NSW PHARMACIST VACCINATION STANDARDS

A. APPROVED VACCINES AND VACCINATION SCHEDULES

Name	Abbreviated/ alternate name	Limitations of use	Patient age
Influenza and coryza vaccine 'Influenza vaccine'			2 years and over
SARS-COV-2 (COVID-19) vaccine			5 years and over
Diphtheria toxoid			5 years and over*
Tetanus toxoid			5 years and over*
Pertussis antigen			5 years and over*
Hepatitis A vaccine	Hep A		5 years and over*
Hepatitis B vaccine	Hep B		5 years and over*
Japanese encephalitis vaccine	JE		5 years and over*
Measles vaccine	MMR		5 years and over*
Mumps vaccine			5 years and over*
Rubella vaccine			5 years and over*
Meningococcal vaccine	MenACWY or MenC		5 years and over*
Meningococcal B vaccine	MenB		5 years and over*
Poliomyelitis vaccine	Polio		5 years and over*
Cholera vaccine[Δ]			5 years and over*
Varicella vaccine	VZV		5 years and over*
Haemophilus influenzae vaccine	Haemophilus influenzae type b (Hib) vaccine		5 years and over*
Rabies vaccine[β]	Rabies and other lyssaviruses	Intramuscular injection (IMI) pre- exposure prophylaxis treatment only for people who are not immunocompromised	5 years and over*
Typhoid vaccine[Δ]			5 years and over for injectable typhoid vaccine* 6 years and over for oral typhoid vaccine*

Human papillomavirus vaccine	HPV		9 years and over*
Mpox (Monkeypox) vaccine	Modified vaccinia Ankara – Bavarian Nordic	JYNNEOS brand only. Sub-cutaneous injection for primary preventative vaccination (PPV) only. Only in pharmacy settings that are authorised vaccination settings under the *NSW Health State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine*	Non-pregnant eligible people 16 years and over under the *NSW Health State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine**
Recombinant varicella zoster virus glycoprotein e antigen vaccine	Zoster vaccine	Shingrix vaccine brand only	18 years and over*
Pneumococcal vaccine		Pneumococcal conjugate vaccine only	18 years and over*
Recombinant Respiratory Syncytial Virus pre-fusion F protein vaccine	RSV vaccine	Arexvy and Abrysvo brands only **Abrysvo is the only RSV vaccine approved for use in pregnant women.**	Arexvy for 60 years and over AND for 50-59 years who are at increased risk for RSV disease* Abrysvo for 60 years and over and pregnant women[α] from 28 weeks' gestation for each pregnancy*

* Refer to the NSW Immunisation webpage for advice on eligibility for State funded and National Immunisation Program vaccines.
[α] Pregnant women should be asked to confirm their gestational age prior to vaccine administration (verbal confirmation is acceptable) and advised about other pregnancy vaccines including influenza and pertussis.
β Patients must be educated about first aid and the need to seek medical assessment for exposure to rabies or Australian Bat Lyssavirus regardless of having been vaccinated.
Δ Self-administration by patients is permissible exclusively for oral vaccine formulations.

B. GENERAL REQUIREMENTS

A registered pharmacist initiating and administering a vaccine under their 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).

Vaccination recommendations for individuals and administration processes must be in accordance with the digital edition of the Australian Immunisation Handbook (AIH). If advice is not available in the AIH, the Australian Technical Advisory Groups on Immunisation

(ATAGI) recommendations must be followed or if relevant, as indicated in the Therapeutic Goods Administration (TGA) approved product information.

C. COMPETENCY, TRAINING AND SCOPE OF PRACTICE

Competency and General Training

A 'pharmacist immuniser' is a registered pharmacist who has successfully 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 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 should adopt the '*Practice guidelines for the provision of immunisation services within pharmacy*' (current edition) – Pharmaceutical Society of Australia.

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,
- ensure that they have the required knowledge for all authorised vaccines that they intend to administer,
- have access to and comply with the *Australian Immunisation Handbook,* Australian Technical Advisory Group on Immunisation (ATAGI) recommendations, and the Therapeutic Goods Administration (TGA) approved Product Information for all vaccines that they administer as well as the *National Vaccine Storage Guidelines – Strive for 5*' (current edition),
- maintain their authority to immunise by annually reviewing best practice policy for immunisation and ensuring 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

In addition to the above requirements, for the purposes of supply and administration of any COVID-19 vaccine, a pharmacist immuniser must review the NSW Health guidance on management of COVID-19 vaccines specific to each of the vaccines that the immuniser will be administering (https://www.health.nsw.gov.au/Infectious/covid-19/vaccine/Pages/document-centre.aspx#administration-downtime).

Scope of Practice

The pharmacist immuniser must:

- only administer a vaccine while employed or engaged to provide immunisation services.
- practice within their scope of practice, professional knowledge and expertise when undertaking vaccination and managing adverse events following immunisation.

D. ADMINISTRATION AREA AND EQUIPMENT

The pharmacist immuniser must ensure that the following equipment and processes are in place at all times:

I. A purpose-built vaccine refrigerator with a continuous temperature data logger programmed to alarm when a temperature outside the +2°C to +8°C range is recorded,
II. Equipment and effective cold chain management protocol in place in preparedness for power outage/refrigerator failure and offsite/outreach immunisation clinics in full accordance with the '*National Vaccine Storage Guidelines – Strive for 5*' (current edition),
III. An in-date and complete anaphylaxis response kit, with in-date adrenaline (epinephrine) for use in the treatment of anaphylaxis,
IV. An appropriately sized sharps container to dispose of clinical waste including used syringes and needles,
V. An emergency response protocol (preferably laminated) on display including (but not limited to) anaphylaxis response kit contents, phone access (particularly in rural/remote area) and pre-identified roles and responsibilities during a severe event following immunisation,
VI. Staffing and supervision of patients planning according to expected patient throughput to ensure safety delivery of care, including maintaining sufficient staff to support required post-vaccination observation periods and ensuring adverse events are responded to promptly and effectively,
VII. Access to the '*Australian Immunisation Handbook*' and '*National Vaccine Storage Guidelines – Strive for 5*' (current edition), and
VIII. A process to regularly monitor on-line updates to the '*Australian Immunisation Handbook*', including prior to administering any vaccine.

Immunisation room/area

Immunisation encounters must be conducted in an immunisation room/area in a pharmacy, hospital (including but not limited to bedside) and/or offsite/outreach immunisation clinics such as those in residential aged care and disability facilities (including but not limited to bedside) and must be consistent with the following:

I. is not used as a dispensary area; Other suitable areas of a pharmacy may be temporarily transitioned into an immunisation room/area provided all requirements below are met,
II. is a professional space that is functional, safe, and maintained to a high standard of cleanliness and tidiness,
III. while in the immunisation room/area the patient has no access to schedule 3, 4, and 8 substances[1], compounding materials and patients' records,
IV. entry to and exit from the vaccination area must avoid any area where a patient has access to any Schedule 3, 4 and 8 medicines, compounding materials and patients' records, including walking through the dispensary,
V. provides auditory and visual privacy to ensure a confidential conversation with the patient and private exposure of the vaccination site,
VI. has adequate lighting,
VII. is maintained at a comfortable ambient temperature,

[1] Vaccines stored in refrigerators within immunisation rooms/areas to which members of the public have access, must be secured with locks to prevent unauthorised access.

VIII. has a ready access to a hand washing facility and/or medical grade hand sanitisation products,

IX. has sufficient bench space (with an impervious surface) to prepare vaccinations, and a minimum of two chairs[2] (for the patient and vaccinator and parent/guardian where appropriate),

X. has equipment to perform first aid treatment and has documented CPR and anaphylaxis treatment procedures including an in-date and complete anaphylaxis response kit, with in-date adrenaline (epinephrine) for use in the treatment of anaphylaxis,

XI. has space for the patient to lie down when necessary and sufficient space for the vaccinator and appropriately trained person to manoeuvre and perform first aid treatment and CPR procedures where required,

XII. has unhindered and easy access to the area for emergency services such as paramedics with stretcher to facilitate the management of potential significant adverse events following immunisation.

E. VACCINE STORAGE AND TRANSPORT

Schedule 4 vaccines must be stored, monitored and transported (to off-site/outreach immunisation clinics) in accordance with each of the requirements under the *Poisons and Therapeutic Goods Regulation 2008, National Vaccine Storage Guidelines – Strive for 5*, *NSW Health Vaccine Storage and Cold Chain Management Protocol* and as stated on the respective manufacturer's pack or for the COVID-19 vaccines, in accordance with the TGA approved Product Information, as well as the following requirements:

I. vaccine fridge temperature monitoring records must be completed as per the *National Vaccine Storage Guidelines – Strive for 5', retained* for 2 years and provided to the local public health unit (PHU) if requested.

II. vaccine storage self-audits records must be completed as per the *National Vaccine Storage Guidelines – Strive for 5', retained* for 2 years and provided to the PHU if requested.

III. cooler temperature recordings for off-site/outreach immunisation services must be completed in accordance with the *National Vaccine Storage Guidelines – Strive for 5*, retained for 2 years and provided to the PHU if requested.

IV. Instances of vaccine fridge temperatures outside the +2°C to +8°C range and/or light exposure involving National Immunisation Program (NIP) or NSW state funded vaccines must be recorded and reported to the local PHU on 1300 066 055. Affected vaccines must be quarantined at +2°C to +8°C and labelled 'Do not use' until further instruction is provided by the PHU. Cold chain breach and/or light exposure affecting privately funded vaccines must be consulted with the relevant manufacturers.

V. Expired NIP and NSW state funded vaccines must be discarded appropriately and recorded onto the NSW Vaccine Centre Online Ordering System.

F. 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 and the digital *Australian Immunisation Handbook*.

[2] The chair provided for the patient cannot be a stool or a chair with wheels.

For all vaccines, the pharmacist immuniser must:

- take a medical and allergy/ hypersensitivity history,
- not administer (and/or supply oral typhoid and cholera vaccines) to a person with a contraindication to any vaccine as listed in the:
    - digital *Australian Immunisation Handbook*
    - TGA approved Product Information
- refer patients with a contraindication or precaution to the vaccine to a medical practitioner,
- provide information in relation to the benefits and risks of the specific vaccine and explain the rationale and purpose of the vaccine to the patient (or parent /guardian) to ensure informed consent,
- ensure that any consenting person has the authority to consent for the individual, such as for children or other person under the care of a parent/guardian,
- check the vaccine's expiry date before vaccine administration (and/or supply of oral typhoid and cholera vaccines)
- check an individual's vaccination status on the Australian Immunisation Register (AIR) **prior** to administering a vaccine (or supplying oral typhoid and cholera vaccines),
- subsequently record any vaccines administered (except for mpox[3] vaccines) onto the AIR (in outreach immunisation services this can be done by other immunisers who have access to the AIR).
- Before supplying oral typhoid and cholera vaccines, provide the patient (and or parent/guardian) with comprehensive instruction (such as the Consumer Medicine Information summary) on oral typhoid and cholera vaccines' regimen, storage and preparation of each dose and administration.

Vaccination Administration Record

Pharmacist immunisers must

- report all vaccines except for mpox[3] vaccines to the AIR, preferably within 24 hours of administration but must be within 10 business days,
- contact the patient[4] to confirm that the oral typhoid and/or cholera vaccines were appropriately self-administered by the patient prior to recording the vaccination onto the AIR and ask the patient whether they have experienced any adverse events following self-administration of the oral vaccine(s), and
- report pregnancy status at the time of vaccination onto the AIR as appropriate.

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

I. person's name, address, date of birth and contact details,
II. 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. vaccine brand, batch number and expiry date,
IV. vaccination site,
V. date of administration,

[3] Mpox vaccine administration should be reported to AIR, unless the patient specifically opts out of the vaccine being recorded on AIR. If vaccine administration is not recorded on the AIR, authorised vaccination providers must be able to provide a record of vaccine use as per the *NSW Health State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine*.

[4] If the patient is not contactable, the pharmacist immuniser is not required to record the administration of oral typhoid and oral cholera vaccines onto the AIR.

VI. pharmacist immuniser name and contact details and their certificate of accreditation number,
VII. pharmacy address or other vaccination premise, and
VIII. unique reference number for the supply and administration.

A pharmacist immuniser that supplies an oral typhoid or cholera vaccine without a prescription must make a record of the vaccination with the following information:

I. person's name, address, date of birth and contact details,
II. 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. vaccine brand, batch number and expiry date,
IV. supply site,
V. date of supply,
VI. pharmacist immuniser name and contact details and their certificate of accreditation number,
VII. pharmacy address or other vaccination premise, and
VIII. Unique reference number for supply

Patient Consent Record

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 all vaccines listed in this document in accordance with the Health Records and Information Privacy Act 2002:

- for 7 years, or
- until the patient is 25 years old if the patient was under 18 years old at the time of vaccination.

If verbal consent is obtained for vaccines, there must be documented evidence of verbal consent made by the pharmacist immuniser, in the person's record. Verbal consent should be recorded in electronic records by way of a typed note (or by a check box in a local pharmacy software for recording verbal consent for vaccination that is manually checked by the health practitioner) which is recorded against the patient's clinical notes. Users of the electronic records must enter their access credentials against these entries. 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.

G. POST VACCINATION CARE

For vaccines administered by a pharmacist immuniser, the pharmacist immuniser, must:

- advise the person (or their parent/guardian) to remain at the vaccination premises for 15 minutes post vaccination and must advise the person of possible risks in leaving earlier than 15 minutes,
- either observe or direct an appropriately trained staff member to observe the person for 15 minutes post vaccination, to monitor for acute adverse events or anaphylaxis,
- make notes in the patient record of vaccination (as specified in part F) when the person leaves the pharmacy or other premises earlier than 15 minutes post vaccination,
- provide each patient (and/or parent/guardian) with post-vaccination care as per the advice in the digital *Australian Immunisation Handbook* or the latest 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.

For oral typhoid and oral cholera vaccines supplied by a pharmacist immuniser, the pharmacist immuniser, must:

- provide each patient (and/or parent/guardian) with instructions on post-vaccination care as per the advice in the digital *Australian Immunisation Handbook* or the latest TGA Product Information in relation to:
  - what to expect following vaccination, and
  - provide advice on when to seek medical attention following each vaccine dose.
- ask the patient whether they have experienced any adverse events when contacting the patient to confirm that the oral typhoid and/or cholera vaccines were appropriately self-administered.

Adverse Events

The pharmacist immuniser must:

- be competent to manage anaphylaxis post vaccination including the use of adrenaline consistent with the digital *Australian Immunisation Handbook*,
- ensure an ambulance is called to attend a person who experiences anaphylaxis post vaccination,

notify the adverse events following immunisation (AEFI) to the local public health unit by telephone on 1300 066 055 immediately after the response to an event and at the latest within the next business day. This includes AEFIs related to any vaccines including but not limited to oral travel vaccines reported by the patient after they have left the pharmacy or outreach immunisation clinic.

Vaccine Administration Errors

Vaccine administration errors must be disclosed to the patient, recorded onto the AIR and reported to the local public health unit by telephone on 1300 066 055.

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Population and Public Health
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