

## NSW PHARMACIST VACCINATION STANDARDS

### A. APPROVED VACCINES AND VACCINATION SCHEDULES

Name	Abbreviated/ alternate name	Limitations of use	Patient age
SARS-COV-2 (COVID-19) vaccine <sup>§</sup>		In accordance with Therapeutic Goods Administration (TGA) approved Product Information and Australian Technical Advisory Group on Immunisation (ATAGI) recommendations <sup>#</sup>	5 years and over
Triple antigen vaccine Diphtheria-tetanus-acellular pertussis combination <sup>†</sup> :	dTpa		12 years and over*
Hepatitis A vaccine <sup>†</sup>	Hep A		5 years and over*
Hepatitis B vaccine <sup>†</sup>	Hep B		5 years and over*
Human papillomavirus vaccine <sup>†</sup>	HPV		12 years and over*
Influenza and coryza vaccine 'Influenza vaccine' <sup>†</sup>			5 years and over*
Japanese encephalitis vaccine <sup>†</sup>		Mandatory completion of the additional training module: <i>Japanese encephalitis - A learning resource for immunisation providers</i> hosted by the Pharmaceutical Society of Australia or the Pharmacy Guild of Australia	5 years and over
Measles-mumps-rubella combination vaccine <sup>†</sup>	MMR		12 years and over*
Meningococcal vaccine (ACWY only) (quadrivalent) conjugate vaccine <sup>†</sup>	MenACWY		14 years and over*
Poliomyelitis vaccine <sup>†</sup>			5 years and over
Typhoid vaccine <sup>†</sup>		Intramuscular injection (IMI) formulation only	5 years and over
Zoster vaccine <sup>†</sup> Recombinant varicella zoster virus glycoprotein e antigen vaccine		Shingrix vaccine brand only	50 years and over

§ ATAGI advice in regard to medical contraindications, precautions, vaccine administration in pregnancy, use of vaccines and vaccine use as a booster dose/s must be adhered to. A person with any precaution or contraindication (other than the person is on anti-coagulation therapy) to a vaccine must be referred to a medical practitioner.

# Where the TGA approved Product Information and ATAGI recommendations differ, the advice of ATAGI must be followed.

†Vaccination recommendations for individuals and administration processes must be in accordance with the digital edition of the Australian Immunisation Handbook.

\* Refer to the NSW Immunisation webpage for advice on eligibility for State funded and National Immunisation Program vaccines.

### B. GENERAL REQUIREMENTS

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) (see

<https://www.legislation.nsw.gov.au/view/html/inforce/current/sl-2008-0392#sec.48A> which prescribes rules for: -

- Completing an accredited vaccination training course,
- Recording each vaccination in accordance with the regulation requirements, and
- Conducting vaccinations under standards approved by the Health Secretary (these Standards).

### **C. COMPETENCY, TRAINING AND SCOPE OF PRACTICE**

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

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

The Pharmacist immuniser must only administer a vaccine while employed or engaged to provide immunisation services.

The pharmacist immuniser must ensure that they have the required knowledge for all authorised vaccines that they intend to administer. For all vaccines (other than COVID-19 vaccines), the pharmacist immuniser must ensure that they comply with the digital Australian Immunisation Handbook and in accordance with the TGA approved Product Information. For COVID-19 vaccines pharmacist immunisers must comply with ATAGI recommendations, including number of primary course and booster doses, dose intervals, patient age and any other recommendations or restrictions. Where the Product Information and ATAGI recommendations differ, the advice of ATAGI must be followed.

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.

The pharmacist immuniser must have access to, and comply with, the following: -

- *'The digital Australian Immunisation Handbook'* – Australian Government Department of Health; and
- The TGA approved Product Information for each vaccine; and
- *'National Vaccine Storage Guidelines – Strive for 5'* (current edition) – Australian Government Department of Health; and
- ATAGI recommendations on administration of COVID-19 vaccines (if administering these vaccines).

#### **General 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 must hold a certificate confirming competency to vaccinate following completion of an accredited training program for all authorised vaccines that they intend to administer.

The pharmacist immuniser must hold a cardio-pulmonary resuscitation (CPR) certificate issued within the last 12 months. If the pharmacist is administering vaccines to people aged less than 14 years of age, the CPR certificate must include paediatric CPR training.

To maintain authority to immunise, the pharmacist immuniser must annually review best practice policy for immunisation and ensure their competence for each vaccine they administer. This may be, but is not limited to, attendance at seminars on current practices, or formal immunisation update courses.

An intern pharmacist who holds a certificate confirming competency to vaccinate following completion of an accredited training program for all vaccines they intend to administer, is only able to administer specified vaccines under the direct supervision of a pharmacist immuniser who holds certification to vaccinate for the relevant vaccine.

### **COVID-19 vaccine training**

For the purposes of supply and administration of any COVID-19 vaccine, a pharmacist immuniser, in addition to the above requirements, must also successfully complete:

- Core COVID-19 training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health and Aged Care in partnership with the Australian College of Nursing; and
- To administer a specific COVID-19 vaccine, the relevant vaccine specific additional COVID-19 training modules from the *COVID-19 Vaccination Training Program* developed by the Commonwealth Department of Health and Aged Care in partnership with the Australian College of Nursing for all vaccines that the pharmacist immuniser is administering.

The pharmacist immuniser must review all relevant training modules when notification of updates are received.

### **Japanese encephalitis vaccine training**

For the purposes of supply and administration of any Japanese encephalitis vaccine, a pharmacist immuniser, in addition to the above requirements, must also successfully complete the *Japanese encephalitis - A learning resource for immunisation providers* hosted by the Pharmaceutical Society of Australia or the Pharmacy Guild of Australia.

## **D. ADMINISTRATION AREA AND EQUIPMENT**

Schedule 4 vaccines must be stored in accordance with each of the requirements under the *Poisons and Therapeutic Goods Regulation 2008*, *National Vaccine Storage Guidelines 'Strive for 5'*, and as stated on the respective manufacturer's pack or for the COVID-19 vaccines, in accordance with the TGA approved Product Information.

A pharmacist immuniser may administer the approved vaccines to eligible patient groups (noting age limitations specified on page 1 of this document) in healthcare, suitable retail, community, residential, workplace, and education settings provided that all conditions in these standards are met including those outlined below.

The pharmacist immuniser must ensure that when administering vaccines that at least one other health practitioner or appropriately trained pharmacy staff member is present, this includes when vaccinating offsite from the community pharmacy. The pharmacy staff member must be an appropriately trained person who is able to recognise signs of anaphylaxis and seek help.

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 room for the purpose of providing vaccination services.

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

- I. The room or area is not to be used as a dispensary, storeroom, staff room or retail area,
- II. Provide adequate privacy,
- III. Have adequate lighting,
- IV. Be maintained at a comfortable ambient temperature,
- V. Have a hand sanitisation facility,
- VI. Have ready access to a hand washing facility,
- VII. 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
- VIII. Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar).

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): -
  - I. A temperature-monitored refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines or temperature monitored portable cooler for mobile clinics,
  - II. All necessary consumables required for vaccine administration,
  - III. An appropriately sized sharps container to dispose of clinical waste including used syringes and needles,
  - IV. An in-date and complete anaphylaxis response kit, with in-date adrenaline (epinephrine) for use in the treatment of anaphylaxis
  - V. An emergency response protocol (preferably laminated) on display,
  - VI. Access to *'The digital Australian Immunisation Handbook'*,
  - VII. Access to *'National Vaccine Storage Guidelines – Strive for 5'* (current edition), and
  - VIII. A process to regularly monitor on-line updates to *'The digital Australian Immunisation Handbook'* or ATAGI recommendations (if administering COVID-19 vaccines), including prior to administering any vaccine.

## **E. PATIENT CONSENT, ELIGIBILITY AND RECORDS**

### **General**

The pre and post-vaccination assessment and administration of each vaccine must be undertaken in accordance with the procedures specified in the TGA approved Product Information, the digital *Australian Immunisation Handbook*, or for the COVID-19 vaccination in accordance with ATAGI recommendations.

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.

For all vaccines, the pharmacist immuniser must take a medical and allergy/ hypersensitivity history.

The pharmacist immuniser must not vaccinate a person with a contra-indication to any vaccine as listed in the:

- I. The digital *Australian Immunisation Handbook*
- II. TGA approved Product Information
- III. ATAGI recommendations for the COVID-19 vaccine that is being administered.

Should the patient have a contraindication or precaution to the vaccine, refer the patient to a medical practitioner. However, a pharmacist immuniser may supply/administer COVID-19 vaccine to:

- a person who is on anti-coagulation therapy; or
- a pregnant woman with no other medical contraindication or other precaution with the Pfizer vaccine or Moderna vaccine. Novavax vaccine may only be administered to a pregnant woman in accordance with ATAGI recommendations.

Informed consent requires that the pharmacist immuniser provides 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).

When consenting a child or other person under the care of a parent/guardian, the pharmacist immuniser must ensure that the consenting person has the authority to consent for the individual.

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.

### **Vaccination records**

All vaccines administered by the pharmacist immuniser must be reported to the AIR, preferably within 24 hours of administration but must be within 10 business days.

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

- I. The person's name, address, date of birth and contact details,
- II. 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'),
- III. The brand, batch number and expiry date of the vaccine,
- IV. The part of the body to which the vaccine was administered,
- V. The date on which the vaccine was administered,
- VI. The pharmacist's name and contact details and his or her certificate of accreditation number,
- VII. The address of the pharmacy or other vaccination premises at which the vaccination was administered, and
- VIII. A unique reference number for the supply and administration.

The pharmacist immuniser must obtain informed written or verbal consent from the patient (or parent / guardian) before the vaccination and must retain proof of consent for seven years (in accordance with the *Health Records and Information Privacy Act 2002*), for all vaccines listed in this document (excluding COVID-19 vaccines the consent for which must be obtained in accordance with the below requirements).

If verbal consent is obtained for vaccines other than COVID-19, 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.

#### **COVID-19 vaccination records**

The pharmacist immuniser must obtain written or other electronic evidence of consent from each patient to whom a COVID-19 vaccine is supplied and retain a copy of that consent. To the extent administration or supply occurs in a school setting, appropriate informed consent must have been provided by the parent/guardian of the patient.

The Australian Government Department of Health *COVID-19 vaccination – Consent form* is to be used in obtaining consent. The pharmacist immuniser must provide the patient/parent/guardian with the relevant Australian Government COVID-19 vaccine Patient Information Sheet.

#### **F. POST VACCINATION CARE**

The pharmacist immuniser must advise the person (or their parent/guardian) to remain on the pharmacy or other vaccination premises for 15 minutes post vaccination and must advise the person of possible risks in leaving earlier than 15 minutes.

The pharmacist immuniser must either observe, (or direct an appropriately trained pharmacy staff member to observe), the person for 15 minutes post vaccination to monitor for acute adverse events or anaphylaxis.

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

The pharmacist immuniser must provide each patient (and/or parent/guardian) with post-vaccination care as per the advice in the digital *Australian Immunisation Handbook* or the latest ATAGI or TGA Product Information in relation to what to expect following vaccination, and provide advice on when to seek medical attention, following each administration of a vaccine.

#### **Adverse events**

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

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

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



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