COVID-19 Vaccine Roll-out through Community Pharmacies

ONBOARDING PACK

Part 1 of 3

November 2021 Version 4

This Onboarding Pack provides information and advice specific to the administration of the Vaxzevria (AstraZeneca), the Spikevax (Moderna), and the Comirnaty (Pfizer) vaccine in a community pharmacy.

This version replaces previous versions

Important update information for your pharmacy

1. Before you order

Before you place your first order you must ensure that your pharmacy has a clear understanding of the specific requirements associated with the vaccine your pharmacy is administering – this onboarding pack provides information for the following vaccines:

- Vaxzevria (AstraZeneca)
- Spikevax (Moderna)
- Comirnaty (Pfizer)

Please read as it highlights important information and actions you need to take. It also highlights matters that may differ compared to the AstraZeneca, Pfizer and Moderna vaccine.

It is expected you that will review all parts of the revised Onboarding Pack (Parts 1, 2 and 3).

Prior to ordering, please also ensure your pharmacy can continue to meet the ATAGI requirements and the CVCP Program Rules, available via the links below.

- ATAGI requirements
- CVCP Program Rules.

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 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.

2. Placing an order

The process for ordering the Pfizer (Comirnaty) vaccine in the COVID-19 Vaccine Administration System (CVAS) is the same as that for Spikevax (Moderna) and Vaxzevria (AstraZeneca) vaccines. To commence ordering, your pharmacy will need to complete the following steps:

- Log into CVAS using your username and password. No cohort code or site code are required
- A screen will appear that contains the vaccine-specific site requirements. You must read the requirements and confirm that you can meet these by completing the site declaration for the vaccine you are ordering.

  Note: If your pharmacy cannot meet the Pfizer site requirements you will not be able to participate further in the Pfizer vaccine rollout. Please note that a compliance and audit program is in place to ensure community pharmacies meet all relevant requirements.
- You will be required to re-enter your public clinic hours for the purpose of the Vaccine Clinic Finder (VCF). CVAS will ask you to re-enter your pharmacy's Moderna and AstraZeneca hours (noting these may have changed) and then enter your Pfizer hours.
- Ideally, the hours for each vaccine should be different to ensure you can comply with requirements to separate administration of different vaccines by space or time. Please refer to Section 8 (page 30) of the revised Onboarding Pack for further details and guidance.
- After completing the above step, you will be able to place an order, and the Pfizer vaccine will appear in your order options list.

- CVAS will indicate the number of Pfizer doses you can order as part of your first and subsequent fortnightly orders. Please note that the number may differ across pharmacies and states/territories – the PPA had no role in setting these numbers and there is no ability to have this number adjusted.

If you have any issues with the CVAS declaration or placing your order, please contact the Vaccine Operations Centre on **1800 318 208** or COVID19VaccineOperationsCentre@health.gov.au between 7am to 10pm AEDT.

3. Before receiving your first order

Before receiving your first order, pharmacy immunisers must have completed the COVID-19 Vaccination Training Program Core Modules as well as the vaccine-specific training modules, available here.

Note: Pfizer-specific training modules have recently been updated and will be regularly updated in future.

4. Preparing to commence vaccinations

Understanding vaccine specific requirements and establishing an appropriate clinical environment

It is important for pharmacies to recognise that the Pfizer and Moderna vaccines are more complex to manage within a clinical setting than the AstraZeneca vaccine due to their specific requirements for storage and handling.

Where clinics are administering more than one brand of COVID-19 vaccine, it is important to ensure that:

- patients receive the appropriate vaccine, and at the recommended interval,
- vaccines are stored and prepared correctly, and that 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.

Please refer to Section 8 (page 30) in this Pack for further details and guidance.

Online bookings

Your pharmacy may wish to set up additional online bookings so patients can make appointments for Pfizer vaccinations. There is no change to this process from that used for existing vaccines. The most commonly used booking providers have confirmed that bookings for all available vaccines are supported and have advised the PPA as follows:

- GuildCare - more information about booking setup will be provided here
- MedAdvisor - will shortly email pharmacies with setup instructions.

Booking providers will work directly with Health Direct to list your updated booking links for Pfizer on the VCF website on your behalf. It may take up to 10 business days from your initial CVAS Pfizer order date for your booking link to appear on the VCF, therefore, please do not contact the PPA about a missing booking link until at least 10 days have passed.

If you have an existing Moderna or AstraZeneca booking link, the Pfizer booking link will be added and two or three links will appear for your pharmacy.

5. Before vaccinating each patient – check eligibility and obtain consent

Eligibility

Prior to vaccinating each patient your pharmacy must ensure that all patients are eligible to be vaccinated with the specific vaccine.

The Commonwealth vaccination program currently allows for:

- the Moderna and Pfizer vaccine to be administered to patients that are aged 12 and over.
- the AstraZeneca vaccine to be administered only to patients aged 18 years and older.

Please regularly review the eligibility requirements listed on the COVID-19 Vaccine Clinic Finder.

In addition, state and territory governments may have different requirements. Please make sure you also check what is allowed in your jurisdiction here. Again, these may change over time so please review regularly.

Third doses

The Australian Technical Advisory Group on Immunisation (ATAGI) has recommended that individuals aged 12 and above who are severely immunocompromised receive a third dose of COVID-19 vaccine as part of the primary course. A list conditions is available on the Department's website.

An mRNA vaccine (Pfizer or Moderna) is preferred to AstraZeneca for a third primary dose. AstraZeneca can be used for individuals who have:

- received AstraZeneca for the first two doses if there are no contraindications or precautions for use; or
- had a significant adverse reaction after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis, myocarditis)

The recommended interval for the third dose is 2 to 6 months after the second dose of vaccine.

Booster doses

All individuals aged 18 years and over are eligible for a single COVID-19 booster dose if they had their second dose of their primary course COVID-19 vaccination at least 6 months ago.

ATAGI have recommended that the highest priority groups to receive booster doses of COVID-19 vaccines are those with risk factors for severe COVID-19 and/or those at increased occupational risk of COVID-19. For a list of these priority groups, visit the Department's website.

The recommended interval for the booster dose is 6 months or more after completion of the primary COVID-19 vaccine course.

Pfizer is recommended and TGA-approved as a single booster dose. Pfizer can be used as a booster dose regardless of which vaccine type was used for the first 2 doses. At this time, Moderna is not approved for use as a booster dose. Although not preferred, AstraZeneca can be used as a booster for individuals who have:

- received AstraZeneca for the first two doses if there are no contraindications or precautions for use; or
- had a significant adverse reaction after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis, myocarditis).

Consent

Pharmacies must also ensure that patients provide informed consent.

- find the consent form here and;
- patient information relevant to the particular vaccine here.

6. Vaccine Administration Claim Lodgement

Please refer to the Program Rules for the latest information on *Vaccine Administration Claim Lodgement.*

7. Questions and contacts

- **ordering -** please contact the Vaccine Operations Centre between 7am to 10pm (AEDT) at COVID19VaccineOperationsCentre@health.gov.au or on 1800 318 208
- registering and claiming via the **PPA Portal** or about your **VCF listing** – please contact the PPA Support Centre at support@ppaonline.com.au or 1800 951 285.
- **clinical issues** – please contact the National coronavirus and COVID-19 vaccine helpline at covidvaccineenquiries@health.gov.au or 1800 020 080.

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

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Abbreviations

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

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 8 November 2021, community pharmacies participating in the COVID-19 Vaccination in Community Pharmacy (CVCP Program) will be able to administer the Comirnaty (Pfizer) vaccine in addition to the Spikevax (Moderna) vaccine and the Vaxzevria (AstraZeneca) vaccine – collectively referenced throughout this document as the COVID-19 vaccine.

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 with regard to 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) will be referred to as AstraZeneca, the Spikevax (Moderna) as Moderna; and the Comirnaty (Pfizer) as Pfizer.

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.

Complete?	Task
☐	Have you registered the Pharmacy for the Australian Immunisation Register (AIR)?
☐	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)?
☐	Do you have an appointment system in place, and can you accept on-line bookings?
☐	Have you and your staff completed the COVID-19 Vaccination Training Program and reviewed all updates?
☐	Have you and your staff completed the COVID-19 Vaccine Training Modules?
☐	Have you familiarized yourself with the type of assistance the Vaccine Operation Centre (VOC) can provide?
☐	Have you registered to the COVID-19 Vaccine Administrative System (CVAS)?
☐	Have you reviewed the ordering and stock management timeframes and requirements and prepared relevant policies and procedures to receive, store and handle vaccines?
☐	Have you ordered vaccine stock and any consumables you will require?
☐	Do you have your anaphylaxis kit ready?
☐	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?
☐	Have you reviewed the 'COVID-19 Pre-Vaccination Checklist' provided in Part II of the Onboarding Pack, to be used for all vaccinations?
☐	Have you prepared the 'Patient Consent' forms for all vaccinations?
☐	Have you reviewed the 'Post-Vaccination Checklist' for use after vaccine administration?
☐	Have you reviewed the COVID-19 Vaccination in Community Pharmacies (CVCP) Program Rules?
☐	Have you registered for the CVCP Program via the Pharmacy Programs Administrator (PPA) Portal in order to submit claims for payment?

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.

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 any of the following to report to the AIR.

- **Professional services software** – this is the preferred option. A number of products are integrated with the AIR. The most common include: GuildLink (GuildCare NG); MedAdvisor (PlusOne); or Simple Retail (Aquarius). Community pharmacies will need to complete an Online Claiming Provider Agreement form to register their software for reporting vaccinations to the AIR.
- **Clinician Vaccine Integrated Platform (CVIP)** – this is a free application provided by the Australian Digital Health Agency for used by pharmacies who do not already have and do not intend to purchase professional services software that reports 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 24-48 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. **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**.

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.

The preferred minimum interval between receiving a COVID-19 vaccine and any other vaccine excluding influenza vaccine is 7 days.
A shorter interval is acceptable if there is:

- increased risk of COVID-19, or another vaccine-preventable disease (for example, a COVID-19 outbreak, influenza outbreak, tetanus-prone wound)
- logistical issues.

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, My Health Record and/or CVIP.

C/…

GUIDANCE

PRODA (or Provider Digital Access)

Most digital services that report to AIR, including some software providers, CVIP 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.

Clinician Vaccine Integrated Platform (CVIP)

The CVIP can be used to report vaccination information to the AIR. CVIP can only be used by pharmacies who do not already have professional services software that reports to the AIR. It is free to use and available online through a web browser or can be downloaded as an app. To use the CVIP you must be registered with PRODA and have an AIR provider number.

In addition to AIR reporting CVIP, can help with managing vaccinations, it includes features for:

- Patient self-check in
- Viewing AIR history
- QR Code scanning to quickly record the supply of a vaccine
- End-of-day reconciliation with uploaded AIR encounters.

Information on the steps required to register and use the CVIP can be found on the CVIP website.

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 CVIP or HPOS.

LINKS

Create a PRODA account

Find out about CVIP

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)

CVIP Helpline: call 1800 723 471 (choose option 3) (24 hours, 7 days)

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 ofthe 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 geta 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).

If you have an online booking system that is integrated with the VCF, your available appointments will be shown to consumers to help them find clinics with capacity.

The VCF requires vaccine type specific booking links that direct patients to the appropriate COVID-19 vaccine type appointments for the pharmacy.

Please consider this if you are currently using booking systems that offer appointments for other services at your pharmacy.

TO DO

- ☐ Set up your system and processes to take appointments
- ☐ Ask your booking system provider whether they are integrated with the NHSD and VCF
- ☐ Nominate your vaccination site booking system when you register for CVAS

LINKS

Vaccine Clinic Finder

KEY CONTACTS

You can send any questions on the **Commonwealth booking system** to:

Digital.CV19@Health.gov.au

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 a third vaccine branded appointment, so **it is important they know as soon as possible if you will be providing Pfizer vaccinations**.

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.

Clinics without an online booking system can contact commercial providers or use the Commonwealth Booking Platform (CBP). The CBP is a COVID-19 vaccination booking system that is specifically designed for COVID-19 vaccines. It complies with government requirements around accessibility, privacy and security, and is available at zero cost to your practice.

Please note: The Commonwealth Booking Platform is time-limited for the vaccine rollout and can only be used by clinics if you don't already have an online booking service provider.

If you do not have an existing booking system and would like more information about the CBP, please visit: https://practices.healthengine.com.au/commonwealth-booking-platform-explained
or email Digital.CV19@health.gov.au.

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.

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.

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 and/or Moderna) module.

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.

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.

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

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.

6. ORDERING & STOCK MANAGEMENT

GUIDANCE

Vaccine Operations Centre

The Commonwealth Department of Health has established a Vaccine Operations Centre (VOC). Following on-boarding, 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:

- 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.

The VOC hours of operation are between 7am to 10pm (AEDT), 7 days a week. *Please note that from 18 December 2021 – 30 January 2022 VOC hours of operation will be between 8am – 8pm (AEDT).*

COVID-19 Vaccine Administrative System (CVAS)

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

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 the CVAS online deliveries management portal.

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

- **Vaccination Site Readiness Checklist and Declaration for the AstraZeneca, Moderna and Pfizer vaccines.**

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) Product Information, click here.
For COVID-19 Spikevax (Moderna) Product Information, click here.
For COVID-19 Vaxzevria (AstraZeneca) Product Information, click here.
Access the National Vaccine Storage Guidelines here.

CVAS Portal Registration

Pharmacies already onboarded for Moderna will only need to complete the Declaration for the Pfizer vaccine (Skip to Step 3).

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 and Pfizer vaccine.** Once you have completed the declaration, you are registered for the CVAS online portal and can access the order forms. Please place your first order as soon as possible.

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

CVAS has been updated to allow you to order the Pfizer vaccine in addition to the AstraZeneca and Moderna vaccines. After your site is activated for Pfizer you will be prompted to complete the Pfizer declaration when you next log in to CVAS. You will need to complete the declaration before you are able to place an order for Pfizer.

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

All community pharmacies who order Moderna or Pfizer 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, but you will have to make separate orders for each vaccine and related consumables**. 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.

Pharmacies do not need to hold back stock for the second dose.

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.

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, AstraZeneca 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.

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 allowed 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 maximumof 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.

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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 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 and Moderna);
- record the fridge temperature must be recorded when mRNA vaccines are finally stored;
- check the package for signs of damage or tampering;
- check the temperature logger for indications of cold chain breach; and
- visually inspect the internal contents of the package.

To store thawed Pfizer 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 (31 days for Pfizer, and within 30 days for Moderna) from the date of defrosting.These requirements mirror cold chain requirements that pharmacies may already apply to other vaccines (refer to the National Vaccine Storage Guidelines 'Strive for 5').

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 fridge temperature must be recorded when vaccines are finally stored. The Pfizer and Moderna Delivery Acceptance Report will include a section for you to add the date your doses were defrosted and the subsequent defrost expiry date. This **report must be submitted as soon as possible on the day of delivery.**

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)**.

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.

The *Vaccine Stock Management Report* should be **completed by 9pm (local time) Friday every week** via the Stock Management tab in CVAS and 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 AstraZeneca, Pfizer and Moderna.

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
- potential/actual cold chain breach.

Due to the **short shelf life of** the Pfizer vaccine (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.

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 recipient of the vaccine at the site should be responsible for placing a use by/defrost date on each tray upon arrival.

An **unopened Pfizer vaccine may be stored at +8°C to +25°C up to 2 hours** after removal from refrigerated conditions.

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. 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.**

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°Cto +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.

Transfer of stock between pharmacies must be captured within the *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 Department of Health.

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.
    - 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.
- Any unused vaccine or waste material should be disposed of in accordance with local requirements in a clinical waste bin and the VOC should be notified through the COVID-19 Vaccine Administrative System (CVAS).

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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.

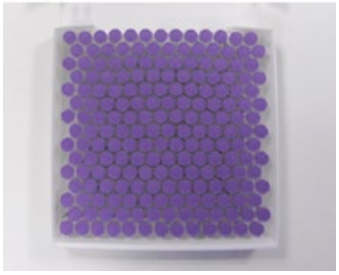
If these options have been exhausted, then pharmacies can contact the VOC, which depending on the quantity (10 vials or more for Moderna and Pfizer and 20 vials or more for AstraZeneca) may be able to arrange for its collection, transfer or disposal. Please note, the VOC is unable to accommodate all 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 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) – NEW INFORMATION

Packaging Information
Each vial is a 2 mL 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 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 +2ºC to +30ºC *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

- 4hydroxybutyl)azanediyl)bis (hexane-6,1-diyl)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'.

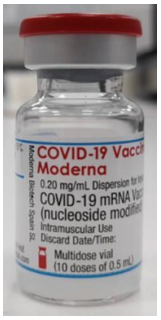
Consumables
The below Pfizer consumables that will be delivered separately to your vaccine include:

- 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.

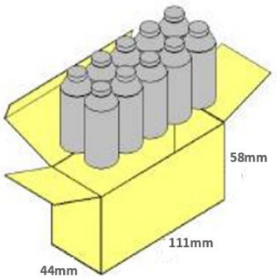
Dimensions for the 5mL MDV carton

- **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.

7. PATIENT VACCINATION PROCESS

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. A primary course i.e. Dose 1 and Dose 2, of the same vaccine is preferred for effective COVID immunisation.

ATAGI recommends **Pfizer** doses be administered at least 3 weeks or 21 days apart, with a minimum interval between doses of 19 days, while the interval for Moderna doses is 4 weeks (28 days). It is recommended to complete both doses within 6 weeks. ATAGI have released advice about dose intervals in outbreak settings.

The AstraZeneca dosing interval remains at 12 weeks (84 days), unless in an outbreak setting, in which case the above guidance should be considered.

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.

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
  - 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)

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 both the first and second vaccine doses to the patient. Consent should also be obtained prior to **third dose** and **booster doses**.

Proof of vaccination

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

- COVID-19 digital certificate
- Immunisation history statement
- International COVID-19 Vaccination Certificate for overseas travel.

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.

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

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

REPORT AN AEFI

☐ Register for AEMS

Links

Find out about the AEMS

COVID-19 Vaccine Side Effect Checker

Contacts

AEMS 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

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 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

The Pfizer vaccine is more complex to manage within a clinical setting than the 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 three 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.

Prior to vaccination

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.

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 & otherequipment
- Accreditation & other regulatoryrequirements
- Accessibility & cultural safety
- Management of the CP
- Consumables

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.

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.

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:

Description	MMM 1 Service Fee	MMM 2-7 Service Fee
First Dose	$16	$19
Second Dose (same Vaccination Provider)	$26	$29
Second Dose (other Vaccination Provider including other Pharmacies)	$16	$19
Third Dose (for severely immunocompromised only)	$16	$19
Booster Dose	$16	$19

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.

RESOURCES

For more information visit the CVCP Program webpage here.

For assistance regarding payments and claiming, visit the program FAQs page.

More information on how to register a new Service Provider account on the PPA Portal can be found here.

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 integratedclaiming.** 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 8am – 8pm (AEDT).

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

Australian Digital Health Agency Clinician Vaccine Integrated Platform (CVIP)

- **Email:** COVID19Platform@digitalhealth.gov.au

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

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

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

11. Appendix B – Resources and Links

ATAGI clinical guidance on use of COVID-19 vaccine in Australia	https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021
ATAGI immunisation provider guide to obtaining informed consent	www.health.gov.au/resources/publications/covid-19-vaccination-atagi-immunisation-provider-guide-to-obtaining-informed-consent-for-covid-19-vaccine
Australia's COVID-19 Vaccine strategy	https://www.health.gov.au/resources/publications/covid-19-vaccination-australias-covid-19-vaccine-national-roll-out-strategy
Australian Immunisation Handbook	https://immunisationhandbook.health.gov.au/
Australian Immunisation Register (AIR)	https://www.servicesaustralia.gov.au/individuals/services/medicare/australian-immunisation-register
Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG)	https://www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg
Clinician Vaccine Integrated Platform (CVIP)	https://www.digitalhealth.gov.au/healthcare-providers/cvip
COVID-19 Vaccine Administrative System (CVAS)	https://cvas.health.gov.au/vaccineorder
Consent Form for Pharmacies	https://www.health.gov.au/resources/publications/covid-19-vaccination-consent-form-for-covid-19-vaccination
Coronavirus Hotline	https://www.healthdirect.gov.au/coronavirus
COVID-19 Vaccination - Privacy Notice	https://www.health.gov.au/using-our-websites/privacy/privacy-notice-for-covid-19-vaccinations
COVID-19 vaccination decision guide for frail older people, including those in residential aged care facilities	https://www.health.gov.au/resources/publications/covid-19-vaccination-covid-19-vaccination-decision-guide-for-frail-older-people-including-those-in-residential-aged-care-facilities
COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy	https://www.health.gov.au/resources/publications/covid-19-vaccination-covid-19-vaccination-decision-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy
COVID-19 Vaccination Training Modules - including AstraZeneca (Vaxzevria) Module, Moderna (Spikevax) Module and Pfizer (Comirnaty) Module	https://covid19vaccinationtraining.org.au
COVID-19 Vaccine Campaign Resources	https://www.health.gov.au/resources/collections/coronavirus-covid-19-vaccine-campaign-resources

COVID-19 Vaccine Provider Social Media Tiles	https://www.health.gov.au/resources/publications/covid-19-vaccination-covid-19-vaccine-provider-communication-kit-social-media-tiles
COVID-19 Vaccines – Program Landing Page	https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines
Health Professional Online Services (HPOS)	https://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/how-manage-your-details-hpos/using-hpos-messages
Health Workforce Locator – Check your MM Category	https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator/health-workforce-locator
National Vaccine Storage Guidelines 'Strive for 5'	https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5
PBS Approved Suppliers Portal	https://pbsapprovedsuppliers.health.gov.au/
Pharmacy Programs Administrator (PPA)	https://www.ppaonline.com.au/
PRODA (Provider Digital Access) account	https://www.servicesaustralia.gov.au/organisations/business/services/proda-provider-digital-access
Pharmaceutical Society of Australia – COVID-19 Information for Pharmacists	https://www.psa.org.au/coronavirus/
Pharmacy Guild of Australia – resources for pharmacies, available from Services Australia Claiming Provider Agreement Form	https://www.servicesaustralia.gov.au/organisations/health-professionals/forms/hw027
Product and Vaccine consumer information	Vaxzevria (AstraZeneca) https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-01194-1 Spikevax (Moderna) http://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-01968-1 Pfizer (Comirnaty) https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-01092-1&d=20211021172310101
Reporting and managing adverse vaccination events	https://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events
Translation and Interpreting Service	https://www.tisnational.gov.au/
Vaccine Clinic Finder	https://covid-vaccine.healthdirect.gov.au/eligibility