

NSW Pharmacist Vaccination Standards

A pharmacist immuniser in NSW may administer the following vaccines to the specified age ranges:

- Influenza vaccine: Individuals aged 10 years and over
- Measles – mumps – rubella combination vaccine (MMR): Individuals aged 16 years and over
- Diphtheria – tetanus – pertussis combination vaccine (dTpa): Individuals aged 16 years and over
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S) vaccine: Individuals aged 40 years and over, or in an outbreak situation (as advised by the Australian Technical Advisory Group on Immunisation), individuals aged 18 years and older.

An intern pharmacist is not authorised to administer or supply the COVID-19 Vaccine AstraZeneca.

A registered pharmacist initiating and administering a vaccine under his/her own authority in NSW must comply with the following three components of clause 48A of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) (available at <https://www.legislation.nsw.gov.au/view/html/inforce/current/s1-2008-0392#sec.48A> which prescribes rules for: -

- A. Completing an accredited vaccination training course,
- B. Recording each vaccination in accordance with the regulation requirements, and
- C. Conducting vaccinations under approved practice standards. The Practice Standards, as approved by the Chief Health Officer, NSW Health (as a delegate of the Secretary, NSW Health), are set out at Part C below.

A. Pharmacist Training

A 'pharmacist immuniser' is a registered pharmacist who has completed a training course that complies with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines' (current version). The training course must be conducted by an Australian Pharmacy Council accredited pharmacy education program provider.

The pharmacist immuniser must ensure that they have completed training for all authorised vaccines that they intend to administer.

For the purposes of supply and administration of a COVID-19 Vaccine AstraZeneca (ChAdOx1-S) vaccine, a pharmacist immuniser, in addition to the above requirements, must also successfully complete:

- a. Core COVID-19 training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing; and

- b. Additional COVID-19 training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health in partnership with the Australian College of Nursing and listed below:
 - i. For the purposes of supply and administration of Oxford University/AstraZeneca vaccine, the training module on the Oxford University/AstraZeneca vaccine.

A pharmacist immuniser must ensure they remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for the COVID-19 vaccine.

B. Recording Vaccinations

Under cl.48A of the *Poisons and Therapeutic Goods Regulation 2008*, the pharmacist immuniser must make a record of the vaccination with the following information: -

- a) The person's name, address, date of birth and contact details,
- b) The name and contact details of the person's primary medical practitioner (if no current practitioner, record last medical practitioner seen or 'no primary medical practitioner'),
- c) The brand, batch number and expiry date of the vaccine,
- d) The part of the body to which the vaccine was administered,
- e) The date on which the vaccine was administered,
- f) The pharmacist's name and contact details and his or her certificate of accreditation number,
- g) The address of the pharmacy at which the vaccination was administered, and
- h) A unique reference number for the supply and administration.

Additional record keeping requirements that must be complied with are set out at Part C, Section 4 of the Practice Standards Below.

C. Practice Standards

1. General Requirements

1.1. The pharmacist must hold a certificate confirming competency to vaccinate following completion of an accredited training program for all authorised vaccines that they intend to administer as specified in Part A (above).

1.2. An intern pharmacist who holds a certificate confirming competency to vaccinate following completion of an accredited training program, is not able to administer the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) vaccine, and is only able to administer other specified vaccines under the direct supervision of a pharmacist immuniser who holds certification to vaccinate for the relevant vaccine.

1.3. To maintain authority to immunise, the pharmacist immuniser annually reviews best practice policy for immunisation. This may be, but is not limited to, attendance at seminars on current practices, or formal immunisation update courses.

1.4. The pharmacist must obtain a cardio-pulmonary resuscitation (CPR) certificate annually.

1.5. The pharmacist immuniser must practice within the scope of pharmacist practice, professional knowledge and expertise when undertaking vaccination and providing management of an adverse event.

1.6. The pharmacist immuniser must comply with the following: -

- a) '*The digital Australian Immunisation Handbook*' – Australian Government Department of Health, and
- b) '*National Vaccine Storage Guidelines – Strive for 5*' (current edition) – Australian Government Department of Health.

1.7. The pharmacist immuniser should adopt or follow the following professional guidelines: -

- a) '*Practice guidelines for the provision of immunisation services within pharmacy*' (current edition) – Pharmaceutical Society of Australia, and/or
- b) '*Guidelines for Conducting Immunisation Services within a Community Pharmacy Environment*' (current edition) – Pharmacy Guild of Australia.

1.8. The pharmacist immuniser must ensure that when administering vaccines that at least one other appropriately trained pharmacy staff member is present. The pharmacy staff member must be trained to assist the pharmacist immuniser in an emergency.

1.9. The pharmacist immuniser must check an individual's vaccination status on the Australian Immunisation Register (AIR) prior to administering a vaccine and subsequently record any vaccines they administer in accordance with Part B above, and Section (4) below.

2. Administration area and Equipment

2.1. A pharmacist immuniser may administer influenza vaccine, measles-mumps-rubella combination vaccine and diphtheria-tetanus-pertussis combination vaccine in the following settings:

- Retail (community) pharmacy (approved under Schedule 5F of the *Health Practitioner Regulation National Law (NSW)*)
- General Practice
- Aboriginal Medical Service
- Local Council Clinic
- Private Hospital
- Public Hospital and health service
- Community Health Centre
- Residential Care Facility
- Staff Occupational Health Clinic (clinics held in the workplace to vaccinate staff).

2.2 A pharmacist immuniser may supply/administer the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) to eligible patient groups under the Commonwealth vaccination program in the following settings:

- Retail (community) pharmacy (approved under Schedule 5F of the *Health Practitioner Regulation National Law (NSW)*) registered to participate in the COVID-19 vaccination program; and
- Residential Care Facility; and
- General Practice clinic registered to participate in the COVID-19 vaccination program; and
- Aboriginal Medical Service registered to participate in the COVID-19 vaccination program.

Note: pharmacist immunisers in public health facilities are outside scope of the approval under clause 48A of the *Poisons and Therapeutic Goods Regulation 2008* and are instead subject to NSW Health policy directives and a separate authority and conditions. Pharmacist immunisers in public health facilities may not immunise under these standards.

The pharmacist immuniser must conduct the vaccination in an immunisation service room, consulting room or immunisation area; this may be a dedicated space or an existing consulting room for the purpose of providing vaccination services.

2.3. The immunisation service room, consulting room or immunisation area must be consistent with the following: -

- a) The room or area is not to be used as a dispensary, storeroom, staff room or retail area,
- b) Provide adequate privacy,
- c) Have adequate lighting,
- d) Be maintained at a comfortable ambient temperature,
- e) Have a hand sanitisation facility,
- f) Have ready access to a hand washing facility,
- g) Have sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the vaccination and an accompanying person, and to allow the pharmacist immuniser adequate space to manoeuvre, and
- h) Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar).

2.4. The pharmacist immuniser must have the following equipment consistent with;

- *'The digital Australian Immunisation Handbook'*, and
 - *'National Vaccine Storage Guidelines – Strive for 5'* (current edition): -
- a) A temperature-monitored refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines or temperature monitored portable cooler for mobile clinics,
 - b) All necessary consumables required for vaccine administration,
 - c) An appropriately sized sharps container to dispose of clinical waste including used syringes and needles,
 - d) An in-date and complete anaphylaxis response kit,
 - e) An emergency response protocol (preferably laminated) on display,
 - f) Access to *'The digital Australian Immunisation Handbook'*,
 - g) *'National Vaccine Storage Guidelines – Strive for 5'* (current edition), and
 - h) A process to regularly monitor on-line updates to *'The digital Australian Immunisation Handbook'*, including prior to administering any vaccine.

3. Patient Consent and Eligibility

3.1.

- a) The pharmacist immuniser must obtain informed written or verbal consent from the patient before the vaccination and must retain proof of consent for seven years (in accordance with the *Health Records Information and Privacy Act 2002*), for all vaccines listed in this document (excluding AstraZeneca the consent for which must be obtained in accordance with paragraph (b) below).

The pharmacist immuniser must also provide information in relation to the benefits and risks of the specific vaccine, explaining the rationale and purpose of the vaccine to the patient (or parent / guardian).

- b) The pharmacist must obtain written or other electronic evidence of consent from each patient to whom the approved vaccine is supplied and retain a copy of that consent. The Australian Government Department of Health COVID-19 vaccination – Consent form for COVID-19 vaccination is to be used in obtaining consent.

- The pharmacist immuniser must not supply or administer the COVID-19 vaccine to a patient who is not able to consent to the treatment on their own behalf.
- Provide information in relation to the benefits and risks of the specific vaccine, explaining the rationale and purpose of the vaccine to the patient.
- Provide the patient with the relevant *Patient Information Sheet: COVID-19 vaccination – Information on COVID-19 AstraZeneca vaccine*.
- Ensure that the patient is able to understand the information sheet and has had the opportunity to ask any questions. The use of the patient-completed screening tool in the Patient Information Sheet may assist but does not replace relevant history taking by the pharmacist, including ensuring the patient understands the questions that are asked, and identifying any language or communication barriers that may prevent informed consent, before proceeding.
- Ensure the patient has had the opportunity to discuss benefits and risks using the latest available benefits and risks information and advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and the Therapeutic Goods Administration (TGA).
- Should the patient have further questions or concerns regarding the benefits and risks of vaccination, refer the patient to a medical practitioner.
- A pharmacist immuniser must ensure they remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements for the COVID-19 vaccine.

- c) For all vaccines, the pharmacist immuniser must take a medical and allergy/ hypersensitivity history. Check with the patient if they:

- Are currently well
- Have any known allergies or hypersensitivities
- Are currently taking any relevant medications or have received any recent vaccination
- Have pre-existing medical condition(s) where the use of the vaccine may be contraindicated, or precautions may be required.

While undertaking a medical history, ensure the patient understands the questions that are asked, and refer the patient for medical assessment should any health

concerns or questions be identified. Should the patient have a contraindication or precaution to the vaccine, refer the patient to a medical practitioner.

3.2. If verbal consent is obtained for dTpa, MMR or influenza vaccine, there must be documented evidence of verbal consent made by the pharmacist immuniser, in the person's record. For electronic records, include a typed record of verbal consent in the person's file. People need to give explicit verbal consent before receiving any vaccine, even if they gave written consent at previous vaccination encounters for the same vaccine.

3.3. The pharmacist immuniser must undertake a thorough pre-vaccination assessment in accordance with the recommendations in *'The digital Australian Immunisation Handbook'*.

3.4. During pre-vaccination assessment, the pharmacist immuniser must check if the person is eligible for funded vaccines and advise all individuals who are identified as eligible for this, and of how to access the funded vaccines.

3.5. The pharmacist immuniser must not vaccinate a person with a contra-indication or precaution to vaccines listed in the

- *'The digital Australian Immunisation Handbook'*, or
- by the Australian Technical Advisory Group on Immunisation (ATAGI), or
- the current Therapeutic Goods Administration Approved Product Information (PI) for the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) solution for injection multidose vial.

A person with a contra-indication or precaution to a vaccine must instead referred to a medical practitioner.

The pharmacist must not supply or administer the COVID-19 vaccine to a person who has experienced a serious adverse event after the first administration of the COVID-19 vaccine.

4. Recording and Reporting

4.1. The pharmacist immuniser must record the vaccination with the detail required under clause 48A(2) of the *Poisons and Therapeutic Goods Regulation 2008* (as specified in Part B) and a copy of this record should also be kept for seven years.

4.2. All vaccines administered by the pharmacist immuniser must also be reported to the Australian Immunisation Register (AIR).

5. Post Vaccination Care of the Patient

5.1. The pharmacist immuniser must advise the person to remain on the pharmacy premises for 15 minutes post vaccination and must advise the person of possible risks in leaving earlier than 15 minutes.

5.2. The pharmacist immuniser must either observe, (or direct an appropriately trained pharmacy staff member to observe when the service is conducted in a retail pharmacy), the person for 15 minutes post vaccination to monitor for acute adverse events or anaphylaxis.

5.3. The pharmacist immuniser must make notes in the record of vaccination (as specified in part B) when the person leaves the pharmacy or other premises earlier than 15 minutes post vaccination.

5.4. The pharmacist immuniser must provide each patient with post-vaccination care as per the latest Australian Government, ATAGI or TGA advice in relation to what to expect following vaccination with the COVID-19 AstraZeneca vaccine, and when to seek medical attention following each administration of the vaccine. In particular, provide advice to immediately seek medical review for any new, severe or persistent headache, stomach (abdominal) pain, chest pain, vomiting or visual symptoms, bruising or petechial haemorrhages between 4 and 30 days after vaccination with COVID-19 Vaccine AstraZeneca.

6. Management of Adverse Events

6.1. The pharmacist immuniser must be competent to manage anaphylaxis post vaccination including use of adrenaline consistent with '*The digital Australian Immunisation Handbook*'.

6.2. The pharmacist immuniser must ensure an ambulance is called to attend a person who experiences anaphylaxis post vaccination.

6.3. A pharmacist immuniser must ensure they remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions for the COVID-19 vaccine.

6.4. Immediately after the response to an adverse event is affected, the pharmacist immuniser must notify the adverse event to the local public health unit by telephone on 1300 066 055.

D. Distribution and cold chain management

COVID-19 Vaccine AstraZeneca

- The Commonwealth Department of Health is responsible for the distribution of the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) to the wholesaler.
- The pharmacist immuniser may administer a COVID-19 Vaccine AstraZeneca (ChAdOx1-S) only where the vaccine has been:
 - distributed by the Commonwealth to a COVID-19 vaccine provider (under the Commonwealth Department of Health COVID-19 vaccine program), OR
 - obtained from an *authorised person* under the NSW licence at **Annexure A** which allows for supply of the COVID-19 vaccine between *authorised persons* at listed vaccine providers. This includes *authorised persons* at GP respiratory clinics, NSW Health vaccination clinics, Aboriginal Community Controlled Health Services in NSW that are registered to participate in the COVID-19 vaccination program; GP clinics in NSW that are registered to participate in the COVID-19 vaccination program; and community pharmacists approved under Schedule 5F of the *Health Practitioner Regulation National Law* (NSW) that are registered to participate in the COVID-19 vaccination program.
 - Note the NSW licence allows for an *authorised person* at a COVID-19 vaccine provider (under the Commonwealth Department of Health COVID-19 vaccine program), who has been supplied COVID-19 vaccine by the Commonwealth Department of Health, to supply that vaccine to another

authorised person operating at another COVID-19 vaccine provider (under the Commonwealth Department of Health COVID-19 vaccine program).

- An *Authorised person* means a person licensed or authorised to supply or be in possession of the vaccine under the *Poisons and Therapeutic Goods Act 1966* or *Poisons and Therapeutic Goods Regulation 2008* in accordance with the provisions of the Act and regulation. This includes an authorised nurse immuniser, registered pharmacist, medical practitioner and nurse practitioner.
- On-supply may only be unopened vials of vaccine
- The authorised person supplying must make a record of the supply and give a copy to the recipient.
- All cold chain breaches for the COVID-19 Vaccine AstraZeneca (ChAdOx1-S) must be reported to the Commonwealth Department of Health.



Kerry Chant
Chief Health Officer

28 July 2021

Poisons and Therapeutic Goods Act 1966 – Section 9
Poisons and Therapeutic Goods Regulation 2008 – Clause 162 and 163
Licence to supply by wholesale certain restricted substances

Licence No Covidvax 002

1. The licence dated 9 June 2021 and annexed to this instrument is revoked.
2. This licence is issued to the following persons (*the licensee*) who have been supplied the restricted substance (specified at Schedule 1) by the Commonwealth Department of Health:
 - a) An *authorised person* at a *GP respiratory clinic* (GPRCs) that has registered to participate in the COVID-19 vaccination program
 - b) An *authorised person* at a NSW Health vaccination clinic
 - c) An *authorised person* at a *Commonwealth vaccination clinic* (CVCs)
 - d) An *authorised person* at an Aboriginal Community Controlled Health Service that has registered to participate in the COVID-19 vaccination program
 - e) An *authorised person* at a GP clinic that has registered to participate in the COVID-19 vaccination program
 - f) An *authorised person* at a community pharmacy approved under Schedule 5F of the *Health Practitioner Regulation National Law (NSW)* that has registered to participate in the COVID-19 vaccination program.
3. This licence only authorises the supply by wholesale of the restricted substances specified in Schedule 1, subject to the conditions specified in Schedule 2, including condition 2 which limits supply by wholesale of the substances to a community pharmacy, which can only receive the substance listed at Schedule 1(b).
4. This licence is subject to the conditions set out in Schedule 2.
5. This licence remains in force until **31 January 2022** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- An *Authorised person* means a person licensed or authorised to supply, dispense or be in possession of the restricted substance (specified at Schedule 1) under the *Poisons and Therapeutic Goods Act 1966 (the Act)* or *Poisons and Therapeutic Goods Regulation 2008 (the Regulation)* in accordance with the provisions of the Act and regulation.
- A *GP respiratory clinic* is a clinic listed on the Australian Government Department of Health website as a *Coronavirus (COVID-19) GP respiratory clinic*.
- A *Commonwealth vaccination clinic* is a clinic established and operated by the Commonwealth.

Schedule 1 – restricted substances for supply by wholesale

The following SARS-COV-2 (COVID-19) VACCINES:

- a. COMIRNATY-BNT162b2[mRNA] (Pfizer Australia Pty Ltd) (Pfizer Vaccine)
- b. COVID-19 Vaccine AstraZeneca (AstraZeneca Pty Ltd) (AstraZeneca Vaccine)

Schedule 2 — Schedule of conditions

1. The Schedule 1(a) restricted substances can only be supplied by wholesale to an <i>authorised person</i> at: a) GP respiratory clinics (GPRCs) in New South Wales that have registered to participate in the COVID-19 vaccination program; b) NSW Health vaccination clinics; c) Commonwealth vaccination clinics (CVCs); d) Aboriginal Community Controlled Health Services in New South Wales that have registered to participate in the COVID-19 vaccination program; and e) GP clinics in New South Wales that have registered to participate in the COVID-19 vaccination program.
2. The Schedule 1(b) restricted substances can only be supplied by wholesale to an <i>authorised person</i> at: f) GP respiratory clinics (GPRCs) in New South Wales that have registered to participate in the COVID-19 vaccination program; g) NSW Health vaccination clinics; h) Commonwealth vaccination clinics (CVCs); i) Aboriginal Community Controlled Health Services in New South Wales that have registered to participate in the COVID-19 vaccination program j) GP clinics in New South Wales that have registered to participate in the COVID-19 vaccination program; and k) community pharmacies approved under Schedule 5F of the <i>Health Practitioner Regulation National Law (NSW)</i> that have registered to participate in the COVID-19 vaccination program.
3. The Schedule 1 restricted substances must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.
4. The licensee must notify the Secretary, NSW Health, of any requests for supply of the Schedule 1 restricted substances in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.
5. Records of supply related to the supply of the Schedule 1 restricted substance can only be issued in the name of the authorised person supplying and supply must be made to the authorised person receiving the supply.
6. The licensee must make, and hold for a period of at least 2 years, a record of the supply of the Schedule 1 restricted substance, and provide a copy to the recipient.
7. The licensee must comply with any record keeping requirements imposed by the Commonwealth Department of Health.
8. The licensee must comply with storage and any cold chain requirements, including during transit of the product, in accordance with the Product Information Sheet for the Schedule 1 restricted substance.
9. Appropriate cold chain records that comply with the Product Information sheet for the Schedule 1 restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.

Poisons and Therapeutic Goods Act 1966 – Section 9
Poisons and Therapeutic Goods Regulation 2008 – Clause 162
Licence to supply by wholesale certain restricted substances

Licence No. COVIDvax001

1. This licence is issued to the following persons (*the licensee*) who have been supplied the restricted substance (specified at Condition 1) by the Commonwealth Department of Health:
 - a) An *authorised person* at a *GP respiratory clinic* (GPRCs) that has registered to participate in the COVID-19 vaccination program
 - b) An *authorised person* at a NSW Health vaccination clinics
 - c) An *authorised person* at a *Commonwealth vaccination clinic* (CVCs)
 - d) An *authorised person* at a Aboriginal Community Controlled Health Service that has registered to participate in the COVID-19 vaccination program; and
 - e) An *authorised person* at a GP clinic that have registered to participate in the COVID-19 vaccination program
2. This licence only authorises the supply by wholesale of the restricted substances specified in Schedule 1.
3. This licence subject to the conditions set out in Schedule 2.
4. This licence remains in force until **31 January 2022** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- An *Authorised person* means a person licensed or authorised to supply or sell, or be in possession of the restricted substance (specified at Schedule 1) under the *Poisons and Therapeutic Goods Act 1966 (the Act)* or *Poisons and Therapeutic Goods Regulation 2008 (the Regulation)* in accordance with the provisions of the Act and regulation.
- A *GP respiratory clinic* is a clinic listed on the Australian Government Department of Health website as a *Coronavirus (COVID-19) GP respiratory clinic*.
- A *Commonwealth vaccination clinic* is a clinic established and operated by the Commonwealth.

Schedule 1 – restricted substances for supply by wholesale

The following SARS-COV-2 (COVID-19) VACCINES:

- COMIRNATY-BNT162b2[mRNA] (Pfizer Australia Pty Ltd) (Pfizer Vaccine)
- COVID-19 Vaccine AstraZeneca (AstraZeneca Pty Ltd) (AstraZeneca Vaccine)

Schedule 2 – Schedule of conditions

1. The Schedule 1 restricted substances can only be supplied by wholesale to an *authorised person* at:

a) GP respiratory clinics (GPRCs) in New South Wales that have registered to participate in the COVID-19 vaccination program; b) NSW Health vaccination clinics; c) Commonwealth vaccination clinics (CVCs); d) Aboriginal Community Controlled Health Services in New South Wales that have registered to participate in the COVID-19 vaccination program; and e) GP clinics in New South Wales that have registered to participate in the COVID-19 vaccination program.
2. The Schedule 1 restricted substances must only be supplied in the unopened ARTG registered packs or, in the alternative, unopened vials as received from the supplier.
3. The licensee must notify the Secretary, NSW Health, of any requests for supply of the Schedule 1 restricted substances in quantities which appear to be inconsistent with the activities of the business for which it is being supplied.
4. Records of supply related to the supply of the Schedule 1 restricted substance can only be issued in the name of the authorised person supplying and supply must be made to the authorised person receiving the supply.
5. The licensee must make, and hold for a period of at least 2 years, a record of the supply of the Schedule 1 restricted substance, and provide a copy to the recipient.
6. The licensee must comply with any record keeping requirements imposed by the Commonwealth Department of Health.
7. The licensee must comply with storage and any cold chain requirements, including during transit of the product, in accordance with the Product Information Sheet for the Schedule 1 restricted substance.
8. Appropriate cold chain records that comply with the Product Information sheet for the Schedule 1 restricted substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.