

COVID-19 CACCINATION Onboarding factsheet for pharmacies

Note this factsheet is specific to community pharmacies and should be read in addition to the Primary Care onboarding pack and separate clinical factsheets that are specific to vaccine types.

Version 2 – October 2023

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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
COVID-19	Coronavirus Disease 2019
COVID-19 Vaccine	Collective references to the Spikevax Moderna Bivalent (BA.4-5) 12 years+ (PFS), the Comirnaty Pfizer Bivalent (BA.4-5) 12 years+ (Grey), Comirnaty (Pfizer) for 5-11 years (Orange) and Nuvaxovid (Novavax) vaccines
CVAS	COVID-19 Vaccine Administrative System
CVCP	COVID-19 Vaccination in Community Pharmacy
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
РРА	Pharmacy Program Administrator
PPE	Personal Protective Equipment
PRODA	Provider Digital Access
SF	Service Finder
TGA	Therapeutic Goods Administration
VOC	Vaccine Operations Centre

Onboarding Checklist

Further detail on each will be provided in the following sections.

-	
Complete?	Task
	Does the Pharmacy have an Australian Immunisation Register (AIR) provider number?
	Is your pharmacy ready to report to AIR through either your professional services software or directly via Health ProfessionalOnline Services (HPOS)?
	Do you have an appointment system in place, and can you accept online bookings?
	Have you familiarised yourself with the type of assistance the Vaccine Operation Centre (VOC) can provide?
	Have you completed your registration in 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 'Obtaining Consent & 'COVID-19 Pre-Vaccination Checklist' provided below in Checklists for Pharmacies, to be used for all vaccinations?
	Have you prepared the 'Patient Consent' forms for all vaccinations? (including, where applicable, the special consent form for parents/guardians of children?
	Have you reviewed the 'Post-Vaccination Checklist' for use after vaccine administration?
	Have you reviewed the COVID-19 Vaccination in Community Pharmacies <u>(CVCP Program</u> <u>Rules?</u>
	Have you registered for the CVCP Program via the <u>Pharmacy Programs Administrator</u> (PPA) Portal in order to submit claims for payment?

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). <u>Healthcare providers should check a patient's immunisation</u> <u>history before administering a COVID-19 vaccine</u>. This is an expectation of all health care professionals prior to vaccinating patients.

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

- provider information: provider number, name and contact details
- personal information of the individual vaccinated: Medicare number (if applicable), name, contact details, date of birth and gender
- vaccine information: brand name, dose number and batch number and date of administration
- country of administration (if received overseas)
- COVID-19 vaccine batch number

Reporting timely, high quality and accurate vaccination information ensures that the AIR maintains a complete and reliable dataset to enable the monitoring of immunisation coverage and administration. It also ensures that individuals have a complete record of their vaccinations that can be provided as evidence for education, employment, and/or travel purposes.

Vaccination providers should use the latest version of their clinical software to make sure they meet reporting requirements. The Department will continue to work with Services Australia to help software developers and vaccination providers meet their reporting obligations.

It is important to ensure that this information is accurate prior to reporting to the AIR.

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 <u>Department's website</u>.

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 vaccination encounters to AIR.

Vaccination information reported to the AIR can be viewed within 24 to 48 hours through some professional services software, the AIR site or My Health Record.

Uploading to the 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 professional services 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 there is existing record in the 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 to report subsequent vaccination encounters or until a Medicare registration is completed.

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 <u>website</u>.

Check Immunisation History

Please remember to check each patient's medical history before administering a vaccine, including through your professional services software, the AIR site and/or My Health Record.

ATAGI recommends that patients receiving a COVID-19 vaccination should receive their primary course (i.e. Dose 1 and Dose 2) with 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 and Aged Care <u>website</u>.

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 <u>PRODA account</u>.

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 March 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.

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 <u>Online Claiming Provider Agreement</u> <u>Form (HW027)</u>
- □ Apply for a PRODA account for your organisation and have your staff apply, if needed
- □ If you don't have a software provider or your software provider does not currently report to AIR, register for HPOS.

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.**

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 nonmetropolitan regions, as described in the table below:

Description *For vaccinations administered from 1 July 2023	MM 1 Service Fee	MMM 2-7 Service Fee
COVID-19 Vaccine Administration Payments (from 1 July 2023)	\$27.35	\$30.50
Flag fall Payment (in reach for vulnerable patients) (From 1 July 2023)	\$122.40	

Portal Registration and Claiming

To submit claims under the CVCP Program 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 <u>here</u> 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 and Aged Care of their selection to participate in the COVID-19 national vaccine rollout
- in instances where there has been a full change of ownership and the old pharmacy was participating in the CVCP program, the new pharmacy agrees that, it also the same ATAGI site requirements .

Only the 'Main Authorised Person' (MAP) for the pharmacy account may register the pharmacy for the Program.

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

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 <u>PPA Resources webpage</u>.

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.

Checklists for Pharmacies

GUIDANCE

We have provided a number of checklists to help pharmacies with the day-to-day operation of the vaccination service in accordance with ATAGI best practice guidelines and Commonwealth Department of Health and Aged Care reporting requirements.

These lists are intended as guidance documents only and we encourage you to adapt them to suit your situation.

The following checklists are provided below:

- Obtaining consent & pre-vaccination checklist
- Resuscitation/Anaphylaxis response kit checklist
- Post-vaccination checklist.

Obtaining Consent and COVID-19 Pre-Vaccination Checklist

Discussion checklist for providers to ensure patients are well informed when deciding to receive theCOVID-19 vaccine.

Contraindications, Precautions and Special circumstances provided on the next page.

Tick when discussed/confirmed:		
	Benefits of vaccination	
	Possible risk of contracting/transmitting COVID-19 despite vaccination	
	Requirement for 2 doses in the primary course schedule and recommendation for a booster dose as per current recommendations	
	Need to continue other public health measures (e.g. physical distancing, hand washing, wearing a face mask, COVID-19 testing and quarantine/isolation as required)	
	Safety of COVID-19 vaccines, including current safety investigations into rare conditions (including myocarditis/pericarditis for mRNA vaccines)	
	Management of side effects and seeking medical attention for side effects	
	Adverse events monitoring	
	Reporting of all vaccinations to the AIR	
	Vaccination data will be provided to a 3rd party for claiming purposes as a condition of subsidised access to the COVID-19 vaccine	
	Provide information sheet on the specific vaccine the patient will receive (note there is a special information and consent resource for parents/guardians of children aged 5 – 11)	
	Check for contraindications to COVID-19 vaccination	
	Check precautions for COVID-19 vaccination	
	Check patient details against AIR records. In most cases the same brand should be used for second dose, except if anaphylaxis occurred after the first dose. Check correct dose interval for brand and booster.	
	Check patient Medicare number (or where none provided, seek confirmation from the patient that they do not hold, or are ineligible to hold, a Medicare/DVA card)	
	Confirm eligibility	
	Obtain informed consent either verbally or using written form (ensure you ask the correct consent questions for children aged 5 – 11 years – available <u>here</u>).	

Obtaining Consent and COVID-19 Pre-Vaccination Checklist

Contraindications

- Patients with contraindications to COVID-19 Vaccine Moderna, i.e.
 - Anaphylaxis to a previous dose of COVID-19 Vaccine Moderna, or to an ingredient of the vaccine
- Patients with contraindications to COVID-19 Vaccine Pfizer, i.e.
 - Anaphylaxis to a previous dose of COVID-19 Vaccine Pfizer, or to an ingredient of the vaccine
- Patients with contraindications to COVID-19 Vaccine Novavax, i.e.
 - Anaphylaxis to a previous dose of COVID-19 Vaccine Novavax, or to an component of the vaccine
- Any other serious adverse event that an experienced immunisation provider or medical specialist has confirmed was cause by a previous dose of the COVID-19 vaccine, without another cause identified.

Precautions

- Acute illness, e.g. fever ≥38.5°C
- Bleeding disorder or receipt of anticoagulant therapy
- Suspected immediate generalised allergic reaction to a previous dose of COVID-19 vaccine
- Generalised allergic reaction to any component of the COVID-19 vaccine to be administered
- Prior anaphylaxis to other vaccines or to medications (injectable or oral) where polyethylene glycol or polysorbate 80 could conceivably be the cause
- Known systemic mast cell disorder with raised mast cell tryptase that requires treatment.

Special Circumstances warranting discussion before vaccination

- Pregnancy
- Immunocompromised
- Past history of COVID-19 or ongoing illness from COVID-19
- People with a history of any of the following conditions can receive the Pfizer or Moderna COVID-19 vaccines, but should seek advice from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended.
 - Recent (within the past 3 months) myocarditis or pericarditis (heart inflammation)
 - Acute rheumatic fever (with active heart inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure.

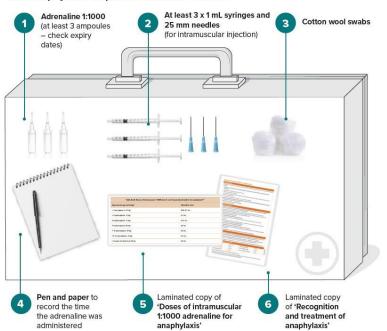
Resuscitation / Anaphylaxis Response Kit Checklist

Recommended checklist for minimum required equipment to be kept on hand in the event of an anaphylactic reaction to the vaccine following administration.

Equipment Required

- □ 3 x adrenaline (1:1000) ampoules which are in date.
- □ 3 x drawing up needles.
- □ 3 x 1mL syringes.
- 3 x 25mm, 22 25 gauge needles for intramuscular injection.
- □ 3 x cotton swabs.
- Pen and paper for documenting the resuscitation events.
 1 x laminated copy of the '*Table. Doses of intramuscular 1:1000 adrenaline for anaphylaxis*' from the AIH.
- 1 x laminated copy of the '*<u>Table. Recognising and treating anaphylaxis</u>'*.

Infographic available at: <u>https://immunisationhandbook.health.gov.au/resources/publications/preparing-an-anaphylaxis-response-kit#</u>





Post-Vaccination Checklist

Tick when discussed

Seat patient within direct line of sight and monitor for 15 minutes post-vaccination. Longer observation may be required for people with precautions to vaccination
Inform recipient of the brand of COVID-19 vaccine they have received
Inform recipient when the next dose is due (if Dose 1 received), that they have completed the primary vaccination course (if Dose 2 received), or when their booster dose is required
Provide vaccine patient with post-vaccination information sheet on the specific vaccine that the patient received or the Information for parents and guardians:
Document administration of COVID-19 vaccines (including correct brand) in AIR and in local patient record
If applicable, encourage patient to book in second primary dose or booster dose while waiting.