



## ATAGI site requirements for COVID-19 vaccination in community pharmacies

The following site readiness requirements for COVID-19 vaccination in community pharmacies 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/participating community pharmacies must confirm compliance with the minimum requirements outlined in the below requirements prior to delivery of vaccine doses.

### 1.0 Physical environment

- 1.1 Have adequate space for patients waiting to be vaccinated that observes physical distancing requirements, and is sheltered from weather elements
- 1.2 Have a private and quiet 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)
- 1.3 Have a dedicated area (eg clean, and away from direct patient contact and distraction), separate from areas that provide other clinical [pharmacy] services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration
- 1.4 Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for patients, carers/parents and vaccinator(s)
- 1.5 Have adequate space for patients to be seated to wait and be observed post-vaccination that observes physical distancing requirements (note this may be the same as the waiting area) and is in accordance with jurisdictional requirements and guidance
- 1.6 Have safe and directed access in pharmacy 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 refrigerators or cool boxes, etc.)
- 1.7 Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available. Have visual reminders and cues in place to reduce the risk of errors
- 1.8 Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements
- 1.9 Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needle stick injuries
- 1.10 Appropriate security provisions to ensure no unauthorised access to vaccine doses
- 1.11 Have ready access to appropriate emergency equipment for managing anaphylaxis
- 1.12 Other useful information - Advise if you have access to other emergency equipment, such as oxygen or defibrillator

## 2.0 Workforce requirements

- 2.1 Adequate number of appropriately trained staff to ensure clinical safety including:
  - 2.1.1 Vaccinators (COVID-19 trained health worker under the supervision of an Approved Pharmacist and in accordance with state and territory regulations) to prepare and administer vaccines
  - 2.1.2 Team leader (to direct clinic flow)
  - 2.1.3 Clerical staff
  - 2.1.4 First aid staff, additional to vaccinating staff as per jurisdictional requirements
  - 2.1.5 Staff to manage staff/patient/stock safety (if/when required)
- 2.2 Acknowledge that everyone administering vaccines must have appropriate training and/or qualifications in line with jurisdictional requirements, and have received adequate specific training in COVID-19 vaccination, including regarding the use of multi dose vials
- 2.3 Have documented procedure for managing and recording training of staff handling vaccine doses

## 3.0 Cold chain management

- 3.1 Have adequate number and capacity of refrigerators to store vaccines (in addition to usual pharmacy stock requiring refrigeration), with refrigerators to be maintained and monitored at 2 – 8 degrees Celsius
- 3.2 Have appropriate 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 till the time they are administered
- 3.3 Have specific procedures associated with receipt of vaccine doses including packaging acceptance, temperature checks
- 3.4 Sites [community pharmacy] must be able to adhere to the Strive for 5 guidelines<sup>1</sup> and will need to have or be able to develop policies for cold chain management including:
  - 3.4.1 Able to monitor the temperatures of the refrigerator(s) where vaccines are stored
  - 3.4.2 Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator (or freezer, where relevant) and responding at times where clinic [community pharmacy] may not have any staff present

*More guidance regarding cold chain management will be provided by the Commonwealth.*

<sup>1</sup> Australian Government Department of Health. National Vaccine Storage Guidelines – Strive for 5. Canberra ACT: Department of Health; 2019. Available from: <https://www.health.gov.au/sites/default/files/documents/2020/04/national-vaccine-storage-guidelines-strive-for-5.pdf>

#### 4.0 Multi-dose vial administration

- 4.1 Have a process in place to vaccinate multiple patients per vial/dose (minimum number of patients to be specified by the Australian Government)

#### 5.0 Technology and Record Keeping

- 5.1 Access to community pharmacy service management system (eg MedAdvisor or Guild Care etc) or other patient management system and Australian Immunisation Register via Provider Digital Access (PRODA)
- 5.2 There will be a requirement for the ability to connect with and use a National Booking System, as necessary.
- 5.3 Ability to meet mandatory requirements regarding reporting of all vaccine administration into AIR within an appropriate timeframe, ideally within 24 hours
- 5.4 Have a process of obtaining and recording informed consent  
Be able to identify individuals where immunisation should take place in a specialist facility (eg history of anaphylaxis), or where further consultation may be required (eg pregnancy)
- 5.5 Be able to develop policies and procedures for:
  - 5.5.1 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)
  - 5.5.2 Labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry
  - 5.5.3 Recording and reporting of vaccines used and stock on hand and those discarded, including reasons for discarding, and vaccine wastage
- 5.6 Ability to monitor, manage and report adverse events (including complying with relevant state/territory requirements) following immunisation, including anaphylaxis and emergency management ie calling for an ambulance.

#### 6.0 Waste disposal

- 6.1 Facilities to dispose of all waste, including sharps and unused vaccine appropriately in accordance with standard precautions (TGA, OGTR (if appropriate) and other regulatory requirements for vaccines)

#### 7.0 Personal protective and other equipment

- 7.1 Appropriate PPE, as per requirements in the Australian Immunisation Handbook and jurisdictional requirements
- 7.2 Labels for syringes (if filling in advance)
- 7.3 Antimicrobial /disinfectant wipes to clean stations between patients
- 7.4 Sanitation equipment for administration site

## 8.0 Accreditation and other regulatory requirements

- 8.1 Approved Section 90 Pharmacy
- 8.2 All immunisers to be authorised under the relevant state or territory Public Health Act/ Medicines and Poisons Act to provide vaccines
- 8.3 Have AIR registration required for the relevant community pharmacy, as advised by the Commonwealth
- 8.4 Compliance with compulsory COVID-19 training

## 9.0 Accessibility and cultural safety

- 9.1 Will need to be able to develop [or have existing] policies and procedures for ensuring services are culturally safe for Aboriginal and Torres Strait Islander peoples
- 9.2 Will need to have arrangements for identification of and assistance for those with additional or specific needs, including:
  - Ensuring culturally appropriate policies and procedures for multicultural communities
  - Qualified interpreters available when needed such as through the Australian Government Translating and Interpreting Service (TIS)
  - Translations to languages other than English
- 9.3 Will need to have arrangements to provide accessibility to those with Disability (including intellectual disability and those with other mobility issues)

## 10.0 Management of the community pharmacy

- 10.1 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](#))
- 10.2 Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements)
- 10.3 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 [community pharmacy vaccination] session
- 10.4 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
- 10.5 Has process in place to manage injuries to workforce (e.g. needle stick injury)
- 10.6 Process in place to prevent and manage violence or aggression in the clinic

## 11.0 Vaccine administration equipment requirements for each patient vaccination - *the Commonwealth will provide majority of consumables required for the vaccine*

Ability to securely store items listed below:

- 11.1 Sterile 2mL or 3mL syringes (latex free)
- 11.2 Sterile drawing up needle (19 or 21 gauge recommended to reduce risk of coring)
- 11.3 Sterile administration needle (22-25 gauge), 25mm for adults, 38mm for very large or obese person
- 11.4 Alcohol wipe (for vials)
- 11.5 Cotton wool ball
- 11.6 Hypoallergenic tape or latex free band aid
- 11.7 Dish for drawn up vaccine (kidney dish)
- 11.8 Sharps containers
- 11.9 Containers for disposal of biohazardous waste
- 11.10 Saline (as required)
- 11.11 Adrenaline 1:1000
- 11.12 1mL 'single use only' syringes, with 23 gauge needle
- 11.13 Paediatric and adult size Guedel airways