



COVID-19 Primary Care Vaccination Program

ONBOARDING PACK

17 January 2024 - Version 14

This version of the Onboarding Pack replaces previous versions as it contains additional information as well as updated numbers and links.

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Version 2 – 14 March 2021 Version 8 – 7 March 2022

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Version 4 - 28 June 2021 Version 11- 1 September 2023

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Site Registration

GUIDANCE

The **COVID-19 Vaccine Administrative System (CVAS)** has been developed to manage all logistical elements of the COVID-19 Vaccination Program (Program) and allows a point in time view of the COVID-19 vaccines across the delivery chain. This includes receipt of the vaccine stock at sites, vaccination of patients, and subsequent monitoring for adverse reaction.

To formalise your participation in the Program, you must first register to obtain access to CVAS.

Sites can login to CVAS to complete registration of their account for the Program.

You may receive emails from various areas within the Department of Health and Aged Care (the Department), and we recommend you save these email addresses to make sure you receive all important correspondence.

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

- 1. Your 8 character 'Cohort Registration Code'. This code is contained within your invitation letter.
- 2. Your unique 'Site Registration Code'. All sites will receive their unique individual code via an email from no-reply@cvas-mail.health.gov.au, which will also include a link for you to follow to access the CVAS registration page.

To register with CVAS

- Follow the link within your site registration code email and enter in your Cohort Registration Code and Site Registration code.
- You will then be prompted to create a password and confirm your site details. These details have been pre-populated from your expression of interest.
- You will be asked to provide additional information that will be used to link your site to all other components of the roll-out – including to your booking systems and stock delivery.
- Complete the relevant **Site Readiness Checklist and Declarations** (including for all vaccines your site will be administering). Once you have completed the declarations, you are registered to participate in the Program and can place your first vaccine order.

All details provided to the Department will be used for the purposes of administering the 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.

Accessing CVAS after Registration

As part of the CVAS registration, you will need to create a password and will be advised of a username in the format site1234.gp@cvas.health or site1234.ph@cvas.health.

Use this username and password to log onto CVAS.

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

If any of the details you provided when registering for CVAS change, please log back into CVAS and update these details.

The details in CVAS are used to communicate critical information relating to the vaccine program, ordering, and reporting. It is important the contact details in CVAS are up to date so sites do not miss any program updates that may occur.

You must use CVAS for all ordering and reporting that is required for participation in the Program:

- create orders according to your site's fortnightly ordering schedule and allocation;
- report at the time they arrive that you have accepted vaccine deliveries (Delivery Acceptance Reports due as soon as possible on the day of receiving the delivery);
- complete Vaccine Stock Management Reports every week by Friday 9pm;
- submit Wastage Reports for wastage of 10 vials (or 100 doses or more of single dose pre-filled syringes) or more in a single event (less than this is reported in weekly Vaccine Stock Management Reports) within 2 hours of the incident occurring; and
- requests to commence or remove any vaccine products.

More detail on the use of CVAS and the reporting requirements can be found in Section: Stock Management.

How we use and disclose information from the CVAS

The Department will use the information collected from your EOI to:

- create and populate an account in CVAS
- verify the type of Site Identifier that is required, and to generate the Site Identifier for the vaccination provider (this may include using your ABN provided to obtain the relevant PIP number or AIR provider number from our other systems)
- generate and send on-boarding materials and access codes to you, to allow you to register your Users and use the CVAS
- operate CVAS, including storing and displaying information about your site, and its Users and Distribution Contacts, so that the information does not need to be provided a second time.

We will disclose logistics (including site details and details about orders for vaccine and related products) and the contact details for Distribution Contacts, to our Logistics and Distribution Partner, who will deliver the vaccines and related products to your site.

We may disclose site information to other entities, such as State or Territory governments, for the purposes of facilitating or monitoring the vaccine rollout.

Site information and clinic contact details are provided to the Australian Digital Health Agency (ADHA) to assist providers to register in Provide Connect Australia. This enables providers to directly manage and update their clinic details on the Service Finder, operated by Healthdirect Australia. Site information data (excluding any personal information) is stored by Healthdirect Australia in the National Health Services Directory (NHSD), which may be disclosed for non-commercial uses to other entities in the healthcare sector, such as Primary Health Networks or State and Territory governments. Use of the NHSD is governed by the **NHSD Terms of Use**.

In order to monitor the COVID-19 vaccine rollout, we transfer site-related information such as the site type (i.e., General Practice or Pharmacy) and site location, vaccine and vaccine product information, from the CVAS into a Vaccine Data Solution (Data Solution). However, personal information about Users and Distribution Contacts (including contact details) that are stored in the CVAS are not transferred to the Data Solution. The Data Solution is a software solution hosted in Australia that we use to monitor coverage and logistics for COVID-19 Vaccines. The Data Solution generates reports and statistics that do not contain any personal information.

TO DO

- □ Follow the link in your CVAS invitation email to register your site and complete the online **Site**Readiness Checklist and Declaration Form.
- ☐ Save the below addresses as email contacts:
 - COVID19VaccineOperationsCentre@Health.gov.au
 - no-reply@cvas-mail.health.gov.au
 - No-Reply.Vaccine@health.gov.au

Training

GUIDANCE

Healthcare providers who are immunisers will need to ensure that their professional immunisation training, as required by jurisdictional and professional standards, is up to date.

Following the closure of the COVID-19 Vaccination Training Program (CVTP) on 1 October 2023, the Department of Health and Aged Care have published two new resources to assist vaccine providers. These include a **COVID-19 Vaccine Reference Guide** and the **complete CVTP module set**. These documents supplement existing COVID-19 reference resources.

COVID-19 reference resources*

- The COVID-19 Vaccine Reference Guide is a free, downloadable resource designed to support vaccine
 providers to manage the unique storage, handling and administration requirements of COVID-19
 vaccines.
- The CVTP module set comprises all the 18 vaccination training modules and their associated resources.
- The COVID-19 Vaccines in Australia provides key differences between each
 COVID-19 vaccine approved for use in Australia as per the Australian Technical Advisory Group on Immunisation (ATAGI) guidelines.
- ATAGI Recommended COVID-19 Vaccines Doses poster outlines the COVID-19 vaccine doses recommended for each age and population group.

The Vaccine Operations Centre (VOC) on 1800 318 208 or **COVID19VaccineOperationsCentre@Health.gov.au** will remain available for clinical questions regarding COVID-19 Vaccine administrations.

^{*}Please ensure you refresh your saved weblinks to the COVID-19 resources, as the documents continue to be updated regularly.

Digital Services

Australian Immunisation Register (AIR)

Sites are encouraged to check each patient's medical history before administering a vaccine, including through the AIR, and/or My Health Record.

It is mandatory under the *Australian Immunisation Register Act 2015* (AIR Act) to report vaccinations to the AIR. Information on the AIR can only be collected, used and disclosed for the purposes in the Act 2015 and is protected under the Privacy Act 1988. **Every COVID-19 vaccine should be reported to the AIR** within 24 hours and no later than 10 working days after vaccination.

To ensure accurate and complete reporting of vaccination information to the AIR, providers must provide the following information:

- provider information: provider number, name and contact details;
- **personal information of the individual vaccinated:** Medicare number (if applicable) and the individual patients reference number, name, contact details, date of birth and gender;
- vaccine information: brand name, dose number, batch number and date of administration;
- country of administration (if received overseas); and
- 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 third-party 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.

You may use any of the following digital services to report to the AIR:

- third party software this is the preferred option, and several commercial products are already integrated with the AIR.
- the AIR site via Health Professional Online Services (HPOS) this is a free secure way for providers to interact electronically with Services Australia, including to submit immunisation encounters to AIR.

It is important that the **Department** has all AIR IDs used by your site to report vaccine administrations to the AIR. **Please let the VOC know if your AIR provider number changes or you have additional ones at your site.**

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 TGA, and
- if an individual received the vaccination on or after 1 March 2020.

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

Recording non-Medicare eligible vaccinations in AIR

Where an individual does not have an Individual Healthcare Identifier (IHI) or a Medicare number, vaccination information **must** still be reported to the AIR.

- 1. **Search for individuals in the AIR** to create a new AIR record (check existing records to avoid creating a duplicate record and include as much detail as possible in new records to allow for future matching).
- A Supplementary Identification Number (SIN) record will be created in the AIR, which can be used for subsequent immunisation encounters or until a Medicare registration has been completed PRODA or Provider Digital Access.

PRODA is an authentication tool used by Services Australia to allow individuals and organisations to interact with their system.

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

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 locations reporting vaccinations to the AIR must ensure they are correctly linked to the location where they will be providing vaccinations in PRODA. 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.

Updating your details with Medicare – for Medicare eligible sites

Your Medicare provider number is used to claim, bill, refer or request Medicare services. You will need more than one provider number if you:

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

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

Service Finder and Online Bookings

Service Finder operated by Healthdirect Australia, provides a single portal where people can access all COVID-19 vaccination providers across Australia.

All approved COVID-19 vaccination sites must be listed on Service Finder to ensure timely and transparent access for all people living in Australia. Sites are encouraged to accept bookings from all eligible people where supply allows, and demand exists.

The Department will arrange the initial publication of your site's details on the Service Finder within 2 weeks of placing your first order.

Please see the Service Finder and Online Bookings Factsheet for information about how to maintain your site and COVID-19 vaccine service information.

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- □ Contact your software provider to find out if you can automatically report to AIR, if an update to your software is required, and if you need a PRODA account
- ☐ If you do not have a software provider, register for access to the AIR site (through HPOS)
- □ Provide all AIR ID's to the VOC
- ☐ Apply for a PRODA account if you need to
- □ Update your Medicare provider number details via HPOS
- □ Read the Service Finder and Online Bookings factsheet

Eligibility & Clinical Considerations

GUIDANCE

Primary Course (2 doses)

All individuals aged 5 years and over in Australia are eligible to receive a primary course of COVID-19 vaccination. Additionally, some individuals aged 6 months – 4 years are eligible for a primary course of COVID-19 vaccination. A primary COVID-19 vaccination course consists of 2 doses for individuals without severe immunocompromise.

The vaccine type individuals receive depends on many factors (including age) and the current advice relating to vaccine suitability. Further advice on vaccine suitability is available on the Department's **website** and in the **Vaccine Comparison Poster**.

Patients may choose to book an appointment with their preferred healthcare professional to discuss their circumstances and get advice on which vaccine type is best for them.

Third primary dose

The Australian Technical Advisory Group on Immunisation (ATAGI) has recommended that individuals aged 6 months and over who are severely immunocompromised should receive a third primary course dose of COVID-19 vaccine, 2 months after their second primary dose. A list of conditions where this is recommended and further advice relating to vaccine suitability is available on the Department's website.

	First 2023 COVID-19 dose (February 2023 guidance)*		Second 2023 COVID-19 dose (September 2023 guidance)*	
Age	At risk#	No risk factors	At risk#	No risk factors
<5 years	Not recommended	Not recommended	Not recommended	Not recommended
5-17 years	Consider	Not recommended	Not recommended	Not recommended
18-64 years	Recommended	Consider	Consider if severe immunocompromise^	Not recommended
65-74 years	Recommended	Recommended	Consider	Consider
≥ 75 years	Recommended	Recommended	Recommended	Recommended

- *XBB.1.5-containing vaccine preferred for all doses. For eligible children aged 6 months to 4 years, use Pfizer Original 6 month - <5 year formulation (maroon cap) as the only available formulation for this age group.
- *Includes those with a medical condition that increases the risk of severe COVID-19 illness (refer to
 the Australian Immunisation Handbook COVID-19 Chapter) or those with disability with significant
 or complex health needs or multiple comorbidities which increase the risk of poor outcomes from
 COVID-19.
- ^For details, refer to the ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised

Patients may choose to book an appointment with their preferred healthcare professional to discuss their individual circumstance.

Vaccination sites are encouraged to continue to support access to vaccination for priority groups such as older people, residential aged care and disability care residents, those with underlying medical conditions, Aboriginal and Torres Strait Islander people, and those who are housebound.

Please refer to the Department of Health and Aged Care website for up-to-date advice on vaccine eligibility. Vaccination after testing positive for COVID-19

There is minimal benefit from having a COVID-19 vaccine dose soon after infection. Much of the population are currently well-protected against severe disease from COVID-19 due to 'hybrid immunity', a combination of protection from previous vaccination and prior infection, which provides protection against severe COVID-19.

However, ATAGI notes that current SARS-CoV-2 testing rates have dropped significantly, so from a practical perspective it is challenging for many individuals to know if they have had a recent infection. Where previous infection details are unknown, it is appropriate to proceed with a COVID-19 vaccination for eligible people.

Additionally, a person may be vaccinated earlier than the recommended interval in exceptional circumstances, such as before starting an immunosuppressant, before overseas travel or if someone cannot reschedule vaccination easily (such as in an outreach vaccination program).

There are no additional safety concerns for individuals receiving a COVID-19 vaccine who may have had undetected SARS-CoV-2 infection within the past 6 months.

Co-administration of COVID-19 vaccination and a flu vaccine

A COVID-19 vaccination and an influenza vaccination can be administered at the same time and may be provided to patients during the same attendance. Further information regarding payment for co-administration can be found in the applicable attachments.

Checking Immunisation History and Proof of Vaccination

Healthcare providers should check each patient's immunisation history (through AIR and/or My Health Record) before administering any COVID-19 vaccine. Vaccination information can be viewed within 24 to 48 hours of vaccine administration through clinical information software, professional services software, and/or My Health Record.

The AIR provides three options for providing evidence of COVID-19 vaccinations:

- COVID-19 Digital Certificate for individuals who have received all required doses of a vaccine approved for use in Australia or recognised by the TGA.
- Immunisation History Statement displays all vaccinations and medical contraindications, including for COVID-19, that an individual has had that have been reported to the AIR.
- International COVID-19 Vaccination Certificate for individuals, with a valid passport, who have received at least one dose of a COVID-19 vaccine.

Individuals can access their proof of vaccination online using their Medicare online account through myGov or their Medicare Express Plus App.

Patients are to be advised that their vaccination details must be reported to the AIR. This will include some <u>personal information</u>. For COVID-19 vaccines, the Department will use de-identified immunisation information to report on the rollout.

Consumers, including individuals without a Medicare card, can also request their proof of vaccination by calling the **Australian Immunisation Register Helpline** on 1800 653 809. It can take up to 14 days to arrive by post.

Please remember that you can print a patient's immunisation history statement or COVID-19 digital certification from the AIR website if they ask for proof of immunisation. This is especially pertinent for patients who may not have access to a smart phone, who are unable to print this themselves, or those who do not have a Medicare card.

The **Translating and Interpreting Service** (TIS National) can provide information for consumers in English and other languages about obtaining proof of vaccination.

The Australian Government in collaboration with states and territories is monitoring the data for COVID-19 Medical Exemptions. Fraudulent or inappropriate COVID-19 Medical Exemptions (which do not meet the guidelines) will be reviewed and may result in Health Professionals being investigated by the appropriate regulatory body or face criminal charges.

Consent

As with all vaccines, informed consent is required before administering any COVID-19 vaccine dose and providers are required to document consent in a patient's medical record. Verbal or written consent is acceptable.

Vaccinators and support staff in primary care settings can access interpreters from <u>TIS National</u> to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

The **Australian Immunisation Handbook** can assist vaccination providers with discussions around consent and any medical contraindications or issues that may arise in your conversations with patients.

Adverse Events

Sites are encouraged to follow their usual process to report any Adverse Events Following Immunisation (AEFIs) to the relevant State or Territory Public Health Unit.

The 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 1300 MEDICINE on 1300 633 424.

Where a patient experiences an adverse event following the administration of a COVID-19 vaccine, these must be reported, and standard adverse event processes should be followed. This includes reporting to the TGA, as well as any relevant jurisdiction reporting requirements. More information about the possible side effects of COVID-19 vaccines are available at HealthDirect website.

Delivery Models

GUIDANCE

Sites can administer all COVID-19 vaccines currently approved for use in Australia and part of the Australian COVID-19 vaccination program. Most COVID-19 vaccines approved by the TGA come in **multidose** vials, however Moderna have some vaccines that come in **a single dose pre-filled syringe**.

Any mRNA vaccines that have been thawed **cannot** be re-frozen.

Please refer to the Vaccine Comparison Poster for the current vaccines available in the program.

The COVID-19 vaccines approved by the TGA have different clinical considerations and complexity for managing within a clinical setting due to the specific requirements for storage, handling and cold-chain.

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.

The Vaccine Storage Guidelines 'Strive for 5' provides information and advice for vaccine storage management for Australian immunisation service providers, from medical practices to large hospitals, clinics and outreach providers.

'Strive for 5' refers to 5 degrees Celsius (°C) — that is, the point midway between $+2^{\circ}$ C and $+8^{\circ}$ C which is the temperature range recommended for vaccine storage. Many vaccines are damaged or destroyed at temperatures outside this range.

These guidelines:

- describe the best approach to ensure that clients receive effective and potent vaccines
- describe the 'cold chain' and provide advice on what should be done in the event of a cold chain breach
- include resources such as checklists, charts, posters and stickers.

Prior to vaccination

Processes should be developed to ensure that patients are booked in to receive the correct vaccine (see Service Finder and Online Bookings Factsheet).

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.

The person responsible for administering the vaccine should **re-check** which vaccine the individual is to receive prior to administration and that the dose for the vaccine is correct. Check the individual's vaccination record via the AIR to confirm if they have previously received a dose of COVID-19 vaccine, so that the same brand is administered (if required) within the appropriate interval.

Patients must be given/directed to the appropriate after-care sheet for their individual vaccine, ideally with written instructions for their next appointment date and time if appropriate.

Vaccine preparation area

If the same fridge is to be used for more than one vaccine, store the clearly labelled vaccines in separate areas of the fridge i.e. different shelves within the fridge with colour coded signage.

Use clearly labelled separate preparation areas for each vaccine.

Once the vaccines have been drawn up, transfer them to the administration area specific to that vaccine.

There must be regular clinical oversight to ensure that the correct preparation and drawing up process is applied in relation to each vaccine, and the dose preparation and drawing up process for the relevant vaccine is checked by a senior and experienced clinician at the start of each shift.

Off-site Vaccinations

Sites may undertake off-site vaccinations such as pop-up clinics, in-reach/out-reach clinics, as well as home visits within their existing dose allocation.

The ATAGI issued a statement on considerations for establishing drive-through COVID-19 vaccination sites.

Information on administering COVID-19 vaccines off-site is available on the Advice for Providers webpage, and all vaccine providers are encouraged to familiarise themselves with their responsibilities in administering these clinics, including (but not limited to):

- meeting all legislative and program requirements.
- ensuring appropriate clinical governance and patient safety; and
- maintaining vaccine integrity and cold chain (including ensuring that thawed mRNA vaccines in multidose vials (MDVs) do not exceed the transport time limit, time limit does not apply to Novavax or Moderna single dose, pre-filled syringes.

Please note, all vaccination providers who choose to administer COVID-19 vaccines off-site retain all legal responsibility for ensuring staff, patient, and community safety.

Please consider if your site has the appropriate indemnity insurance to undertake activities off-site.

When administering vaccines off-site, be aware of any applicable storage and handling considerations, including those for pre-drawn doses, for COVID-19 vaccines. More advice is available on the COVID-19 vaccine allocations, storage and handling **webpage**.

TO DO

Plan for how your clinic will operate vaccination sessions separated by time or space.

Vaccine Administration Errors

GUIDANCE

Vaccine Administration Errors

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current guidance outlined in the **Australian Immunisation Handbook COVID-19 Chapter**, including where guidelines have recently changed. **If a VAE occurs at your site, please contact the VOC to inform them**. Once they have received all the relevant details relating to the incident, they will review and provide advice relating to the incident.

The Department works closely with sites, including if they have not complied with requirements of the Program due to genuine mistakes. Matters of non-compliance by healthcare providers and vaccine mismanagement are taken very seriously. Where there are patient safety concerns or non-compliance with the Program, appropriate action will be taken. When Sites confirm/acknowledge the declarations to participate in the Program, the site has committed to having processes and policies in place prior to the commencement of administering COVID-19 vaccines. The Department reserves the right to review, pause and/or withdraw any site from participating in the Program for suspected non-compliance to requirements outlined in the site readiness and vaccine declaration form. Where serious non-compliance is substantiated, a site will be permanently removed from participating in the Program.

Ways to prevent VAEs include:

- Check the Australian Immunisation Register (for previous vaccine doses, brands, and age)
- Check age of patient and eligibility for vaccination & vaccine type
- Check the manufacture (batch) expiry date of the vaccine (including any extensions that may apply)
- Check the thaw expiry date of the vaccine (for mRNA vaccines only)
- Keep up to date with the latest ATAGI guidance

The **ATAGI clinical guidance on COVID-19 vaccine administration errors** provides advice on the management of a range of possible COVID-19 vaccine administration errors, including when a replacement (repeat) dose is recommended and steps a vaccine provider should take when a VAE occurs.

Potential cold chain breaches including those that may relate to a vaccine administration error should be reported to the VOC using the **Cold Chain Breach (CCB) reporting form**.

Stock Management

GUIDANCE

Clinics 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.

Ordering Stock

Each site is allocated a maximum fortnightly allocation per vaccine type (allocation details are located within the ordering tab in CVAS).

It's important that all participating sites manage their vaccine stock. You can do this by:

- skipping orders and only ordering when you need to (you do not need to order every fortnight);
 and/or
- ordering less than your maximum allocation, and/or
- transferring excess stock in line with the COVID-19 Vaccine Transfer Policy.

CVAS requires sites to complete their most recent stock management report prior to placing their next order. CVAS also requires sites to complete their most recent vaccine delivery acceptance report for that vaccine type prior to placing their next order.

All orders are due by midnight Friday, for delivery the following fortnight.

If your site is administering more than one COVID-19 vaccine, you will be able to make **separate orders for each vaccine**. To place an order for a certain vaccine type, you **must** first complete the relevant vaccine Site Readiness Declaration.

Deliveries will arrive during business hours between Monday to Friday on or before the delivery date indicated at the time of placing your order. Orders can be changed or cancelled through CVAS up to 7 days in advance of the Requested Delivery Date (RDD). If you wish to make a change outside of this timeframe, you will need to contact the VOC. Deliveries are not made on weekends or public holidays.

Consumables

Consumables will be delivered separately to your vaccines, as the cold chain requirements of vaccines cannot be compromised. You may receive your consumables orders together, please ensure you are aware of which consumables are for which vaccine product.

Under the COVID-19 Vaccination Program, the Department monitors the ordering and distribution of COVID-19 vaccines and consumables across the country.

It is recommended that you:

- Review your current consumables holding and only re-order stock you reasonably expect to use;
- Ensure that any consumables ordered via CVAS are only used for the COVID-19 Vaccination Program;
 and
- Only dispose of COVID-19 Vaccination Program waste in the provided sharps bins.

If you do not require consumables, you are able to order vaccines separately in CVAS.

When entering how many doses you require in an order for 'Vaccine and Paired Consumables' you will see
an option to select a 'Vaccine Only' checkbox. Selecting this checkbox will allow you to place your order for
vaccines without paired consumables.

- Alternatively, if you do not select the 'Vaccine Only' checkbox, you are able to order <u>fewer</u> than the default maximum number of consumables associated with that vaccine order.
- You can reduce the number of packs of each paired consumable item by clicking on the pencil icon when hovering over the consumables item. Type in a smaller quantity of packs needed, or zero (0) if you do not require any, and then hit Save.

Please note: You may not receive the same brand/type of consumable with every order. If there are any occasions of limited stock, a clinically appropriate/comparable consumable may be substituted until stock has been replenished.

Orders requiring approval

If you are placing an order in CVAS when you have a large amount of vaccine stock on hand, your order will require approval from the Department. You will be requested to provide a reason why you require large amounts of stock to support the order request. The primary contact identified in CVAS for your site will receive an email from CVAS advising if your order has been approved or rejected. If your order is approved, it will retain the RDD that was displayed at the time of placing the order.

Alternatively, if you have a large amount of stock on hand at your site, you may receive a **warning message** reminding you to only order what you need. You may continue to place an order in these circumstances but please consider how you will manage your site's stock to minimise wastage.

Requesting changes to your site's access to vaccine products

Sites can submit requests to activate, reactivate or deactivate access to one or more vaccine products directly through CVAS.

To submit a request, log into the CVAS portal, navigate to the 'Manage Account' tab and click the 'Update Vaccine Access' button and follow the prompts.

To help you easily identify what vaccine products you currently have access to, when submitting a request there is a 'View Existing Vaccine Access' button. This button can be clicked to open a new tab, showing a summary of all vaccine products you are currently approved to order.

If you select to deactivate access to a vaccine product, it means that you are withdrawing from ordering the selected vaccine product. You must have **no stock on hand** of the vaccine type to be able to submit a request. You will not be able to administer any doses, receive stock transfer from other sites, or complete any required reporting including Delivery Acceptance, Stock Management and Wastage reporting for the withdrawn vaccine product.

Once you have completed all the required information the request will be sent to the Department for review. The primary contact will be notified of the outcome of the request by email. You can check the status of requests at any time through the 'Manage Account' tab under 'My Recent Vaccine Access Requests'.

CVAS Delivery Acceptance and Stock Management Reporting

As a requirement for participating in the COVID-19 vaccination program, all sites are required to complete delivery acceptance, stock management and wastage reporting in the COVID-19 Vaccine Administration System (CVAS).

- **Delivery acceptance reports** are due on the day of receiving your vaccine delivery, no later than 9pm local time on the day of delivery.
- Stock management reports are due every week no later than 9pm local time Friday.

• Wastage reports are due within two hours of any wastage incident involving 10 or more vials of a vaccine product or 100 or more single dose, pre-filled syringes (i.e. 10 or more boxes) for vaccines that are delivered in pre-filled syringes.

CVAS requires your delivery acceptance reports to have been submitted **before new orders can be placed**. This will assist in keeping program reporting as up to date as possible and will support upcoming functionality in CVAS, that will pre-populate your correctly entered delivery acceptance information into your weekly stock management reports.

Delivery Acceptance

Reports must be submitted by 9pm on the day of delivery. mRNA vaccine Delivery Acceptance Reports will include a section for you to add the date your doses began to thaw and the subsequent thaw use by date.

When undertaking the acceptance process, you will need to:

- follow the instructions from the delivery partner (e.g. check the temperature logger for indications of a cold chain breach);
- check the defrost date and time on the vial packaging or the box containing the vials of the mRNA vaccines, the thaw use by date, and the vial expiry date for all vaccine types;
- move vaccines to the correct cold chain conditions as soon as they are received;
- record the fridge temperature when the vaccines are finally stored;
- check the package for signs of damage or tampering; and
- visually inspect the internal contents of the package to ensure delivery is correct.

DHL Deliveries

DHL shippers contain between 1 and 3 foam inserts.

Shippers can be kept for a maximum of 30 days before being returned via DHL couriers. The temperature probe which arrives with the thermal shipper is re-useable and **must be sent back** with the shipper.

Cold Chain Packaging Collection

When drivers deliver vaccines, they are not always able to stay for the pick-up of the cold chain packaging. If the driver is unable to collect the packaging, you can arrange collection by emailing: dhlcontroltower@dhl.com

Managing Stock

To ensure vaccine stock is appropriately managed and accurate reporting is available to support the Program, sites are required to report stock levels via CVAS.

It is mandatory for all sites to complete a *Vaccine Stock Management Report* weekly for all vaccines they are configured to administer. The report captures:

- details of stock on-hand;
- the number of doses administered to patients during the week;
- any transfers to or from other sites; and
- any wastage of doses from the stock.

Wastage can be recorded in the week that it occurs, or the week immediately thereafter if the wastage occurs late on a Friday.

Please ensure Stock Management Reports <u>are accurate</u>, and include all doses administered, delivered, transfers and/or wasted in the week. Your usage for the week and your current Stock on Hand levels should

equate to the number of vaccines you had on hand at the start of the week. If there is a discrepancy you will need to explain why this has occurred.

Sites need to complete a *Vaccine Stock Management Report* in CVAS no later than <u>9pm (local time) Friday every week</u>. This report will include questions for **each vaccine that your site is configured to administer**, even if you have not administered or received any doses of that vaccine in the reporting period. The report is not submitted until sites have completed reports for all vaccines they are configured to administer.

Note: CVAS requires you complete your latest Vaccine Stock Management Report before you can place a new order for any vaccine.

Please note: it is a criminal offence under section 137.1 of the *Criminal Code Act 1995* to provide false or misleading information to the Australian Government.

CVAS draft Stock Management Reporting feature

You will be able to save your Stock Management Report as a draft after entering the required information for each vaccine type your site is configured to administer.

Any draft report will remain available for 48 hours from when it was started, or until 9pm local time Friday (whichever is earliest). If not completed by this time your draft will be discarded, and a new report will need to be started.

Your draft Stock Management Report is not finalised until it has been fully completed for each vaccine type and submitted.

The completed report will retain the previously entered data in the system. Please ensure when finalising future Stock Management Reports, that you review and update any of this draft information if it has since changed and submit your report no later than 9pm local time each Friday.

Stock Transfers

All participating primary care sites may transfer vaccines to other participating primary care sites.

Both the transferring and receiving site must be configured for the vaccine type that is being transferred and open vials cannot be transferred between sites. Moderna single dose, pre-filled syringes are the only pre-filled syringes that are allowed to be transferred to sites, provided they have not been opened. It is recommended these are transferred in their original box. The Vaccine Operations Centre does not need to be notified or approve of transfers between participating sites.

Further information regarding transferring vaccines between primary care sites is available here.

It is critical that cold-chain storage and handling requirements for the vaccines are maintained at all times and are not breached during the stocktake or transfer process.

Excess or Expiring Stock

Vaccine stock can be transferred between sites to assist with minimising vaccine wastage and repositioning stock where it is needed most. If stock is unable to be redistributed locally, please contact the VOC who may be able to assist with redirection of:

- 10 or more vials of mRNA vaccines (Pfizer or Moderna)
- 10 or more vials of Novavax.

The VOC may be able to assist with redirection of Moderna pre-filled syringes.

Please note, the longer the shelf life of your vaccine the more likely they will be able to assist with redistribution.

Please make sure any wastage of expired stock is reported within CVAS.

Wastage

Sites should utilise the opportunity to vaccinate patients wanting a COVID-19 Vaccine at the time of the request. While we encourage sites to reduce any wastage of COVID-19 Vaccines, we understand that this is not always possible, due to vials being multi-dose vials and the lower demand of vaccination rates.

It is ok to open a multi-dose vial to vaccinate one patient.

Wastage could occur through multiple situations:

- doses left over at the end of the day;
- damaged vials;
- expiry (either thaw use by dates or manufacture expiry date); or
- a potential/actual cold chain breach.

Cold chain breach

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 at the appropriate cold chain temperature, and the VOC should be notified. If vaccines are stored or handled outside the conditions listed, complete the **Cold Chain Breach (CCB) reporting form** and email it to

COVID19VaccineOperationsCentre@health.gov.au. Quarantine the vaccines within appropriate cold chain requirements, and label them with 'Do not use, do not discard' until you have been provided with advice by the VOC.

The Department may be able to replace the damaged stock based on availability of stock and the individual circumstances for the wastage incident.

Reporting

The single reporting mechanism for reporting all wastage incidents is CVAS. The definition and threshold for being required to report 'major wastage' is 10 or more vials of a single vaccine type in a single incident or 100 or more single dose, pre-filled syringes (i.e. 10 or more boxes) for vaccines that are delivered in pre-filled syringes. You must report any wastage of 10 or more vials in one incident via the Wastage Report in CVAS as soon as possible and at least within 2 hours of the incident.

Wastage less than 10 vials in a single incident or less than 100 or more single dose, pre-filled syringes (i.e. less than 10 boxes) for vaccines that are delivered in pre-filled syringes can be reported through the **Weekly Vaccine Stock Management Report.**

You must complete your Stock Management Report no later than 9pm local time each Friday.

Disposal

Vaccines that are considered wastage (either due to expiry, damage, cold chain breach, or being excess vaccines) must be disposed of in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheets for the COVID-19 vaccine type being disposed of. <u>Vaccines</u> cannot be disposed of in the sink, toilet, or disposed of through the regular garbage disposal processes.

Blocked Sites

Sites that meet the metrics of high current stock on hand and relatively low administrations as a proportion of their orders (considering stock expiry) may have their earliest next order date changed to prevent them from ordering. If you have had your earliest next order date changed, you will not be able to place an order for this vaccine until your excess stock on hand levels have reduced.

It will not impact the other vaccines that you are ordering and administering. The Department will continue to review your stock levels to ensure you do not have excess stock on hand.

If you have queries regarding this, please contact your Primary Healthcare Network (PHN) or the VOC at COVID19VaccineOperationsCentre@health.gov.au

Additional Orders

If you require additional doses you can submit a request for an additional order directly in CVAS.

A link will be visible on the Orders tab stating 'If you are running low on stock and require additional doses, you can Request an Additional Order'. By clicking the 'Request an Additional Order' link you can enter your requested vaccine product, number of doses and whether you require paired consumables to match the requested order.

Please note, if you have not yet placed an order for the requested vaccine product in your regular order cycle, you will be redirected instead to place an order through the New Order button in the Orders tab.

At the time of placing the request you will be shown your allocation, your most recently reported stock on hand, and the total number of doses for orders that are yet to be delivered to your site for that vaccine product. This will provide you with an overview that will assist you in determining how many additional doses your site is seeking at that time.

You will need to provide a reason why you require the additional doses.

Once you have submitted your request, the Department may contact you if your additional order request can be fulfilled by redirection of excess vaccine stock from a nearby site. Redirection of excess doses helps to collectively minimise wastage across the country.

If excess doses are not available nearby, the Department will assess your request and either approve or reject the additional order. Assessment will take into consideration vaccine usage at your site, availability and equitable distribution of supply around Australia. If approved, an order will be created for you.

If your request is unsuccessful, you can refer to your CVAS account for details on when your site is next able to place an order for the requested vaccine product, try submitting a request at another time, or try requesting an additional order for an alternative vaccine product.

You will receive an email from CVAS advising you of the outcome of your request for an additional order, and you can check the status of your additional order request at any time through 'Recent Requests for Additional Orders' under the Orders tab.

Please note that every effort will be made to accommodate the request for additional doses, however it does not guarantee you will receive a delivery of the chosen product in the requested week.

If you need any assistance completing your CVAS reporting or have any questions, please contact the Vaccine Operations Centre (VOC) on 1800 318 208 or via email at: COVID19VaccineOperationsCentre@health.gov.au

Communications

GUIDANCE

Provider Kit

To support vaccination providers, the Department has developed a Provider Kit. This kit can be found on the Department's **website** and will be updated as required.

Free Interpreting Service

The Free Interpreting Service aims to provide equitable access to key services for people from culturally and linguistically diverse (CALD) backgrounds, with limited or no English language proficiency.

Medical practitioners and pharmacies can book an interpreter to assist with their patient consultations using most third-party video conferencing platforms. These platforms may include Healthdirect Video Call, Skype, WebEx, and Zoom. Vaccine Providers will need to register for a TIS code to use the Free Interpreting Service.

You can register with TIS National online.

Primary Care Bulletins

The Department distributes regular bulletins (or ad-hoc as required) to primary care providers via PHNs to ensure you have the most up to date information. Please contact your PHN, the PPA or Relationship Manager if you are not receiving them.

ATAGI Advice

Read more about the latest ATAGI advice, resources and other information for COVID-19 vaccination providers on the Department's **website**.

Social Media

Follow the Australian Government Department of Health and Aged Care on social channels for updates:

- Facebook
- Instagram
- Twitter

Compliance & Quality Assurance

GUIDANCE

The Department takes allegations of Program and Medicare non-compliance by participating sites and health care providers very seriously and all tip-offs will be reviewed in accordance with the Department's compliance assessment procedures. The Department may pursue a range of responses including education, review, audit and investigation into breaches of Australian laws.

Community Pharmacy (CP) assurance is now aligned with all Program quality and assurance activities under the one framework.

The Department reserves the right to review, pause and/or withdraw any sites from the Program where suspected non-compliance of the requirements outlined within the vaccine declaration form and ATAGI site requirements have been investigated and the actions deemed non-compliant. This includes charging patients for COVID-19 related services.

All clinical and non-clinical staff participating in the Program are required to adhere and consent to the guidelines as outlined within the vaccination declaration form and ATAGI site requirements.

Reminder - it is a criminal offence under section 137.1 of the *Criminal Code Act 1995* to provide false or misleading information to the Australian Government.

Receipt of a complaint

A complaint or tip-off against a site must disclose the behaviour or conduct that would fall short of the Program requirements, standard of care and diligence reasonably expected by you or your site to maintain when participating in the Program. The complaint must relate to medical professional standards and/or Program requirements that have been set out in the on-boarding (or as otherwise advised), including in the expression of interest, signed declarations and those relating to vaccine handling and administration.

What happens if a complaint is made about you?

If a complaint is received about you or your site, the Department will:

- consider the information received;
- gather any additional information associated with the allegation; and
- undertake a preliminary investigation of the allegation.

We will then contact you and provide a written notice of the next steps in the process.

If the written notice states that your site's participation in the Program has been temporarily paused while the Department investigates the complaint, you must immediately comply with the conditions outlined in the notice. This may include ceasing administration of COVID-19 vaccines, ceasing to claim related Medicare items or CVCP fees, or ceasing to order additional doses and related consumables for COVID-19 vaccines.

Right of Response

You will be provided an opportunity to respond if you receive notice of a complaint. Your notice will include a timeframe in which this response should be provided. The Department will assess any additional evidence that you provide or that we find in the notice period.

If you do not respond or do not respond in this timeframe, a decision will be made based on the information the decision-maker has.

Assessment of Evidence

The Department will assess the evidence using a reasonable person test. Examples of evidence you could provide to us could include:

- proof the complainant has identified the wrong site or practitioner; or
- documentation refuting the complaint, for example relevant policies, processes and procedures that are in place at your site.

Decision Making

The Department will always provide you with a written notice of the decision. If you respond to the notice, the Department will review the contents of your response and provide you with a notice of the decision within 7 days. If you do not respond within the timeframe the decision maker will make a determination based off the information at hand. This decision is final regardless of information provided at a later date and will take immediate effect or take effect from the time nominated in the notice, and could include:

- Pausing your ability to order and administer COVID-19 vaccines. This may be while investigations are being carried out, (this may occur in relation to complaints made to us and complaints made to professional bodies).
- 2. Remove your site from participating in the Program. This will occur if the complaint is credible, substantiated by evidence and the seriousness of the complaint justifies such action; and/or if at any point you provide information that is false or misleading.
- 3. No further action if we are satisfied through consultation and investigation no further action is required.

If the decision is made to remove your site from the Program, your site cannot reapply to participate in the Program. We will organise for all COVID-19 vaccines you may have in your inventory to be collected and redistributed where possible. Related COVID-19 Medicare items or CVCP fees will not be able to be claimed from the date the decision takes effect.

EXAMPLES

The Department may investigate the following complaints and tip offs:

- Charging out of pocket expenses to patients for vaccine services
- Not meeting the Australian Immunisation Handbook and ATAGI clinical/site requirements
- Not obtaining informed consent from patients
- Not confirming the identity of the patient to be vaccinated
- Not providing adequate product information to patients pre and post vaccination
- Inadequate vaccine storage practices
- Vaccine administration errors
- Repeated cold chain breaches leading to vaccine wastage

Change of Ownership

If your site has a change of ownership please advise the VOC or your local PHN (for general practices) as soon as possible. If you still have COVID-19 vaccine doses on site that you will utilise, you will need to record a transfer from the old CVAS account to the new CVAS account in your final stock management report. You will need to submit final stock management reports for the existing CVAS account with all doses administered or wasted and showing "0" (zero) doses of any vaccines.

Whether ownership changes or not, if the person who signed any of the site readiness declarations has left the site you will also need to contact the VOC to resubmit the declaration.

You are still able to use your current CVAS account until a new one is created for your site following the change of ownership.

If you have had a change of name you will also need to notify the VOC or your local PHN so this can be amended on CVAS.

Appendix A: Key Contacts

Vaccine Operations Centre (VOC) The VOC is the central point of contact within the Department to assist you with operational components of the COVID-19 vaccine roll-out. Contact details for the VOC are for participating sites only. Please do not provide these details to consumers	► 1800 318 208 © COVID19VaccineOperationsCentre@health.gov.au
Notice of complaint or allegations of a site or provider will be received, or can be sent to:	PCDCompliance@health.gov.au
MBS and Health Insurance Act:	askMBS@health.gov.au
Provider Benefits Integrity	Online tip-off form;
If a site charges for any costs associated with the COVID-19 vaccine, the Department may be contacted via:	provider.benefits.integrity@health.gov.au; or 1800 314 808 (9am to 5pm AEST weekdays).
Sources of distributed information:	No-Reply.Vaccine@health.gov.au
Service Finder	⚠ CV19.Products@health.gov.au
NPS MedicineWise Adverse Medicine Events Line	\ 1300 134 237
Adverse Medicine Events Line	1300 633 424
TGA Enquiries	
Adverse Event Management System	adr.reports@health.gov.au
Adverse Event Following Immunisation (AEFI) Reporting	1300 633 424 (1300 Medicine)
Reports can be submitted directly to the TGA.	TGA website
Where to report Adverse Events in each state and territory:	 ACT: ACT Health website NSW: NSW Health website NT: NT Department of Health website QLD: QLD Health website SA: SA Health website TAS: Tasmanian Department of Health website VIC: SAFEVAC website WA: WA Department of Health website
AIR Support	► 1800 653 809 ② air@servicesaustralia.gov.au
Health Professional Online Services:	1800 653 809
PRODA support	1800 700 199 (option 1) or proda@servicesaustralia.gov.au Monday to Friday, 8am to 5pm local time.

Translation or interpretations	TIS website or 13 14 50
My Health Record Help line	My Health Record Help line
	► 1800 723 471 (choose option 2)
Pharmacy Programs Administrator	• 1800 951 285
The PPA hours of operation are between 9am to 8pm (AET) Monday to Friday	support@ppaonline.com.au
The National Coronavirus Healthline	1800 020 080

Appendix B: Resources

Australian Government Department of Health and Aged Care

- Adverse events
- Australian Immunisation Handbook COVID-19 Chapter
- Consent for COVID-19 vaccination
- National Vaccine Storage Guidelines
- Health Workforce Locator Check your MM Category
- COVID-19 Vaccine Reference Guide
- CVTP module set

Healthdirect

• Service Finder (Previously COVID-19 Vaccine Clinic Finder)

Translating and Interpreting Service National

Information on the TIS

Therapeutic Goods Association

- News and announcements
- Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG)
- Reporting suspected side effects from COVID-19 vaccines
- Vaccine Product Information and Consumer Medicine Information

Services Australia

- Australian Immunisation Register
- Health Professional Online Services
- How to print patients' Immunisation History Statement (for providers)
- How to get proof of COVID-19 vaccinations (for consumers with and without Medicare)
- How to get Immunisation History Statement (for consumers with and without Medicare)
- How to download and print an immunisation history statement or COVID-19 digital certificate from the AIR site using HPOS.
- Medicare Provider Numbers
- PRODA (Provider Digital Access) account
- Update your details general practitioner, nurse practitioner or health professional

MBS Online

COVID-19 MBS items factsheet

Pharmacy

- Pharmacy Programs Administrator (PPA)
- Pharmaceutical Society of Australia COVID-19 Information for Pharmacists
- Pharmacy Guild of Australia resources for pharmacies, available from Services Australia
- Claiming Provider Agreement Form

Appendix C: Acronyms & Abbreviations

Acronyms

ACCHS	Aboriginal Community Controlled Health Services
AEFIs	Adverse Events Following Immunisation
AEMS	Adverse Event Management System
AGON	Australian Government Overseas Network
AHPRA	Australian Health Practitioner Regulation Agency
AIR	Australian Immunisation Register
ATAGI	Australian Technical Advisory Group on Immunisation
CVAS	COVID-19 Vaccine Administrative System
CVTP	COVID-19 Vaccination Training Program
HPOS	Health Professional Online Services
IHI	Individual Healthcare Identifier
OMP	Other Medical Practitioner
PHN	Primary Healthcare Network
PIP	Practice Incentives Program
PPA	Pharmacy Program Administrator
PRODA	Provider Digital Access
RACF	Residential aged care facility
RDD	Requested Delivery Date
SIN	Supplementary Identification Number
SF	Service Finder
TGA	Therapeutic Goods Administration
TIS	Translating and Interpreting Service
VOC	Vaccine Operations Centre

Abbreviations

AIR Act	Australian Immunisation Register Act 2015
Department	The Department of Health and Aged Care
Program	COVID-19 Vaccination Program
Scheme	COVID-19 Vaccine Claims Scheme

Appendix D: ATAGI Site Requirements

The following site readiness requirements for COVID-19 vaccination clinics have been developed by the Australian Government in consultation with expert advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and standards outlined in the Australian Immunisation Handbook. COVID-19 Vaccination sites must confirm compliance with the minimum requirements outlined below (as well as the declaration in relation to COVID-19 Vaccination Site Requirements outlined within the requirement checklist) prior to taking delivery of COVID-19 vaccine doses.

The requirements for Pharmacies are slightly different and can be found here:

1. Physical Environment

- 1.1. Access to toilets for patients (separate to usual practice or clinic toilet) and staff.
- 1.2. Have adequate space for patients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements.
- 1.3. Have a private space for consultation with patients and vaccinator (including obtaining informed consent, answering patient questions and assessment of any conditions that may preclude vaccination or require further assessment and administration of vaccine).
- 1.4. Have a dedicated area, separate from areas that provide other clinical services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration.
- 1.5. Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for patients and vaccinator(s).
- 1.6. Have adequate space for patients to wait and be observed post-vaccination that observes physical distancing requirements (note this may be the same as the waiting area however will still require sufficient physical distancing, and post-vaccine observation cannot take place with patients in cars)
- 1.7. Have safe, risk free and directed access in clinical areas to allow movement of staff between areas while minimising the risk of workplace incidents (e.g. moving doses from preparation area to patient administration area, accessing vaccine refrigerators or cool boxes, etc.).
- 1.8. Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available.
- 1.9. Have visual reminders and cues in place to reduce the risk of errors.
- 1.10. Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements.
- 1.11. Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needle stick injuries.
- 1.12. Appropriate security provisions to ensure no unauthorised access to vaccine doses.

2. Physical Location

- 2.1. Close proximity to sufficient car parking.
- 2.2. Close proximity to public transport (where relevant).
- 2.3. Accessible by other patient transport services (including ambulance).

3. Infrastructure

- 3.1. Reliable water and electricity supply.
- 3.2. Access to telephone and computer networks and internet.
- 3.3. Ability to maintain room temperatures between 19 25 degrees.

4. Workforce Requirements

- 4.1. Adequate number of appropriately trained staff to ensure clinical safety including:
 - 4.1.1. Vaccinators to prepare and administer vaccines,
 - 4.1.2. Authorised immunisation provider (e.g. medical officer or fully trained immunisation registered nurse/nurse practitioner to assess patients and authorise other appropriately trained clinical staff (vaccinator) to administer the vaccine),
 - 4.1.3. Concierge or team leader (to direct clinic flow),
 - 4.1.4. Clerical staff,
 - 4.1.5. First aid staff, additional to vaccinating staff as per jurisdictional requirements,
 - 4.1.6. Security staff (if/when required),
 - 4.1.7. Medical officer (may be the same as the authorised immunisation provider).
- 4.2. Note that everyone administering vaccines must have appropriate qualifications in line with jurisdictional requirements, and consistent with the **National Immunisation Program** and the **Australian Immunisation Handbook**, including regarding the use of multi-dose vials and, to the extent relevant, low-dead volume syringes.

5. Cold Chain Management

- 5.1. Have adequate number and capacity of vaccine refrigerators to store vaccines, with vaccine refrigerators to be maintained and monitored at 2 8 degrees Celsius.
- 5.2. Have appropriate vaccine refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared until the time they are administered.
- 5.3. Have specific procedures in place associated with receipt of vaccine doses including unloading, acceptance, temperature checks, inspection, unpacking and storage to ensure compliance with the COVID-19 Vaccine Acceptance Checklists.
- 5.4. Sites must be able to adhere to the Strive for 5 guidelines and will need to have or be able to develop policies for cold chain management including:
 - 5.4.1. Able to continuously monitor the temperatures of the vaccine refrigerator(s) where vaccines are stored.
 - 5.4.2. Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another vaccine refrigerator and responding at times where the vaccine site may not have any staff present.

6. Technology and Record Keeping

- 6.1. Access to patient management system and Australian Immunisation Register via Provider Digital Access (PRODA).
- 6.2. Linkage with the COVID-19 Vaccine Information and Location Service.
- 6.3. Ability to meet mandatory requirements regarding reporting of all vaccine administration into AIR within 48 hours.
- 6.4. Have a process of obtaining and recording informed consent.
- 6.5. Be able to develop policies and procedures for:
 - 6.5.1. Identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand of product received), and recording immunisation encounters (electronic records are preferable).

- 6.5.2. Labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry.
- 6.5.3. Recording and reporting of vaccines used and stock on hand and any doses discarded, including reasons for discarding, and vaccine wastage.
- 6.6. Ability to monitor, manage and report adverse events following immunisation, including anaphylaxis.

7. Waste Disposal

7.1. Facilities to dispose of all waste, including sharps and unused vaccine appropriately in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheets for the COVID-19 vaccine and any other instructions given by the Australian Government.

8. Personal Protective and Other Equipment

- 8.1. Appropriate PPE, as per requirements in the Australian Immunisation Handbook and jurisdictional requirements.
- 8.2. Adequate supplies of other medical equipment e.g. stethoscopes, examination tables, diagnostic testing equipment.
- 8.3. Labels for syringes (if filling in advance).
- 8.4. Antimicrobial/disinfectant wipes to clean stations between patients.
- 8.5. Sanitation equipment for administration site.

9. Accreditation and other regulatory requirements

- 9.1. Able to claim MBS item numbers for billing (as relevant).
- 9.2. Have the appropriate accreditation where required for the relevant clinic or site, as advised by the Commonwealth (noting that accreditation will inform funding arrangements).
- 9.3. Willingness to comply with compulsory infection control training and external quality assurance procedures.
- 9.4. All immunisers to be authorised under the relevant state or territory's Public Health Act to provide vaccines.

10. Accessibility and Cultural Safety

- 10.1. Will need to be able to develop policies and procedures for ensuring services are culturally safe for Aboriginal and Torres Strait Islander peoples.
- 10.2. Will need to have arrangements for identification of and assistance for those with additional or specific needs, including:
 - 10.2.1. Ensuring culturally appropriate policies and procedures for multicultural communities,
 - 10.2.2. Qualified interpreters available when needed,
 - 10.2.3. Translations to languages other than English.
- 10.3. Will need to have arrangements to provide accessibility to those with Disability (including intellectual disability).

11. Management of the Clinic

- 11.1. Standardised screening process to exclude patients who display symptoms of COVID-19, and refer for appropriate assessment for COVID-19 or other conditions (as per guidance provided in the ATAGI Guiding Principles for Maintaining Immunisation Services during the COVID-19 Pandemic).
- 11.2. Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements).

- 11.3. Clear assignment of duties and responsibilities of all staff and clear plan of workflow, particularly regarding drawing up from a multi-dose vial and administering individual vaccine doses drawn from a particular vial for each clinic session.
- 11.4. Incident management in place, with staff knowledgeable about relevant procedures and able to report any clinical incident (e.g. injury in workplace) to the appropriate health authorities.
- 11.5. Has process in place to manage injuries to workforce or patients (e.g. needle stick injury).
- 11.6. Have a documented process in place to manage any adverse reaction to administration of a vaccine.
- 11.7. Process in place to prevent and manage violence or aggression in the clinic.
- 12. Vaccine administration equipment requirements for each patient vaccination the Commonwealth will provide some consumables including; 1ml syringes, 25mm needles and Sharps waste disposal bins if sites are unable to access supply through existing mechanisms. Consumables will be delivered separately to the vaccine doses.

Ability to procure and securely store items listed below sufficient for the administration of the vaccine doses the vaccine site will administer:

- 12.1. Sterile 1mL, 2mL or 3mL syringes.
- 12.2. Sterile syringes with 0.1mL graduation.
- 12.3. Gauge bevel or narrower.
- 12.4. Sterile drawing up needle (19 or 21 gauge recommended to reduce risk of coring).
- 12.5. Sterile administration needle (22-25 gauge), 25mm for adults, 38mm for very large or obese person.
- 12.6. Alcohol wipe (for vials).
- 12.7. Cotton wool ball.
- 12.8. Hypoallergenic tape or latex free band aid.
- 12.9. Dish for drawn up vaccine (kidney dish).
- 12.10. Sharps containers.
- 12.11. Containers for disposal of biohazardous waste.
- 12.12. Saline.
- 12.13. Adrenaline 1:1000.
- 12.14. 1ml 'single use only' syringes, with 23 gauge needle.
- 12.15. Paediatric and adult size Guedel airways.

Appendix F: General Site Requirements

Receiving vaccine doses

- Specific procedures in place associated with receipt of vaccine doses including unloading, acceptance, temperature checks, inspection, unpacking and storage, to ensure compliance with the COVID-19 Vaccine Acceptance Checklist (as applicable).
- Specific procedures in place to be able to notify the Australian Government immediately in connection with defective doses or any of the matters specified in the COVID-19 Vaccine Acceptance Checklist (as applicable).

Storing vaccine doses

- 1. Documented management procedure describing the quality processes to ensure the safe, secure and appropriate storage of vaccine doses as per the Strive for 5 guidelines.
- 2. Appropriate stock rotation protocols to minimise risk of expired vaccine doses (i.e. first in first out).
- 3. An inventory management system for recording of vaccine stock, product control, expiry date management, use and recording any wastage including the reasons for the wastage occurring.
- 4. Stock management reporting (including the number of doses administered, number of doses remaining, and minor wastage below the threshold of 10 or more vials) must be completed weekly in the CVAS.
- 5. Appropriate procedures in place to ensure storage and handling of the vaccine doses in accordance with the vaccine stability timelines and other storage instructions provided the Australian Government.
- 6. Appropriate security provisions to ensure no unauthorised access to vaccine doses stored in the vaccine site.
- 7. Does the site have controlled access e.g. key to appropriate fridges and/or freezers?
- 8. Ability to continuously monitor and maintain a log of fridge and/or freezer temperatures.
- 9. A documented management approach for any deviation from temperature requirements alarms e.g. use of alarms and a procedure for responding 24/7.
- 10. Agreement to have a process in place to inspect shippers/shipping packages used for transport when they arrive and promptly report any issues to Health.
- 11. A documented procedure in place for complying with the vaccine preparation and administration instructions provided by the Australian Government.
- 12. Appropriate consumables, components or constituent material to be used in the administration of the doses, including those described in item 12 of the ATAGI Site requirements for COVID-19 vaccination clinics below.
- 13. Implemented process for identifying patients at higher risk for reactions immediately post-vaccination.
- 14. A documented procedure in place for disposing of open and unused vaccine and its packaging components in accordance with local requirements for disposal of Schedule 4 medicines and with any return and disposal instructions provided by the Australian Government (which includes that boxes containing the vaccines must be defaced and disposed of by local clinical dosing facility waste management services).
- 15. A documented procedure in place to ensure that the personnel at the vaccine site have not provided, requested or accepted, and will not provide, request or accept, any additional incentive or benefit in connection with the vaccine doses (such as a bribe)
- 16. A documented procedure in place to ensure that any documents and other information received in connection with the vaccine doses (including this checklist and declaration) are maintained in strict confidence, and are not disclosed to any third party without the consent of the Australian Government.

- 17. Appropriate procedures in place to notify the Australian Government immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions (including a failure of cold chain requirements) or use contrary to any handling and storage instructions.
- 18. Ability to continuously monitor and maintain a log of freezer temperatures.
- 19. A documented management approach for any deviation from temperature requirements alarms.
- 20. Agreement to have a process in place to inspect shippers used for transport when they arrive.

Appendix E: Pfizer Site Requirements

This checklist outlines the processes and procedures that need to be in place at each site to ensure quality assurance processes are in place to ensure the potency and shelf life of the Pfizer vaccine is maintained.

Prior to receiving Pfizer Vaccine doses

You **must meet at least one** of the following refrigeration or freezer options, but at a minimum sufficient refrigerator storage capacity, noting general practices will receive thawed Pfizer vaccine:

- 1. The site must have access to at least one of the below refrigeration and/or freezer requirements:
 - 1.1. Sufficient refrigerator (2°C to 8°C) storage capacity in line with projected and actual volumes of the vaccine to be administered.
 - 1.2. Sufficient ultra-low temperature freezer (-25°C to -15°C) storage capacity in line with projected and actual volumes of the Pfizer Vaccine to be administered.
 - 1.3. Sufficient ultra-low temperature freezer (-90°C to -60°C) storage capacity in line with projected and actual volumes of the Pfizer Vaccine to be administered.

Receiving vaccine doses

- 1. Specific procedures in place associated with receipt of vaccine doses including unloading, acceptance, temperature checks, inspection, unpacking and storage, to ensure compliance with the Pfizer Vaccine Acceptance Checklist (see Attachment B).
- 2. Specific procedures in place to be able to notify the Australian Government immediately in connection with defective doses or any of the matters specified in the Pfizer Vaccine Acceptance Checklist.

Storing vaccine doses

- 1. Documented management procedure describing the quality processes to ensure the safe, secure and appropriate storage of vaccine doses as per the Strive for 5 guidelines.
- 2. Appropriate stock rotation protocols to minimise risk of expired vaccine doses (i.e. first in first out).
- 3. An inventory management system for recording of vaccine stock, product control, expiry date management, use and recording any wastage including the reasons for the wastage occurring.
- 4. Appropriate procedures in place to ensure storage and handling of the vaccine doses in accordance with the vaccine stability timelines and other storage instructions provided the Australian Government.
- 5. Appropriate security provisions to ensure no unauthorised access to vaccine doses stored in the Pfizer vaccine hub
- 6. If utilising an existing ultra-low temperature freezer, does the site have controlled access (e.g. key) to freezers (If applicable)
- 7. Appropriate procedures in place to notify the Australian Government immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions (including a failure of cold chain requirements) or use contrary to any handling and storage instructions.
- 8. Ability to continuously monitor and maintain a log of freezer temperatures.
- 9. A documented management approach for any deviation from temperature requirements alarms.
- 10. Agreement to have a process in place to inspect shippers used for transport when they arrive.

Administering Pfizer Vaccine doses

- 1. A documented procedure in place for managing and recording training of staff handling vaccine doses to ensure that vaccines are handled in a safe and lawful manner, including training relating to safe removal of vials from ultra-low temperature shippers, freezers and refrigerators, and compliance with any safety data sheets that have been provided to the site.
- 2. A documented procedure in place for complying with the Pfizer vaccine preparation and administration instructions provided by the Australian Government
- 3. Appropriate safety procedures and controls including safety equipment (PPE), procedures in relation to dry ice handling, any spillage/breakage of vials and other accidents. Wastage of vaccine doses and spills, including the reason for wastage/spills, must be reported to the Australian Government weekly (or immediately in the event of an incident involving wastage or a spill of 10 or more vials) via the Commonwealth COVID-19 Vaccine Administration System (CVAS).
- 4. Appropriate consumables, components or constituent material to be used in the administration of the doses, including those described in item 12 of the ATAGI Site requirements for COVID-19 vaccination clinics below.
- 5. Appropriate procedures in place to notify the Australian Government immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions (including a failure of cold chain requirements) or use contrary to any handling and storage instructions.

Return and disposal of equipment used to deliver Pfizer vaccines

- 1. A documented procedure in place for disposing of open and unused vaccine and its packaging components in accordance with the return and disposal instructions provided by the Australian Government.
- 2. A documented procedure in place to enable return of the Pfizer Vaccine delivery equipment (e.g. Thermal Shipper and temperature monitoring device) within 30 days of delivery in accordance with the return and disposal instructions provided by the Australian Government.

A clean and secure location to store and protect the Pfizer Vaccine delivery equipment after removal of vaccine doses (e.g. Thermal Shipper and temperature monitoring device) with no exposure to weather or pests until collection by logistics provider.

Other site requirements

- 1. A documented procedure in place to ensure that the personnel at the vaccine hub have not provided, requested or accepted, and will not provide, request or accept, any additional incentive or benefit in connection with the vaccine doses (such as a bribe).
- 2. A documented procedure in place to ensure that any documents and other information received in connection with the vaccine doses (including this checklist and declaration) are maintained in strict confidence and are not disclosed to any third party without the consent of the Australian Government.

Appendix F: Moderna Site Requirements

This checklist outlines the processes and procedures that need to be in place at each site to ensure quality assurance processes are in place to ensure the potency and shelf life of the Moderna vaccine is maintained. **Prior to receiving Moderna Vaccine doses**

You **must meet at least one** of the following refrigeration or freezer options, but at a minimum sufficient refrigerator storage capacity, noting most sites will receive thawed Moderna vaccine:

- 1. The site must have access to at least one of the below refrigeration and/or freezer requirements:
 - 1.1. Sufficient low temperature freezer (-25°C to -15°C) storage capacity in line with projected and actual volumes of the Moderna vaccine to be administered; or
 - 1.2. Sufficient refrigerator (2°C to 8°C) storage capacity in line with projected and actual volumes of the vaccine to be administered.

Administering Moderna vaccines

- 2. A documented procedure in place for managing and recording training of staff handling vaccine doses to ensure that vaccines are handled in a safe and lawful manner, including training relating to safe removal of vials from low temperature shippers, freezers and refrigerators, and compliance with any safety data sheets that have been provided to the site.
- 3. Appropriate safety procedures and controls including safety equipment (PPE).
- 4. Procedures in relation to any spillage/breakage of vials and other accidents. Wastage of vaccine doses and spills, including the reason for wastage/spills, must be reported to the Australian Government weekly (or immediately in the event of an incident involving wastage or a spill of 10 or more vials) via the Commonwealth COVID-19 Vaccine Administration System (CVAS). You will no longer be required to call the VOC to report major wastage incidents.
- 5. Appropriate procedures in place to notify the Australian Government within 48 hours if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions (including a failure of cold chain requirements) or use contrary to any handling and storage instructions.

Appendix G: Novavax Site Requirements

This checklist outlines the processes and procedures that need to be in place at each site to ensure quality assurance processes are in place to ensure the potency and shelf life of the Novavax vaccine is maintained. Novavax Vaccine Specific Site Requirements must be completed if the site will be receiving Novavax Vaccine.

Prior to receiving Novavax Vaccine doses

1. Sufficient refrigerator (2°C to 8°C) storage capacity in line with projected and actual volumes of the **Novavax Vaccine** to be administered.

Administering Novavax Vaccine doses

- 1. A documented procedure in place for managing and recording training of staff handling vaccine doses to ensure that vaccines are handled in a safe and lawful manner, including training relating to safe removal of vials from shipping packages and then from refrigerators, and compliance with the Novavax Vaccine Product Information and any safety data sheets that have been provided to the site.
- 2. Appropriate safety procedures and controls including safety equipment (PPE).
- 3. Procedures in place to ensure that
 - 3.1. any spillage/breakage of vials and other incidents including accidental wastage of vaccine doses of less than 10 vials, including the reason for wastage/spills, will be reported to the Australian Government weekly via the Commonwealth COVID-19 Vaccine Administration System (CVAS);
 - 3.2. any incidents involving 10 or more vials must be reported to the VOC immediately
- 4. Appropriate procedures in place to notify the Australian Government immediately if any doses are stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions (including a failure of cold chain requirements) or use contrary to any handling, storage or administration instructions (including use for any purpose other than vaccinating individuals in Australia as part of a two dose course of vaccine, including use as a booster contrary to TGA approval).
- 5. Appropriate procedures are in place to:
 - 5.1. store any doses that may be defective or have been tampered with, (so they can be collected for testing, should the vaccination company formally request / require it); and
 - 5.2. ensure that any incident (including a failure of cold chain requirements) is properly documented, including taking of photos.

Appendix H: Frequently Asked Questions

Can I delay my commencement date?

You can delay your commencement date. You do not need to place an order for vaccines until you are ready to commence receiving them.

When will I receive my Site Registration Code email?

You will receive your code via an email from no-reply@cvas-mail.health.gov.au. Make sure you check your junk mail.

My circumstances have changed since submitting my EOI, affecting my eligibility. How do I update this information?

Updated information, including those relating to changes in circumstance, should be provided to your local PHN or PPA, who will then provide the information to the Department, and a revised eligibility notice will be issued, if required.

Can I get access to the system without actually being a Primary Care Site?

No, as this is a closed system for eligible entities participating in the COVID-19 vaccine roll-out. If you are interested in participating in the roll-out, please contact your local PHN, PPA or NACCHO.

Can influenza & COVID vaccinations be co-administering during the same consultation and what payment can be utilised?

ATAGI has advised that all COVID-19 vaccines can be co-administered (given on the same day) with an influenza vaccine. These services can be provided during the same attendance.

MBS

A vaccine suitability assessment MBS item can be billed for the COVID-19 vaccination. Influenza vaccine services are typically administered with standard MBS attendance items. Note: There are no MBS items for administering an influenza vaccine for and on behalf of a medical practitioner.

While a medical practitioner is under no obligation to bulk-bill a patient receiving an influenza vaccination, a patient who also receives a COVID-19 booster vaccination as part of the same occasion of care **must be bulk-billed** for the MBS COVID-19 vaccine suitability assessment component of the overall service.

CVCP

The COVID vaccine and administration of the vaccine is FREE to the patient.

However, pending the jurisdictional arrangements for your State or Territory, the Influenza vaccine and administration of the Influenza vaccine may incur a fee. Please check your State or Territory clinical arrangements about the fee administration of the Influenza vaccine to patients in your local community.

Pharmacies are encouraged to explain to their patients the possible fees in administering an Influenza vaccine.

The person who was responsible for our CVAS account has moved, subsequently we no longer have the login details for our account. How can I access CVAS to make orders?

To access CVAS and allow your clinic to resume making orders through their original profile, please contact the Vaccine Operations Centre who will assist with logging in. Their contact email is COVID19VaccineOperationsCentre@health.gov.au or call 1800 318 208.

My site has been newly onboarded; however we have been unable to make an order. Why is this occurring?

Where a site is unable to make orders, the most likely cause is the requirement to complete the declaration form with a "Yes" response to all questions. Please contact the Vaccine Operations Centre who will assist you to place an order. Their contact email is COVID19VaccineOperationsCentre@health.gov.au or call 1800 318 208.

My site has placed an order request; however, it has not been approved?

If you place an order in CVAS when you already have a **large amount of vaccine stock on hand**, your order may require approval from the Department.

The Department will assess your stock on hand, administration rates and vaccine wastage. If it is determined that you have sufficient stock on hand the order may not be approved. Once you have reduced your stock on hand you will be able to place another order.

Appendix I: Attachments

The below Attachments will form part of this Onboarding Pack and will be distributed with the pack where applicable.

Vaccine Factsheets:

- Pfizer 6 months to 4 years (Maroon Cap)
- Pfizer 5-11 years (Orange Cap)
- Pfizer Bivalent BA.4-5 12 years+ (grey cap)
- Moderna (XBB.1.5) 12 Years + (PFS)
- Pfizer (XBB.1.5) 12 years + (Grey)
- Pfizer (XBB.1.5) 5 -11 years (Light Blue)

Posters

- Pfizer Bivalent Comparison poster
- COVID-19 Vaccine Comparison poster
- ATAGI recommended COVID-19 doses and vaccines poster
- Air Codes Table
- Don't Forget to Check
- COVID-19 Vaccine Storage poster

Other

- Pharmacy Information Factsheet
- COVID-19 Vaccine Transfer Policy
- Service Finder and Online Bookings
- MBS Payments
- Australian Immunisation Register (AIR) for COVID-19 Vaccine
- ATAGI Additional COVID-19 Booster Advice FAQs
- Immunocompromised Factsheet