



COVID-19 VACCINATION

COVID-19 Vaccine Roll-out

EXPRESSION OF INTEREST TO PARTICIPATE IN FUTURE PRIMARY CARE PFIZER VACCINE PROGRAM

This Expression of Interest is for general practices who are currently participating in the COVID-19 Vaccination Program, as approved as part of the Expression of Interest undertaken from January to March 2021, to indicate their interest to administer the Pfizer vaccine. This would be in addition to their current administration of the AstraZeneca vaccine.

It is anticipated that all participating general practices will be given the opportunity to administer Pfizer **by October 2021**. A limited number of practices may be invited to commence from **July** in areas of need, and for priority populations, based on vaccine supply.

General practices are an integral partner in the COVID-19 Vaccination Program. As at 3 June 2021, over 4.6 million vaccinations have been administered across Australia, of which, over half (more than 2.5 million) have been administered through primary care.

On 22 April 2021, National Cabinet agreed to increase access to the Pfizer vaccine by establishing a Pfizer mass vaccination plan, which includes general practices and Commonwealth Vaccination Clinics, to establish readiness for operations where demand exists and supply is available.

On 24 May 2021, the Therapeutic Goods Administration approved an application from Pfizer Australia to change the current storage conditions for its COVID-19 vaccine. This change extends the approved storage period of unopened thawed vials at 2 - 8°C at the point of use for up to 31 days and enables greater flexibility in storage, transport and deployment of the Pfizer COVID-19 vaccine through increased points of presence across Australia.

This EOI is intended to identify existing participating general practices who are interested in administering Pfizer vaccine, initially to priority populations aged under 50 years eligible in Phase 1 of Australia's Vaccine Roll-out, and for other groups as eligibility changes. This would be in addition to the ongoing administration of AstraZeneca vaccine.

Minimum doses will be 150 per week total (for first and second doses) with an expected average allocation to general practices of 300 Pfizer total doses (for first and second doses) per week in addition to their existing AstraZeneca allocation.

Expression of Interest

Primary Health Networks (PHNs) will coordinate this process within their regions, with general practices asked to confirm that they:

- are interested in administering both the Pfizer and AstraZeneca COVID-19 vaccines;
- have capacity to administer both the Pfizer and AstraZeneca COVID-19 vaccines; and
- meet the Pfizer site requirements (at **Attachment A** – please note that many of these are similar to the AstraZeneca site requirements).

Practices will also be asked to indicate whether they could commence administering Pfizer by July 2021, if invited to do so.

Practices must already be participating in the COVID-19 Vaccination Program. There is no closing date to the EOI, however, to be considered as part of the small number of practices for a potential start in July, practices must indicate their interest to their PHN by midnight Thursday 10 June 2021.

Selection of practices

It is anticipated that all general practices participating in the program and who meet the Pfizer site requirements will be provided with the opportunity to administer the Pfizer vaccine by October. A limited number of general practices may be invited to commence from July in areas of need, based on vaccine supply.

Attachment A: 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. Identified sites must confirm compliance with the minimum requirements outlined below prior to placing an order for the Pfizer vaccine.

Sites will be required to complete the Pfizer Site Readiness Declaration in the COVID-19 Vaccine Administration System (CVAS) as part of the on-boarding process.

Prior to receiving 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. Sufficient refrigerator (2°C to 8°C) storage capacity in line with projected and actual volumes of the Pfizer vaccine to be administered; and/or
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; and/or
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

4. 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**).
5. 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

6. 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
7. Appropriate stock rotation protocols to minimise risk of expired vaccine doses (i.e. first in first out)
8. 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.

9. 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.

10. Appropriate security provisions to ensure no unauthorised access to vaccine doses stored in the Pfizer vaccine hub

11. If utilising an existing ultra-low temperature freezer, does the site have controlled access (e.g. key) to freezers? (If applicable)

12. 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.

13. Ability to continuously monitor and maintain a log of freezer temperatures

14. A documented management approach for any deviation from temperature requirements alarms

15. Agreement to have a process in place to inspect shippers used for transport when they arrive

Administering vaccine doses

16. 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 and freezers and compliance with any safety data sheets provided with the doses

17. A documented procedure in place for complying with the Pfizer vaccine preparation and administration instructions provided by the Australian Government

18. 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 the reason for wastage must be reported to the Australian Government daily (or immediately in the event of material wastage).

19. 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.

Return and disposal of equipment

20. 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

21. A documented procedure in place to enable return of the 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

22. A clean and secure location to store and protect the 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

23. 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)

24. 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.

Attachment B: Pfizer Vaccine Acceptance Checklist

Point of delivery

1. Shipment delivered on the expected date and time of delivery

2. Does the number of trays and vials match with the expected volumes?

Following initial visual inspection of esky delivered (including any security seals, if applicable), the packaging appears to be undamaged and complete.

3. If answer is no, please provide photogenic evidence and detailed description when returning this for. Please include in the “comments” column if this issue has been raised with the DHL support centre and include any applicable reference number provided by DHL.

Confirm that temperature logger included with the packaging indicates that there have been no cold chain breaches during transit (eg for -70°C deliveries confirm that there is a “tick” at the top of the display).

4. If the temperature logger included with the packaging indicates a cold chain breach (eg for -70°C deliveries there is a “cross” at the top of the display), do not open the esky and call Health’s Vaccine Operations Centre immediately on 1800 318 208 (stating that the vaccine came from a DHL esky) to seek instructions and, if instructed by DHL, call DHL’s temperature evaluation team as set out in any DHL materials provided with the vaccine. Until instructions are received from Health, please place the vaccine securely and safely in quarantine in the esky(ies) received and ensure that the vaccine is not moved or unpacked.

5. Labelling and packaging of the vaccine vials delivered is in accordance with the ‘Labelling and Packaging Specifications’ provided separately

Following a reasonable visual inspection of the internal contents of the esky delivered (including vials and/or trays), the vaccine appears to be undamaged and complete.

6. If answer is no, please provide photographic evidence and detailed description when returning this form

*note visual inspection of any vials being maintained at ultra-low temperatures must be completed in less than 3 minutes to maintain cold chain

After delivery

7. For -75°C deliveries, the temperature logger located in the esky has been switched off (hold “STOP” button for 5 seconds).

8. For deliveries with dry ice, the dry ice has been safely disposed of.

The temperature logger is placed inside the empty esky and that esky is returned to the driver

9. OR

The temperature logger is placed inside the empty esky and the new consignment label has been placed over the old consignment label for pick up within 48 hours

Confirm there are no issues to report to Health.

10. If there is any other issue you are concerned about in relation to the vaccine, please contact Health immediately by calling the Vaccine Operations Centre on 1800 318 208 (stating that the vaccine came from a DHL esky) and then provide this Pfizer Vaccine Acceptance Form by email with an explanation of the issue and attaching any photographs to COVID19VaccineAcceptance@health.gov.au.

Storage and handling requirements

The vaccine:

- has been transferred to:
 11. i. a -75°C ($\pm 15^{\circ}\text{C}$) ultra-low temperature ("ULT") freezer; or
 - ii. a $2-8^{\circ}\text{C}$ refrigerator; or
- has been retained in the esky and the dry ice has been replaced.

12. Any emptied eskies and temperature loggers are stored in a clean and secure location until collection
