine data software. You can apply for and manage provider numbers through HPOS.

TO DO

- Apply for an Australian Immunisation Register (AIR) provider number for each of your sites
- Contact your software provider to find out:
  - if it will automatically report COVID-19 vaccinations to the AIR
  - if an update to your software is required; and
  - if you need a PRODA account.
- Declare your software provider with Services Australia using the Online Claiming Provider Agreement Form (HW027)
- Apply for a PRODA account for your organisation and have your staff apply, if needed
- If you don't have a software provider, register for HPOS.

LINKS

Create a PRODA account
Find out more about AIR and HPOS
Check the Pharmacy Guild of Australia Guide for Completing Claiming Provider Agreement Form (HW027)

KEY CONTACTS

GuildCare support: call 1300 647 492 or email support@guildcare.com.au

MedAdvisor PlusOne support: call 1300 893 566 or email support@medadvisor.com.au

AIR and HPOS support: call 1800 653 809 or email air@servicesaustralia.gov.au (8am to 5pm, Monday to Friday)

PRODA support: call 1800 700 199 (choose option 1) or email proda@servicesaustralia.gov.au (8am to 5pm, Monday to Friday)
4. COVID-19 VACCINE INFORMATION & LOCATION SERVICE

GUIDANCE

The COVID-19 Vaccine Information and Location Service includes the Vaccine Clinic Finder (VCF). The VCF is operated by HealthDirect Australia on behalf of the Department of Health. The VCF is based on the existing National Health Services Directory. It provides a ‘front door’ where people can check their eligibility and find out where to get a COVID-19 vaccine, with links to clinics offering vaccine appointments.

Vaccine Clinic Finder

HealthDirect Australia works directly with online booking system providers to integrate your booking profile with VCF. You do not need to contact HealthDirect Australia. The information you provide about your pharmacy and its nominated vaccination site booking system in CVAS will be used to set up your booking profile in the VCF.

All approved COVID-19 vaccination clinics must be listed on the VCF to ensure timely and transparent access for consumers. Consumers will be directed to your pharmacy through the VCF and be able to make a booking online (where available) or by phone. If pharmacies do not have a booking service, they will be shown on the VCF as taking phone bookings only.

HealthDirect aims to list pharmacies on the VCF within 10 days of a pharmacy submitting their first order for vaccine through CVAS. It is essential that information provided in CVAS is correct for consumers to contact your pharmacy (see below).

Updating your Clinic Information on the VCF

VCF Connect has been designed to enable you to self-manage the information published about your services in the Vaccine Clinic Finder.

Registering on VCF Connect

You will receive an email from CV19.Products@health.gov.au notifying you that your pharmacy has been onboarded to VCF Connect.

This email will include information about how to:
• Logon to VCF Connect using your PRODA account,
• Complete your profile,
• Add your sites and;
• Where to get assistance

NOTE: The national rollout to Vaccine Clinics to VCF Connect will occur during February and March 2022 with all manual updates ceasing on 31 March 2022
**Online Booking Systems**

Integrating your booking system with the Vaccine Clinic Finder (VCF) provides faster access to appointments by consumers, enabling them to view availability in real time rather than having to click through to individual clinic websites or having to call the clinic. This reduces pressure on phone lines and staff needed to respond to calls.

If you have an online booking system that you intend to use to manage patients for COVID-19 vaccinations, please read your booking system provider’s guidance material on how to set this up for COVID-19 vaccinations or, if guidance material is not available from your booking system provider or you need additional help, you should contact them directly.

Your booking system provider may need to make changes to support additional vaccine branded appointments, so it is important they know as soon as possible if you will be providing Comirnaty (Pfizer) vaccine for ages 5-11 years (orange cap) or Nuvaxovid (Novavax) vaccines.

The Commonwealth is unable to liaise with your booking system provider to make any changes to the setup of your booking system on your behalf.

**Changing Booking System Providers**

If you change your booking system provider, please be aware that it may take up to 10 days for the details of your new booking system provider to be reflected in the VCF.

Prior to receiving your VCF Connect email invitation you will need to provide the PPA with notification of your new booking systems provider details as soon as possible so they can forward these to HealthDirect Australia who will then make the changes in the VCF for you.

Once you have received the VCF Connect invitation email you will instead need to login to the VCF Connect and make these updates in your VCF Connect account.

**From 31 March 2022, all VCF updates must be made by pharmacies via VCF Connect. No manual updates will be made via the PPA.**
5. TRAINING

GUIDANCE

COVID-19 Vaccination Training

Each health professional involved in the administration of COVID-19 vaccines is required to:

- be authorised to administer vaccinations in their relevant state or territory;
- have completed all necessary immunisation training/qualifications; and
- have completed the COVID-19 Vaccination Training Program, including the relevant specific vaccine (AstraZeneca, Pfizer 12+ years (purple cap), Pfizer 5-11 years (orange cap), Novavax and/or Moderna) modules prior to administering the vaccines.

The training is categorised into two groups, Core and Additional.

- **Core modules** include training for COVID-19 vaccination more broadly.
- **Additional modules** are specific to individual vaccine types.

Non-clinical modules are also available and provide guidance on handling, storage and communication. **Non-clinical staff, especially those who receive or handle vaccines, should complete these modules.**

The training is delivered on an e-learning platform at no cost and does not need to be completed in a single sitting. Users can save their progress and return to complete the relevant modules at a time that suits.

Once all relevant modules are completed each participant will receive a certificate as proof of completion.

All vaccine administrators **must** complete the training before the roll-out at their site, and **each site is required to maintain a record of completion** for all practitioners at their site. Staff will receive a separate certificate on completion of each vaccine module.

**Before vaccinating paediatric groups, please complete the Pfizer (Comirnaty) Paediatric (5 to <12 Years) COVID Training Module as doses are different for adolescents/adults.**

The training modules are updated when required to reflect the latest advice on COVID-19 vaccines. All practitioners are encouraged to log back into the training platform regularly to review the latest advice. Please see the COVID-19 Training Announcement Board for more information.

health.gov.au/covid19-vaccines

TO DO

- Organise for all staff involved in administering the vaccine to register for, and complete, the COVID-19 Vaccination Training Program and record their completion of all modules

LINKS

You can access the training at covid19vaccinationtraining.org.au

More information on the COVID-19 Vaccination Training Program can be found on the Department’s website.

KEY CONTACTS

If you have any technical issues completing the training, there is a pop-up web chat box in the bottom right hand corner of the screen.

The web chat is staffed from 8:30am to 5pm EST Monday to Friday.

We encourage you to attend our weekly Primary Care webinar where we provide you with the latest information on the COVID-19 vaccine roll-out. The weekly Primary Care Webinars are chaired by Professor Michael Kidd AM and have panellists each week. Dr Lucas de Toca from the COVID-19 Program Implementation Primary Care Response is a regular panellist.

The Primary Care Webinar is held from 11:30am – 12pm each Thursday (AEDT) and is available live or on demand.
6. ORDERING & STOCK MANAGEMENT

GUIDANCE

Vaccine Operations Centre

The Commonwealth Department of Health has established a Vaccine Operations Centre (VOC). Following onboarding, the VOC will be your central contact point to assist you with the management of the operations component of the national COVID-19 vaccine roll-out program. The VOC will:

- oversee and manage vaccine allocation and ordering across vaccination sites
- manage and coordinate safe delivery and storage of vaccines with the contracted logistics providers DHL and Linfox
- coordinate the response to incidents impacting the COVID-19 vaccine roll-out program.
- provide support and assistance for CVAS related enquiries

The VOC hours of operation are between 7am to 10pm (AEDT), 7 days a week.

COVID-19 Vaccine Administrative System (CVAS)

You will be required to use the online ordering and inventory management portal, COVID-19 Vaccine Administrative System (CVAS), for ordering vaccines and consumables and completing required reporting (including acceptance of vaccine stock, weekly stock management reports and reports of any wastage of vaccine doses).

The CVAS online portal also provides the Department with end-to-end visibility of vaccine stock. All reports referred to in this section are accessed through your account in the CVAS online portal.

To formalise your participation in the roll-out you must first complete your registration for the CVAS portal which includes completing the:

- Vaccination Site Readiness Checklist and Declaration for the AstraZeneca, Moderna, Pfizer 12+ years (purple cap) Pfizer 5-11 years (orange cap) and Novavax vaccines. You will be required to complete this for each vaccine your site is activated for before you will be able to place an order for that product.

KEY CONTACTS

Vaccine Operations Centre (VOC) - 1800 318 208

The VOC hours of operation are between 7am to 10pm AEDT, 7 days a week.

Email: COVID19VaccineOperationsCentre@health.gov.au

TO DO

- Register for the COVID-19 Vaccination in Community Pharmacies (CVCP) Pharmacy Programs Administrator (PPA) Portal
- Update your details on the PBS Approved Suppliers Portal
- Complete your registration for the COVID-19 Vaccine Administrative System (CVAS)

LINKS

CVAS online portal
For COVID-19 Comirnaty (Pfizer) 12+ years (purple cap) Product Information, click here.
For Comirnaty (Pfizer) for 5-11 years (orange cap) Product Information, click here.
For Spikevax (Moderna) Product Information, click here.
For Vaxzevria (AstraZeneca) Product Information, click here.
For Novavax (Nuvaxovid) Product Information click here.

health.gov.au/covid19-vaccines
CVAS Portal Registration

If you are already onboarded into CVAS and have just been activated to order a new vaccine product, you will only need to complete the declaration for the new product.

Note the Pfizer declaration applies to both the Pfizer 12 years+ (Purple cap) and the Pfizer 5-11 years (Orange cap) formulations and only needs to be completed once.

Please ensure you use Chrome or Firefox (and not Internet Explorer) when logging into CVAS.

To complete the registration process, you will need the following:

1. Access the CVAS online portal registration page and enter your Cohort Registration Code and Site Registration Code.
   
   You will receive a unique eight (8) character ‘Cohort Registration Code’ in the onboarding email sent to you by the PPA. This code is specific to the week you are scheduled to commence.

   Your unique ‘Site Registration Code’ is provided via an email from no-reply@cvas-mail.health.gov.au. This email will be sent to you within 24-72 hours after you receive your onboarding email from the PPA and will include a link to access the CVAS online portal registration page.

2. Create a password and confirm your site details. These details have been pre-populated from your application. You will be asked for additional information to link your site to all other components of the roll-out, including to your booking systems and stock delivery.

   The address used to order COVID-19 vaccines to your pharmacy needs to match your PBS approval number address, to ensure proper linkage within the COVID-19 vaccine data software. PBS approval number details can be managed through the PBS Approved Suppliers Portal.

3. Complete the Site Readiness Checklist and Declaration for the AstraZeneca vaccine, Moderna vaccine, Pfizer for 12+ years (purple cap) Pfizer 5-11 years (orange cap) vaccine and Novavax vaccine. Once you have completed the declarations, you are registered for the CVAS online portal and can access the order forms. Please place your first order as soon as you are ready.

All details provided to the Department of Health will be used for the purposes of administering the COVID-19 Vaccine Roll-out Program and will be managed consistent with obligations under the Privacy Act 1988. Your details may be disclosed to other entities, such as state and territory government agencies or contracted third parties if it is necessary for the monitoring and surveillance of COVID-19 vaccines.

Ordering Stock

Your account in CVAS has been updated to allow you to order the appropriate vaccine type(s). This will include Pfizer 5-11 years (orange cap) vaccine in addition to the Pfizer 12 years+ (purple cap), AstraZeneca, Moderna and Novavax vaccines. After your site is activated for a new vaccine type you will be able to see your order and delivery timeframes for the new product at the top of the banner in the home page of your account. You will also see the new product as an option in the drop down when placing an order. If you haven’t already done the declaration for that product, you will be required to complete the associated declaration before you are able to place an order for the new product.

Sites will be able to place orders via the Orders tab on the CVAS online portal. Orders will need to include a point of contact for delivery acceptance and notifications.

health.gov.au/covid19-vaccines
All community pharmacies who order Moderna, Pfizer 12+ years (purple cap) or Pfizer 5-11 years (orange cap) vaccines will receive the thawed product. This will be delivered between +2°C to +8°C. The process of ordering remains the same regardless of vaccine brand, and you will make separate orders for each vaccine and related consumables you require within that order window. If you experience any issues with your ability to make orders, please contact the VOC.

When placing your order, you will be able to see the Requested Delivery Date (RDD) which indicates the delivery window when your order will arrive. Deliveries will arrive during business hours between Monday to Friday preceding the RDD. Orders can be changed or cancelled through the CVAS online portal until the related ordering window closes by midnight Friday two weeks in advance the RDD. If you wish to make a change outside of this timeframe, you will need to contact the VOC on 1800 318 208.

Pharmacies should consider arranging bookings to allow a period of flexibility around vaccine delivery, for example, by not booking appointments that rely on new stock within 48 hours of anticipated delivery.

All orders are due by midnight Friday, for delivery the following fortnight. Information regarding pharmacy vaccine stock allocation and ordering timeframes may change as the roll-out continues and more vaccine providers are on-boarded. Information on pharmacies’ vaccine stock allocation and ordering timeframe will be notified to pharmacies where it changes.

Consumables

The Australian Government will provide vaccine administration products (consumables) in line with the number of vaccine doses ordered. You can place orders for consumables at the same time as you place an order for vaccine. Note you do not need to place a consumables order each time if you do not need it, you are able to amend the quantities of each consumables item you are ordering. Please only order what you need for administering COVID-19 vaccines.

Consumables will be delivered separately to your vaccine, as the cold chain requirements of vaccines cannot be compromised. If you have placed orders for Pfizer 12+ years (purple cap), Pfizer 5-11 years (orange cap), AstraZeneca, Novavax and Moderna vaccines and consumables and they are due to arrive in the same week, you may receive your consumables orders together. Please ensure you are aware which consumables are for which vaccine product. You can view your past orders in CVAS through the Orders tab at any time if you need to check.

Please note if you are administering Moderna as a booster dose and require additional consumables, you should place a top-up consumables order. Top-up consumables are currently limited to one in-flight order at a time. Sites need to complete Delivery Acceptance of a top-up consumables order before they are able to place another.

If you have trouble obtaining additional ancillary consumables, contact the VOC to discuss as there may be available stock that can be ordered.

Deliveries

The Commonwealth will make deliveries via its preferred logistics partner that delivers the COVID-19 vaccines. Shippers contain between 1 and 3 foam inserts. Shippers can be kept for a maximum of 30 days before being returned via the supplier. The temperature probe which arrives with the thermal shipper is re-useable and must be sent back with the shipper.

health.gov.au/covid19-vaccines
Accepting Stock

Sites will need to complete a Delivery Acceptance Report in CVAS for each vaccine order when accepting delivery from the Commonwealth. This is because these reports directly correlate with the separate orders placed. These mandatory reports must be submitted by 9pm on the day of delivery.

When undertaking the acceptance process, you will need to:

- check the defrost date and time on the vials of the mRNA vaccines: Pfizer 12+ years (purple cap), Pfizer 5-11 years (orange cap) and Moderna;
- check the package for signs of damage or tampering;
- check the temperature logger for indications of cold chain breach;
- visually inspect the internal contents of the package; and
- the fridge temperature must be recorded when vaccines are finally stored.

To store thawed Pfizer 12+ years (purple cap) and Moderna vaccines after they have been received and delivery accepted, transfer the vial trays to a vaccine fridge at +2°C to +8°C for use. The vaccines must be used within 31 days for Pfizer 12+ years (purple cap), and within 30 days for Moderna from the date of defrosting. They are no longer safe to administer to patients after this thawed use by date. These requirements mirror cold chain requirements that pharmacies may already apply to other vaccines (refer to the National Vaccine Storage Guidelines ‘Strive for 5’).

Please monitor both the thaw use by date and the manufacture expiry date for mRNA vaccines.

- The expiry date on the vial indicates the expiry for the vaccine vial. Note that some batches have had their expiry date extended by three months with letters confirming these batches being distributed to all onboarded sites.
- The thaw use by date commences at the time the vials are removed from the freezer or ultra-low storage to commence thawing.
- Whichever date is earliest is the last date the vaccines should be administered to a patient.

The defrost date and time will be visible on the insert containing the vaccine vials. It is recommended that you check the defrost date before you accept your delivery to determine the date at which the vaccines began to thaw. This will be the date used to determine the shelf life.

- The date printed on each individual vial of the Pfizer 5-11 (orange cap) vaccine for the Batch number FP1430 is the manufacture date.
- For all other batches supplied to Australia the expiry date label is on each vial. All thawed deliveries will have a use by date and a thawed date labelled on the carton prior to dispatch from DHL.

The Pfizer 12+ years (purple cap) and Moderna Delivery Acceptance Report will include a section for you to add the date your doses were defrosted and the subsequent defrost/thawed expiry date. This report must be submitted as soon as possible on the day of delivery.

The fridge temperature must be recorded when vaccines are finally stored.

If there is an issue with the product received, sites will need to contact the VOC on 1800 318 208 immediately (within 2 hours of delivery).

Health.gov.au/covid19-vaccines
Managing Stock

To ensure vaccine stock is appropriately managed and accurate reporting is available to support the COVID-19 vaccine roll-out program, sites are required to report stock levels to the VOC via the CVAS online portal using the Vaccine Stock Management Report.

It is mandatory to complete the Vaccine Stock Management Report by 9pm (local time) Friday every week

The Stock Management Report captures:
- details of stock on hand;
- the number of doses administered to patients during the week; and
- any wastage (under 5 vials) from the stock.

This report will include questions for **each vaccine that your practice is administering**. This means you must record your stock on hand for all vaccine products your site is activated for in CVAS of AstraZeneca, Pfizer 12+ years (purple cap), Pfizer 5-11 years (orange cap), Moderna and Novavax vaccines.

*Note: you must complete your latest Stock Management Report before you can place a new order for any vaccine.*

*Please note:* Should a public holiday fall on a Friday or where a pharmacy is not open on a Friday, forms should be completed and submitted by the Thursday.

Given the significance of the COVID-19 Vaccine Program, regular reporting will help to inform equitable vaccine distribution plans and to monitor population engagement. The Australian population is also very interested in the progress of the vaccine roll-out including accurate details on the numbers of people vaccinated and availability of vaccines throughout the supply chain.

**It is critical that cold-chain storage and handling requirements for the vaccines are always maintained and are not breached during the stocktake process.**

Pharmacies should take all necessary steps to minimise stock wastage.

Wastage could occur through multiple situations:
- doses left over at the end of the day (note – bookings should be planned to maximise full use of multi-dose vials)
- damaged vials
- wastage due to expiry (from batch expiry or defrost expiry)
- potential/actual cold chain breach.

Due to the short shelf life of the Pfizer 12+ years (purple cap) (can be stored at +2°C to +8°C for 31 days from the day of thawing) and Moderna vaccine (can be stored at +2°C to +8°C for 30 days from the day of thawing), there is a risk of increased vaccine wastage. Pharmacists should take all necessary steps to minimise stock wastage. **Please monitor both the thaw use by date and the manufacture expiry date for mRNA vaccines.**

The Pfizer 5-11 years (orange cap) vaccine is a different formulation from the Pfizer 12+ years (purple cap) vaccine and is differentiated by an orange cap. After thawing, the shelf life of an unopened vial is 10 weeks or to the manufacture expiry date, whichever is earlier, at +2 °C to +8 °C. The vaccine may be stored pre and post dilution at temperatures between 8°C to 30°C for up to a total of 24 hours. While the information printed on the pack and the vial advises to discard the vaccine 6 hours after opening, the vial...
can be discarded 12 hours after opening. The date on each individual vial of the Pfizer (5-11 vaccine for the Batch number FP1430 is the manufacture date. For all other batches supplied to Australia the expiry date label is on each vial. All thawed deliveries will have a Use by Date and thawed date labelled on the carton prior to dispatch from DHL.

The Pfizer 5-11 years (orange cap) vaccine is presented in a multidose vial containing 1.3 mL of concentrated for suspension for injection vaccine. It must be reconstituted by diluting with 1.3 mL of sterile 0.9% sodium chloride. Do not use bacteriostatic 0.9% sodium chloride. The total quantity after dilution will be 2.6 mL.

When placing the vaccines in the fridge, the expiry dates must be checked, and stock rotated to ensure vaccines are used prior to expiring. It is recommended the staff member of the vaccine at the site should be responsible for placing a use by/defrost date on each tray upon arrival.

A cold chain breach could occur during stock acceptance, stock management or on-site day-to-day. Any stock believed to be affected by a cold chain breach should be immediately quarantined in +2°C to +8°C refrigeration and the VOC should be notified. Stock should be labelled ‘do not use, pending advice from VOC. Do not administer to patients until advice is received. The VOC will provide advice on the use of the stock following receipt of the incident details.

To minimise the incidence and impact of any cold chain breaches, it is encouraged the use of a digital data logger in all vaccine fridges to allow accurate and timely management of any affected stock. We encourage pharmacies to review the “Strive for 5” National Vaccine Storage Guidelines for further information.

Transfer of stock between pharmacies

Available data supports the transportation of one or more thawed vials in liquid state for up to 12 hours at +2°C to +8°C (within the 30 days shelf life at +2°C to +8°C). Once thawed and transported in liquid state at +2°C to +8°C, vials should not be refrozen and should be stored at +2°C to +8°C until use.

It is recommended pharmacies acquire an appropriate supply of ice packs and coolers for use during transport or in the event of a power outage.

To ensure the appropriate temperature is maintained inside the cooler, ice packs must be conditioned prior to use. Please leave packs outside the refrigerator for 1 hour before inserting into the cooler. Please refer to the National Vaccine Storage Guidelines ‘Strive for 5’ for managing and transporting vaccines in eskies or coolers. Vaccines need to have their temperature monitored during transportation to avoid unnecessary wastage.

Transfer of stock between pharmacies must be captured within that week’s Vaccine Stock Management Report by both the transferring and receiving site. If sites transfer vaccines, it is the responsibility of the sites to ensure the cold chain and temperature monitoring are maintained throughout the transfer.

A Vaccine Wastage Report has been developed to capture any wastage incident that exceeds more than 5 vials at one time (wastage threshold).

The Vaccine Wastage Report can be found on the CVAS online portal.

In the event of a potential or actual wastage incident that exceeds the threshold (5 or more vials at a time), sites need to contact the VOC, and complete the Vaccine Wastage Report, including any details of the call immediately.
The Department may be able to replace the damaged stock based on availability of stock and the individual circumstances for the wastage incident.

**DO NOT** discard of any vaccines unless instructed to do so by the VOC.

In the event of a spill, pharmacies should:

- Consider the need for Spill kits, which are recommended to decontaminate any spills.
- Contain the spill to prevent further dispersal.
- Wear appropriate Personal Protective Equipment (PPE) from your spill kit, including single-use gloves, apron, and mask.
- From your spill kit, use the paper towels to soak up the contents of the spilled vial and dispose of the paper towels into the clinical waste bag.
- **If a spill kit is not available**, then the spilled contents can be decontaminated with an appropriate virucidal disinfectant effective against the Genetically Modified Organism (GMO).
  - AstraZeneca (Vaxzevria): recommends an antivirucidal agent registered on the Australian Register of Therapeutic Goods (suitable for adenoviruses) is used and where the manufacturer has confirmed its suitability for adenovirus decontamination.
  - Moderna (Spikevax): recommends any spillages of vial contents should be cleaned up immediately using an agent to inactivate the spill (e.g., Ethanol). Health professionals should follow normal procedures for infection control. Spills of the Moderna vaccine are low-risk.
  - Novavax (Nuvaxovid): spills of the Novavax (Nuvoxovid) vaccine are relatively low risk and can be decontaminated with an appropriate virucidal disinfectant.
  - Pfizer (Comirnaty) also recommends any spillages of vial contents should be cleaned up immediately using an agent to inactivate the spill (e.g., Ethanol). Health professionals should follow normal procedures for infection control. Spills of the Pfizer vaccine are low-risk.

Spills of five or more vials need to be reported to the Vaccine Operations Centre (VOC) immediately by both calling the VOC and submitting a Wastage Report in CVAS.

Any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin.

**Excess / Expiring Stock**

Pharmacies should, in the first instance, seek to use excess stock (contacting regular patients, via local networks) or transfer unopened stock to other vaccinators able to receive the vaccine.

If these options have been exhausted, then pharmacies can contact the VOC, which depending on the quantity (10 or more vials of Novavax, 10 vials or more for mRNA vaccines (Moderna and Pfizer) and 20 vials or more for AstraZeneca) may be able to arrange for its collection, transfer or disposal. Please note, the VOC is unable to accommodate all requests and we ask that pharmacies are patient and provide sufficient information to help their requests be considered (including Batch Number, Expiry Date and Number of doses).

Please be aware that if stock will expire in less than 10 days (for Moderna and Pfizer), or less than 20 days (for AstraZeneca), it is unlikely it will be able to be reallocated or collected by the VOC.

Information to support allocations, storage and handling of vaccinations, including managing stock transfers, is available on the Department of Health’s website on the [COVID-19 vaccination advice for vaccine providers](https://www.health.gov.au/COVID-19-vaccines) webpage. Please also contact the VOC if you need assistance with reducing or cancelling future orders if demand for vaccinations has reduced.
Useful Information - COVID-19 Vaccine Pfizer (Comirnaty) for 5-11 years (orange cap)

Packaging Information
Each vial is a 2mL type 1 glass preservative free multi-dose vial (MDV). Packaging may vary depending on the number of doses ordered. Each box contains 10 vials, with 10 doses of 0.2mL of vaccine per vial when diluted.

Vaccine Appearance
Inside the thawed vial, the vaccine is a sterile white to off-white suspension for injection with a total volume of 2 mL.

Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.

Pfizer COVID-19 vaccine is presented in a multidose vial containing 1.3 mL of concentrated for suspension for injection vaccine. It must be reconstituted by diluting with ONLY 1.3 mL of sterile sodium chloride (0.9%) for injection into the vial. Do not use bacteriostatic 0.9% sodium chloride. The total quantity after dilution will be 2.6 mL. Do not shake the vial. It is preferable to administer vaccine doses immediately after dilution.

Shelf-Life
- After thawing, the unopened vaccine may be stored refrigerated at +2°C to +8°C, protected from light, for a maximum of 10 weeks. Once thawed the vaccine should not be re-frozen.
- After vial puncture and dilution, the vials and the prepared syringes with the vaccine dose must be kept at 2°C to 30°C and used within 12 hours from the time of dilution. Do not freeze the diluted vaccine.
- Additionally, pre-drawn doses kept at room temperature should be used within an hour to minimise any remote potential risk of infection.

Active Ingredient and Excipients
The active ingredient is a single-stranded, 5’-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Other non-active ingredients are included to stabilise the vaccine (listed below).

Excipients
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- distearoylphosphatidylcholine (DSPC)
- cholesterol
- trometamol
- trometamol hydrochloride
- sucrose
- water for injection
This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially ‘potassium free.’ This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free.’

Consumables
The below Pfizer 5-11 consumables that will be delivered separately to your vaccine include:
- Sodium Chloride 0.9% 10mL ampoules
- Saline Needles 22G X 1 IN bevelled 25mm
- Saline Syringe 3mL Luer Slip
- Injection Syringe 1mL Luer Slip
- Low dead space 25 gauge 25mm [1 inch] Orange Long needle.
Useful Information - COVID-19 Vaccine Pfizer (Comirnaty) for 12+ years (purple cap)

Packaging Information
Each vial is a 2mL type 1 glass preservative free multi-dose vial (MDV) and contains 6 doses. Packaging may vary depending on the number of doses ordered. Each box contains 20 or 50 vials.

Vaccine Appearance
Inside the thawed vial, the vaccine is a sterile white to off-white suspension for injection with a total volume of 2 mL.

Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.

The Pfizer 12+ years (purple cap) vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. Do not use any other diluent.

Shelf-Life
- The unopened vaccine may be stored refrigerated at +2°C to +8°C, protected from light, for a maximum of 31 days. Once thawed the vaccine should not be re-frozen.
- The punctured vial may be stored for up to 6 hours at +2°C to +30°C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection.
- Additionally, pre-drawn doses kept at room temperature should be used within an hour to minimise any remote potential risk of infection.

Active Ingredient and Excipients
The active ingredient is a single-stranded, 5’-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Other non-active ingredients are included to stabilise the vaccine (listed below).

Excipients
- (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyI)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- Distearoylphosphatidylcholine (DSPC)
- Cholesterol
- Potassium chloride
- Monobasic potassium phosphate
- Sodium chloride
- Dibasic sodium phosphate dihydrate
- Sucrose
- Water for injections

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Consumables
The below Pfizer 12+ years (purple cap) consumables that will be delivered separately to your vaccine include:
- Sodium Chloride 0.9% 10mL ampoules
- Saline Needles 22G X 1 IN bevelled 25mm
- Saline Syringe 3mL Luer Slip
- Injection Syringe 1mL Luer Slip
- Low dead space 25 gauge 25mm [1 inch] Orange Long needle
Useful Information - COVID-19 Vaccine Moderna (Spikevax)

Packaging Information
Each multi-dose vial (MDV) contains 5 mL of liquid. Each dose is 0.5 mL, meaning there are 10 doses in each MDV. There are 10 MDVs in a carton (outer packaging).

Vaccine Appearance
Inside the vial, the vaccine is a sterile white to off-white suspension for injection with a total volume of 5 mL.

This product is a ready-to-use formulation and does not require dilution.

Shelf-Life
- The unopened vaccine may be stored refrigerated at +2°C to +8°C, protected from light, for a maximum of 30 days. Once thawed the vaccine should not be re-frozen.
- The unopened vaccine may be stored at +8°C to +25°C for up to 24 hours after removal from refrigerated conditions.
- Once the vial is punctured, chemical and physical stability has been shown with storage of Moderna for 19 hours at +2°C to +25°C. However, since this vaccine contains no antimicrobial preservatives, ATAGI recommends that opened vials should preferably be stored at +2°C to +8°C, and the cumulative storage time of opened vials at +2°C to +25°C should not exceed 6 hours.
- Additionally, pre-drawn doses kept at room temperature should be used within an hour to minimise any remote potential risk of infection.

Active Ingredient and Excipients
The active ingredient is mRNA, which encodes for the full-length SARS-CoV-2 spike protein modified with 2 proline substitutions within the heptad repeat 1 domain (S-2P) to stabilise the spike protein into a prefusion conformation. Other non-active ingredients are included to stabilise the vaccine (listed below).

No preservatives are used:
- Heptadecan-9-yl 8-[2-hydroxyethyl-(6-oxo-6-undecoxyhexyl)amino]octanoate
- Cholesterol (enhances membrane fluidity)
- Distearoylphosphatidylcholine
- 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000
- Trometamol
- Trometamol hydrochloride
- Acetic acid
- Sodium acetate trihydrate
- Sucrose
- Water for injections.

Dimensions for the 5mL MDV carton
- Each box contains 10 vials
- Each vial contains 10 doses
- Box Dimensions (L x W x H) - 51 x 126 x 60 (mm).
Useful Information - COVID-19 Vaccine AstraZeneca (Vaxzevria)

Packaging Information
Each multi-dose vial (MDV) contains 5 mL of liquid. Each dose is 0.5 mL, meaning there are 10 doses in each MDV. There are 10 MDVs in a carton (outer packaging). Note that AstraZeneca is also available in 4mL vials.

Vaccine Appearance
The MDV contains liquid which appears as clear to slightly opaque and colourless to slightly brown. There are no visible particles within the MDV.

Opened Vials – Shelf-Life
- 6 hours cumulative total time when at room temperature up to +30°C
- 48 hours since vial penetration when stored in cold chain conditions of +2°C to +8°C

Dimensions for the 5mL MDV carton
- Each box contains 10 vials
- Each vial contains 10 doses
- Box Dimensions (L x W x H)
  - 111 x 44 x 58 (mm)

Active Ingredient and Excipients
The active ingredient is the modified adenovirus (ChAdOx1) containing spike protein genetic code, a GMO. Other non-active ingredients are included to stabilise the vaccine (listed below).

No preservatives are used:
- L-Histidine (an amino acid)
- L-Histidine hydrochloride monohydrate (an amino acid)
- Magnesium chloride hexahydrate (supports many activities inside cells)
- Polysorbate 80 (a stabiliser)
- Ethanol
- Sucrose.
Useful Information - COVID-19 Vaccine Novavax (Nuvaxovid)

The Novavax vaccine is a protein-based vaccine. The primary course dose interval is a minimum of 3 weeks. If the second COVID-19 vaccine dose is an alternative brand, the recommended interval is 4 to 12 weeks after the first dose. The Novavax vaccine comes in a blue-capped multidose vial, with 10 doses per vial and does not require dilution.

Please refer to the TGA, Novavax Training Module, the Product Information, Consumer Medicine Information or ATAGI’s Clinical Guidance for the most up to date information regarding the Novavax vaccines.

Novavax Consumables
The Novavax consumables that will be delivered separately to your vaccine include the below (or similar):

- 1mL low dead volume Luer slip syringe with 0.1mL graduations; and
- Low dead space 25 gauge 25mm needle.

Dimensions for the 5mL MDV carton
- Each box contains 10 vials
- Box Dimensions (L x W x H) – 36 x 92 x 62 (mm)

Vaccine Appearance
A colourless to slightly yellow, clear to mildly opalescent suspension provided in a multidose clear glass vial.

Novavax Orders
Novavax can be ordered in multiples of 100 doses, up to your maximum allocation.

Shelf-Life
- The unopened vaccine may be stored refrigerated at +2°C to +8°C for a maximum of 6 months, protected from light.
- The Novavax vaccine is a thawed vaccine and cannot be frozen.
- The unopened vaccine has been shown to be stable up to 12 hours at 25°C. Storage at 25°C is not the recommended storage or shipping condition.
- Chemical and physical in-use stability of a punctured vial has been demonstrated from the time of first needle puncture to administration for 6 hours at 2°C to 25°C. From a microbiological point of view, after first needle puncture, the vaccine should be used immediately.
- Data on the stability of pre-drawn doses in syringes are absent and storing pre-drawn doses of this vaccine in syringes is not preferred.

Active Ingredient and Excipients
The active ingredient is SARS-CoV-2 rS (NVX-CoV2373). Other non-active ingredients are included to stabilise the vaccine (listed below).

Excipients:
- Dibasic sodium phosphate heptahydrate
- Monobasic sodium phosphate monohydrate
- Sodium chloride
- Polysorbate 80
- Sodium hydroxide (for adjustment of pH)
- Hydrochloric acid (for adjustment of pH)
- Water for Injections
- Adjuvant (Matrix M) Quillaja

saponaria saponins fraction A
- Quillaja saponaria saponins fraction C
- Cholesterol
- Phosphatidyl choline
- Monobasic potassium phosphate
- Potassium chloride

Approximately 3.75 micrograms of sodium per 0.5mL dose, equivalent to approximately 0.2% of the recommended maximum daily intake of 2g sodium for an adult.

Potassium, less than 39 micrograms per 0.5 mL dose, that is to say, it is essentially potassium free.
7. PATIENT VACCINATION PROCESS

GUIDANCE

There is significant demand for safe and effective vaccines to end the COVID-19 pandemic.

Priority groups have been identified using public health, medical and epidemiological evidence, including expert advice from the Australian Technical Advisory Group on Immunisation (ATAGI). This advice is consistent with the World Health Organisation.

This includes people that would be at higher risk of serious illness if they contracted COVID-19 and those most likely to be exposed.

ATAGI has developed several guidance documents to assist vaccine providers to make clinical decisions on who should receive the vaccine.

Dosing schedules

Each vaccine may have a different administration schedule. It is important you refer to the Department of Health website for the most recent ATAGI advice on dosing schedules.

Eligibility

All individuals aged 5 and over are eligible for COVID-19 vaccines:

- Individuals aged between 5 to 11 years can access the children’s formulation of the Pfizer vaccine (5 to 11 years) (ORANGE cap);
- Individuals aged between 6 to 11 years can access paediatric dosage of the Moderna vaccine. The dosage of the Moderna vaccine for children is 0.25 mL which is half the recommended dosage of the Moderna vaccine used for adults.
- Individuals 12 and over can access the Pfizer (12 and over) and Moderna vaccines; and
- Individuals 18 and over can access the Pfizer (12 and over), Moderna, Novavax and AstraZeneca vaccine (AstraZeneca is not preferred for people aged under 60 years).

Vaccination sites are encouraged to continue to support access to vaccination for priority groups such as older people, residential aged care and disability care residents and workers, those with underlying medical conditions, Aboriginal and Torres Strait Islander people, frontline health care workers, quarantine and border workers, and critical and high-risk workers.

LINKS

Visit the COVID-19 Vaccine Clinic Finder.

Patients can obtain proof of vaccination by viewing their immunisation history on Medicare Online, MyGov or Express Plus Medicare mobile app. or by calling the Australian Immunisation Register Hotline on 1800 653 809. For translating and interpreting services call 13 14 50.

RESOURCES

- The Australian Government’s Roll-out Strategy details the when the vaccine will be available
- ATAGI has developed clinical guidance on use of COVID-19 vaccine in Australia in 2021
- Pharmacies should be familiar with the Australian Immunisation Handbook and the National Vaccine Storage Guidelines - Strive for 5
- Consumer Medicines Information
  - AstraZeneca (Vaxzevria) Vaccine, click here
  - Moderna (Spikevax) vaccine, click here
  - Novavax (Nuvaxovid) vaccine, click here
  - Pfizer (Comirnaty) Vaccine, click here
- Services Australia has guidance on how to:
  - Print patients’ IHS (for providers)
  - Get proof of COVID-19 vaccinations (for consumers with and without Medicare)
  - Get IHS (for consumers with or without Medicare)

health.gov.au/covid19-vaccines
Third doses
The Australian Technical Advisory Group on Immunisation (ATAGI) has recommended that individuals aged 5 and over who are severely immunocompromised should receive a third dose of COVID-19 vaccine, two months after their primary course. A list of conditions where this is recommended is available on the Department’s website.

An mRNA vaccine (Pfizer (12 and over) or (5-11 based on patient age) or Moderna or Novavax are preferred for a third primary dose. AstraZeneca can be used for individuals who:

- have had a significant adverse reaction after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis, myocarditis);
- decline receiving an mRNA vaccine.

The recommended interval for the third dose is 2 months after the second dose of vaccine.

Booster Doses
All individuals aged 16 years and over are eligible for a single COVID-19 booster dose, 3 months or more after completion of the primary COVID-19 vaccine course.

The TGA has approved Pfizer (12 years and over) as a single booster dose in people aged 16 years and over and the Moderna vaccine for people aged 18 years and over. Please note the Moderna booster dose is half the Moderna primary course dose (0.25 mL for the booster dose).

Individuals who cannot receive a Pfizer (12 years and over) or Moderna vaccine due to a significant adverse reaction after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis or myocarditis), can receive a single dose of AstraZeneca or Novavax vaccine for their booster. For guidance regarding approved vaccines by age, please visit COVID-19 booster vaccine advice.

Vaccination after testing positive for COVID-19
ATAGI continues to advise that previous infection is not a contraindication to vaccination and vaccination can occur following recovery of acute illness from COVID-19. People who have had COVID-19 can be vaccinated with a COVID-19 vaccine once they recover from the acute illness. There is no requirement to delay vaccination, however vaccination can be deferred for up to 4 months as past infection reduces the chance of reinfection for at least this amount of time.

Further:
- If a patient tests positive for COVID-19 between their first and second doses, or between their second and booster dose, the patient should delay the next dose until they have recovered from the acute illness.
- People with prolonged symptoms from COVID-19 beyond 4 months should be vaccinated on a case-by-case basis.
- Temporary exemption from COVID-19 vaccination: Those with a PCR-confirmed SARS-CoV-2 infection can temporarily defer vaccination up until 4 months after the infection. The time frame for temporary exemptions was previously 6 months. ATAGI has decreased the time allowable for deferral of vaccination after prior SARS-CoV-2 infection to 4 months due to the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021.

You can also seek further advice from a specialist immunisation service if required.


health.gov.au/covid19-vaccines
**Consent**

As with all vaccines, informed consent is required before administering each COVID-19 vaccine dose and providers are required to document it in a patient’s medical record. Verbal or written consent is acceptable. **Consent should always be documented**, e.g. in the patients’ medical record.

If you need phone or on-site interpreting to assist in consultations to ensure informed consent is given for COVID-19 vaccines, call the Pharmacy Priority Line on 1300 131 450. See Part 3 of the Onboarding Pack – Vaccine Provider Communication Kit for how to register for the Free Interpreting Service.

Patients are to be advised that their vaccination details must be reported to the AIR and to the PPA. This will include some **personal information**. For the COVID-19 vaccine, the Australian Government Department of Health will use de-identified immunisation information to report on how the vaccine rollout is progressing.

ATAGI has published an immunisation provider guide to obtaining informed consent for the COVID-19 vaccine. This guide assists immunisation providers to gain consent for COVID-19 vaccination and answers some frequently asked clinical questions. An optional written consent form has been developed as an aid for those providers who choose to use it. **Translated consent forms** are available at health.gov.au.

Consent should be obtained prior to each vaccination dose, regardless of whether your pharmacy administered previous doses to the patient. Consent should also be obtained prior to third dose and booster doses.

There is a special consent form for children aged 5-11 years found [here](#). Younger children require more parental support and often need a longer time for vaccine administration than older children and adults. Parents prefer to be present and may be more likely to have questions for providers, requiring a longer consult than usual. Additional time for vaccinating children aged 5-11 years should be factored into clinic throughput times.

**Proof of vaccination**

There are three ways consumers can show proof of COVID-19 vaccinations:

- COVID-19 digital certificate
- Immunisation history statement

To ensure equitable access to COVID-19 proof of vaccination, vaccination providers are advised to download and print ALL patients’ immunisation history statements or COVID-19 digital certificates from the AIR site on their behalf as a regular course of action.

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**REPORT AN AEFI**

- Register for AEMS

**Links**

Find out about the AEMS COVID-19 Vaccine Side Effect Checker

**Contacts**

ADR portal: email adr.reports@health.gov.au

How to manage and report an adverse event following immunisation (AEFI).

Vaccination providers can report an AEFI or a defect with a vaccine by contacting the TGA on 1800 020 653

You should also report AEFIs to State and Territory contacts:

- **ACT**: ACT Health Protection Services – Immunisation Team (02) 5124 9800
- **NSW**: 1300 066 055 (to connect to your local public health unit)
- **NT**: NT Department of Health 08 8922 8044
- **QLD**: Queensland Health 07 3328 9888, or complete an AEFI initial report form on the Queensland Health website
- **SA**: Immunisation Section, Department of Health 1300 232 272
- **TAS**: submit a AEFI form to tas.aefi@health.tas.gov.au or call 1800 671 738
- **VIC**: SAEFVIC 03 9345 4143 or the SAEFVIC website
- **WA**: WAVSSS 08 9321 1312

AusVaxSafety is also conducting national COVID-19 vaccine safety surveillance in Australia. You can also register your interest in participation at: [www.smartvax.com.au](http://www.smartvax.com.au)
The Services Australia website has information about how providers can print proof of vaccination for all patients, including those who do not have Medicare or an Individual Health Identifier (IHI).

Consumers who have a Medicare number or an IHI can access proof of COVID-19 vaccination using:

- their Medicare Online account on MyGov; or
- Express Plus Medicare mobile app

Consumers, including individuals without a Medicare card OR IHI, can also request their IHS be sent by post by calling the Australian Immunisation Register Helpline on 1800 653 809. It can take up to 14 days to arrive in the mail.

Consumers can access translating and interpreting services by calling 13 14 50.

**Adverse Events Following Immunisation**

You are encouraged to follow your usual process to report any Adverse Events Following Immunisation (AEFIs) to your State or Territory Public Health Unit.

The Therapeutic Goods Administration (TGA) also provides an online **Adverse Event Management System (AEMS)**. In this system, you can report an adverse event associated with a medicine (including complementary, over the counter or prescription medicines) or a vaccine.

If a patient thinks they may be experiencing minor side-effects following vaccination, they can self-check using the [COVID-19 Vaccine Side Effects Symptom Checker](https://covid19-australia.health.gov.au/vaccines/side-effects) or make a report and obtain advice by calling the NPS MedicineWise Adverse Medicine Events line on 1300 134 237 (8am-8pm seven days a week).

You can also get involved in the COVID-19 vaccine safety surveillance conducted through AusVaxSafety by installing the SmartVax software program in your practice.

**Vaccine Vials and Sharps Disposal**

Disposal of vaccine vials and sharps should occur at the point of use. Vaccine vials and sharps should be discarded into an approved sharps container. Expired vaccine vials should also be discarded into an approved sharps container.

**DO NOT** recap sharps before disposal.
8. VACCINATION SETTINGS

GUIDANCE

Both the Pfizer vaccines are more complex to manage within a clinical setting than the Novavax, Moderna and AstraZeneca COVID-19 vaccines due to its specific requirements for handling.

Where clinics are administering more than one brand of COVID-19 vaccine, it is important to ensure that individuals receive the appropriate vaccine (at the recommended interval), vaccines are stored and prepared correctly, and waste is minimised. To support this, a strong clinical governance framework is required, including strict workflows and processes for separating the vaccines either by time or space.

Guidance on processes and flow

It is preferable that pharmacies separate administration of different vaccines by time or space to minimise confusion between the administration of the vaccines. This would include solutions such as:

- providing vaccines in separate spaces within the pharmacy (where possible), with separate staff managing each space; or
- arrange bookings for vaccines at different times or different days.

If appointments for all four vaccines are held onsite at the same time, there should be separate, clearly defined areas for all aspects of the vaccination clinic flow, including vaccine preparation areas. Clear signs and ground markings should be used to distinguish each area.

Ideally, staff should avoid providing different vaccines on the same day, and should check the vaccine, type, and dose interval carefully to avoid errors. Staff designated to each vaccine should not be reallocated to the other vaccine on the same shift.

It is also recommended that different vaccines are not stored or used in the same area of the pharmacy at the same time. To reduce risk of administration error, the paediatric and adolescent/adult formulations of the vials (including both vaccine and saline solution) and prepared doses should be stored separately from each other in clearly marked areas, including in dedicated containers in separate spaces (e.g. in different shelves in a vaccine fridge or separate vaccine fridges where possible). Prepared syringes should be labelled using colour coded labels to differentiate between paediatric and adolescent/adult doses.

Prior to vaccination

Processes should be developed to ensure that patients are booked into the correct clinic.

Ensure that the registration systems and consent questions align to the specific vaccine the person is to receive. Pre-vaccination information provided to the patient should clearly identify which vaccine the person is to receive.

Information relating to pre and post vaccination care should be specific to the vaccine that the person receives. Note there is a standalone information and consent resource for parents/guardians of children aged 5-11 years.

TO DO

□ Plan for how your pharmacy will operate vaccination sessions separated by time or space

LINKS

ATAGI site requirements for COVID-19 vaccination in CPs:
- Physical environment
- Workforce requirements
- Cold chain management
- Multi-dose vial administration
- Technology & record keeping
- Waste disposal
- Personal protective & other equipment
- Accreditation & other regulatory requirements
- Accessibility & cultural safety
- Management of the CP
- Consumables

health.gov.au/covid19-vaccines
9. FUNDING & CLAIMING REGISTRATION

GUIDANCE

Service Fee Structure
To support the national roll-out, participating pharmacies will be paid for each vaccination to ensure equitable access to vaccines without need for patient co-payment. Patients cannot be charged for COVID-19 vaccination services.

Service fees will vary based on region, repeat dose and location of follow-up.

To promote continuity of care and follow-up by the same pharmacy the second dose will be paid at a higher fee. If follow up is performed by a different pharmacy, the payment will be at the base fee.

Patients will be able to choose whether they receive the second dose and where they receive it but booking both appointments at the same time and returning to the same pharmacy is encouraged.

Please note: Pharmacies will receive funding for providing vaccinations to a non-Medicare eligible patient. Pharmacies must seek confirmation from the patient that the patient does not hold, or is ineligible to hold a Medicare/DVA card and should use the ‘Urgent Clinical Need’ special Medicare number (25437529911) when submitting a claim in the PPA Portal for administering vaccinations to these patients.

Region
Funding differs depending on whether your pharmacy is in a metropolitan or non-metropolitan region as classified by the Modified Monash Model (MMM). A higher fee is paid to pharmacies in non-metropolitan regions, as described in the table below:

<table>
<thead>
<tr>
<th>Description</th>
<th>MMM 1 Service Fee</th>
<th>MMM 2-7 Service Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Dose</td>
<td>$16</td>
<td>$19</td>
</tr>
<tr>
<td>Second Dose Administration (where the first administration was undertaken by the same Service Provider)</td>
<td>$26</td>
<td>$29</td>
</tr>
<tr>
<td>Second Dose Administration (where the first administration was undertaken by a different Service Provider)</td>
<td>$16</td>
<td>$19</td>
</tr>
<tr>
<td>Additional Dose (includes third doses for severely immunocompromised patients and Booster Doses)</td>
<td>$26</td>
<td>$29</td>
</tr>
</tbody>
</table>

KEY CONTACTS
For information relating to claiming or payments, go to the PPA website or contact the PPA via:

Phone: 1800 951 285
Email: support@ppaonline.com.au

LINKS
Find your Modified Monash (MM) Category here.

health.gov.au/covid19-vaccines
Portal Registration and Claiming

To submit claims the pharmacy must first:

- have a pharmacy Service Provider account on the PPA Portal
- register the pharmacy’s account for the CVCP Program.

PPA Portal Service Provider Account

If your pharmacy does not have an existing Service Provider account on the PPA Portal please read the Initial Registration Portal User Guide available here on how to set up both your personal log in account and your pharmacy’s Service Provider account.

Registering for the CVCP Program on the PPA Portal

To be eligible to register for and participate in the CVCP Program, a pharmacy must:

- have received notification from the Australian Government Department of Health or State or Territory Department of Health of their selection to participate in the COVID-19 national vaccine rollout
- in instances where there has been a change to the pharmacy’s section 90 approval number, the new pharmacy agrees that, at a minimum, it meets the same requirements as the old pharmacy as described in the original EOI submission to participate.

Only the ‘Main Authorised Person’ (MAP) for the pharmacy account may register the pharmacy for the Program. The MAP will need to provide the pharmacy’s AIR provider number as their CVCP Program Approval Code in the Program Registration form.

A User Guide containing further information on how to register for the CVCP Program and submit CVCP claims can be found on the CVCP Program webpage.

Claiming

Once registered for the CVCP Program pharmacies will be able to make claims via one of two methods:

- by inputting claim data directly into the PPA portal
- integrated claiming through professional services software. Please note, not all professional services software vendors may choose to integrate with the PPA Portal. Please contact your software vendor for information on whether they provide integrated claiming. Information about generating the API key your pharmacy will need to integrate can be found in the PPA User Guide - Integration and API User Keys found under the Portal User Guides section of the PPA Resources webpage.

Claims must be submitted by the end of the next calendar month after the vaccination was conducted (e.g. vaccinations undertaken in July must be claimed by 31 August). However, pharmacies are encouraged to claim as soon as possible after each vaccination is given. Pharmacies should note that whilst they have until the end of the month after the month the vaccination was given to claim, doses should be uploaded into AIR within 24 hours of vaccine administration.

For more information about CVCP Program registration and claiming, visit the CVCP Program webpage.
10. Appendix A – Key Contacts

Vaccine Operations Centre (VOC)
The VOC hours of operation are between 7am to 10pm (AEDT), 7 days a week. Please note that from 18 December – 30 January VOC hours of operation will be between 7am – 9pm (AEDT).

- **Phone:** 1800 318 208
- **Email:** COVID19VaccineOperationsCentre@health.gov.au

Adverse Event Following Immunisation (AEFI) Reporting

- **Phone:** 1300 134 237 (NPS MedicineWise Adverse Medicine Events Line)

Australian Immunisation Register (AIR)
The AIR hours of operation are between 8am to 10pm Monday to Friday (local time)

- **Phone:** 1800 653 809

COVID-19 Vaccine Administrative System (CVAS)
Contact the VOC via the details shown above

National Coronavirus and COVID-19 Vaccine Helpline

- **Phone:** 1800 020 080
- **Email:** covidvaccineenquiries@health.gov.au

PRODA support
The PRODA hours of operation are between 8am to 10pm (local time)

- **Phone:** 1800 700 199
- **Email:** ebusiness@servicesaustralia.gov.au

Therapeutic Goods Administration
The TGA hours of operation are between 9am to 5pm Monday to Friday (AEST)

- **Phone:** 1800 020 653

Pharmacy Programs Administrator
The PPA hours of operation are between 9am to 8pm (AET) Monday to Friday

- **Phone:** 1800 951 285
- **Email:** support@ppaonline.com.au

Vaccine Clinic Finder Connect

- **Phone:** 1800 316 375
- **Email:** CV19.Products@health.gov.au
State and Territory Health Departments – AEFI Reporting

**Australian Capital Territory**
Contact the ACT Health Protection Services – Immunisation Team
**Phone:** (02) 5124 9800

**New South Wales**
Connect to your local public health unit
**Phone:** 1300 066 055

**Northern Territory**
Contact the NT Department of Health
**Phone:** (08) 8922 8044

**Queensland**
Complete an AEFI form [online](#) or contact Queensland Health
**Phone:** (07) 3328 9888

**South Australia**
Contact the SA Department of Health, Immunisation Section
**Phone:** 1300 232 272

**Tasmania**
Complete an [AEFI form](#) email/fax to the address below or contact Tasmanian Public Health
**Phone:** 1800 671 738
**Email:** tas.aefi@health.tas.gov.au
**Fax:** (03) 6173 0821

**Victoria**
Follow the reporting instructions at [SAEFVIC](#) or get in touch via
**Phone:** 1300 882 924 (option 1)
**Email:** saefvic@mcri.edu.au

**Western Australia**
Contact the Western Australia Vaccine Safety Surveillance (WAVSS) System
**Phone:** (08) 9321 1312

## Appendix B – Resources and Links

<table>
<thead>
<tr>
<th>Resource</th>
<th>URL</th>
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</thead>
<tbody>
<tr>
<td>Section</td>
<td>URL</td>
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<td>------------------------------------------------------------------------</td>
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<tr>
<td>including those in residential aged care facilities</td>
<td></td>
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<tr>
<td>breastfeeding or planning pregnancy</td>
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<tr>
<td>COVID-19 Vaccination Training Modules - including AstraZeneca (Vaxzevria) Module, Moderna (Spikevax) Module and Pfizer (Comirnaty) 12+ years (purple cap) and Pfizer (Comirnaty) 5-11 years (orange cap) Module, and Novavax (Nuvaxovid) Module</td>
<td><a href="https://covid19vaccinationtraining.org.au">https://covid19vaccinationtraining.org.au</a></td>
</tr>
</tbody>
</table>

<p>| Pharmacy Guild of Australia – resources for pharmacies, available from Services Australia Claiming Provider Agreement Form | <a href="https://www.servicesaustralia.gov.au/organisations/health-professionals/forms/hw027">https://www.servicesaustralia.gov.au/organisations/health-professionals/forms/hw027</a> |</p>
<table>
<thead>
<tr>
<th>Service</th>
<th>URL</th>
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