Pharmacy Vaccination Program

Tasmanian Pharmacist Immunisation Program Guidelines

Effective 3 January 2024

Version 1.0

Department of **Health**

Tasmanian Government

Contents

Introduction

Immunisation is the safest and most effective way to control many of the world's most important infectious diseases. It has been the single most important advancement in public health over the last century saving more lives than any other health intervention.

Australia has a strong and internationally recognised National Immunisation Program (NIP), with a national average of over 90 per cent coverage for most childhood vaccines[1]. Australia's achievements in immunisation meet international goals set by the World Health Organization under the *Global Vaccine Action Plan*[2] as outlined in the *National Immunisation Strategy*[3].

Opportunities remain to improve vaccination rates for all ages both locally and internationally. Achieving high vaccination coverage rates requires a competent workforce as well as effective clinical governance arrangements for all immunisation programs which are clear, accountable, and effective, with business processes in place to monitor and evaluate performance and provide feedback.

Pharmacist-administered vaccination programs commenced in 2016, with initial scope enabling administration of influenza vaccines to those aged 16 years and older. Over time, the scope of vaccinations offered in community pharmacy have increased.

Enabling Authorised Pharmacist Immunisers (API) to administer vaccines in community pharmacy provides greater public access to vaccination. To independently initiate vaccination (i.e. without prescription) in Tasmania, pharmacists must be authorised as an API and be working under a vaccination program which has been approved by the Director of Public Health (DPH).

These *Tasmanian Pharmacist Immunisation Program Guidelines* (the 'Guidelines') describe the processes and conditions required to be an API in Tasmania and support pharmacies and APIs to conduct safe, high quality vaccination services.

1. Regulations

In Tasmania, the *Poisons Regulations 2018* (the Regulations) enable the Secretary of the Department of Health (DoH) (or his/her delegate) to approve other classes of health professionals to possess and administer medicines (in this case vaccines) independently of a medical or nurse practitioner. The delegate for the DoH Secretary is the DPH.

The Regulations enable the Secretary of the DoH, to approve a Schedule 4 poison for administration by a pharmacist and specifies the conditions in which a pharmacist is authorised to administer to another person as detailed in the Poisons List.

The Regulations and these guidelines define the conditions under which an API is authorised to administer an approved Schedule 4 poison.

[1] DTPa, hepatitis B, MMR, Hib, and polio

[2] Available at: Global Vaccine Action Plan (who.int)

[3] Available at www.health.gov.au/resources/publications/national-immunisation-strategy-for-australia-2019-to-2024

Regulation 82 (d)[4] *of the Poisons Regulations 2018* allows pharmacists who have met certain educational requirements and/or who have been approved by the DPH to administer certain vaccines as listed in Schedule 4 to the Poisons List, provided they are approved vaccines against the diseases listed in Tables 2A, 2B and 2C of these guidelines. The vaccines must only be administered under a current vaccination program approved by the DPH.

In summary, to independently provide approved vaccines in Tasmania a pharmacist must be:

i) Working under a vaccination program approval (as per section 2),

ii) an Authorised Pharmacist Immuniser (as per section 3 and the *Tasmanian Authorised Pharmacist Immuniser Application Guidelines*), and

iii) adhering to requirements specified in these guidelines

2. Vaccination Programs

Vaccination program approvals are required for all pharmacies that employ Authorised Immunisers (AIs; pharmacists and/or registered nurses).

Under all circumstances, the AI must provide vaccination services in accordance with the Regulations and these guidelines. To obtain program approval, at least one pharmacist employed by that pharmacy must be an API and therefore meet all requirements listed in the *Tasmanian Authorised Pharmacist Immuniser Application Guidelines*.

The Responsible Officer is responsible for ensuring all employed AIs meet and maintain the requirements for authorisation.

2.1 About Program Approvals

Pharmacies are required to apply and have a current vaccination program approval by DoH before administering vaccines.

Program approval enables pharmacies to:

- Employ AIs to offer vaccination services;
- Order NIP-funded and/or state-funded vaccines;
- Receive important vaccine updates, such as changes to vaccination schedule(s), new resources and changes to vaccination recommendations.

To apply, a 'Responsible Officer' for the program approval must be nominated; this must be a pharmacist who is employed primarily at the pharmacy and is responsible for the program, as well as ordering and reporting on vaccines, ensuring vaccines are stored appropriately and are administered only to person(s) eligible to receive funded vaccines.

Pharmacies seeking program approval must satisfy all requirements of these guidelines.

[4] Available at: www.legislation.tas.gov.au/view/html/inforce/2019-04-17/sr-2018-079#GS82@EN

All vaccination program holders must ensure vaccines are administered in accordance with the relevant legislation and best practice guidance[5]. Responsible Officers and AIs must:

- Manage cold chain as per the *National Vaccine Storage Guidelines - 'Strive for 5.'* These guidelines outline essential cold chain practices, including use of a purpose-built vaccine refrigerator, data loggers, temperature reporting, training and other considerations[6].
- Maintain vaccines in accordance with the Therapeutic Goods Administration (TGA) approved Product Information.
- Follow clinical guidance outlined in the *Australian Immunisation Handbook (AIH)*[4].
- Comply with the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*[7].
- Deliver vaccinations in a setting that complies with the Tasmanian Pharmacy Authority's (TPA) *Pharmacy Guidelines*[8].
- Adhere to the details provided in their program approval, including details relating to off-site vaccination clinics (see '2.5 Off-Site Vaccination Clinics' below).
- AIs must have access to the Australian Immunisation Register (AIR)[9] and the following resources (including for any off-site vaccination clinics):
    - the *Australian Immunisation Handbook* (online version)
    - the *National Vaccine Storage Guidelines – 'Strive for 5'* (current edition)
    - materials to support communication about vaccination, including *Questions about vaccination*[10] and *Sharing Knowledge About Immunisation*[11].

2.2 Applying for Program Approval and Renewal

Pharmacies can apply for or renew their program approval online via the Immunisation Provider Portal (IPP) or by emailing their completed application form to the Immunisation team.

- The nominated Responsible Officer for the pharmacy must complete a '*Pharmacy Vaccination Program Application Form'* available on the IPP or can be downloaded from the DoH Immunisation webpage[12].
- Additionally, pharmacies applying for program approval for the first time must complete and submit the *Australian Immunisation Register – Application to register as a vaccination provider form (IM004)* with their application. This form should be emailed directly to the Immunisation team, Communicable Diseases Prevention Unit (CDPU).
- Vaccination programs **must be renewed annually**.

[5] Available at immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination

[6] Available at www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5?language=en

[7] Available at nhmrc.govcms.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019

[8] Available at www.pharmacyauthority.tas.gov.au/guidelines/

[9] Access at www.humanservices.gov.au/organisations/health-professionals/services/medicare/australian-immunisation-register-health-professionals

[10] Available at www.health.gov.au/resources/publications/questions-about-vaccination

[11] Available at skai.org.au/

[12] Available at: www.health.tas.gov.au/health-topics/immunisation/immunisation-providers

2.3 Changes to Program Approvals in 2024

From 1 January 2024, all pharmacies that choose to deliver expanded scope vaccines are required to renew their vaccination program approval.

Pharmacies participating in the Australian Government's NIP Immunisation in Pharmacy Program and wish to receive government funded vaccine will be onboarded to the Vaccine Ordering System (VOS).

For the pharmacy to be onboarded to the VOS, the Responsible Officer of the vaccination program and all employed AIs administering expanded scope vaccines must meet all training requirements as specified in the relevant guidelines.

- For APIs refer to the *Tasmanian Authorised Pharmacist Immuniser Application Guidelines.*
- For Authorised Nurse Immunisers (ANIs) refer to the *Tasmanian Authorised Nurse Immuniser Application Guidelines.*

Pharmacies that wish to obtain a NIP vaccine ordering account must provide the following evidence of maintaining cold chain:

- 48-hours of current data from the vaccine refrigerator(s) data logger(s), with data recorded every five (5) minutes, and;
- The vaccine refrigerator(s) temperature chart(s) from the previous month (min-max charts).

2.4 Vaccination Space Requirements

Community pharmacies must vaccinate in an area of the pharmacy that has been assessed against and is considered compliant with section 13 of the TPA's *Pharmacy Guidelines*[13]. Their guidelines state:

- The dispensary, a storeroom, packing room or staff room must not be used for vaccination services. Additionally, the vaccination area should not be accessible via the dispensary.
- The room or area may be dedicated to the purpose, or an existing consulting room may be used. Hand sanitisation facilities must be available in the room.
- The vaccination space must:
    - be clean and hygienic;
    - maintain privacy (both visually and audibly);
    - have sufficient floor area, that is clear of superfluous equipment and furniture, and is able to accommodate three chairs or two chairs and a bed, and enables sufficient room to manoeuvre as required[14]
    - have a bench with an impervious surface of an adequate area.
    - have a sharps bin and a medical waste bin.
    - have an emergency response protocol (preferably laminated) on display, an emergency response kit, and the most recent editions of the *AIH* and *Strive for 5*.
    - be designed and set up to accommodate people with disability.
- Seating is to be made available post-vaccination in a position that allows the vaccinee to remain within the line of sight of the pharmacist or person qualified in first aid for the entirety of the post-vaccination monitoring period. This should either be close to the dispensary or close to the vaccination area.

[13] Available at www.pharmacyauthority.tas.gov.au/guidelines/

[14] Available at: www.pharmacyauthority.tas.gov.au/guidelines/

The TPA *Pharmacy Guidelines* state only a temperature-monitored refrigerator manufactured exclusively for the purpose of storage of vaccines may be used, but can also be used to store other medicines. It must contain a data-logger and if the refrigerator is located outside of the dispensary, be fitted with a lock, with the key under the control of the pharmacist.

The TPA also requires vaccinating pharmacies be compliant with *Strive for 5,* which also recommends the refrigerator used to store vaccines should be a purpose-built vaccine refrigerator, manufactured exclusively for the purpose of storage of vaccines.

An additional refrigerator with a freezer section will be required for storing ice packs and gel packs, as purpose-built vaccine refrigerators do not have freezer compartments.

2.5 Off-Site Vaccination Clinics

APIs linked to an approved program, as defined in these guidelines, may be requested to access a third-party organisation, such as a community health service or residential aged care facility (RACF) to provide a vaccination service. Please note the consent requirements for vaccinating in a RACF which are discussed in section 7.4.

As part of an off-site vaccination service, APIs are responsible for ensuring all requirements within these guidelines are met and maintained, and the clinical setting is appropriate for the administration of vaccines. The following conditions must be met to operate an off-site vaccination service:

- The service must be linked to a community or hospital pharmacy with an existing program approval from the DPH, which includes approval to conduct off-site vaccination services.
- Must adhere to the requirements of the *AIH* and *Strive for 5*, including for any equipment and cold chain requirements.
- Must ensure that the vaccination space allows for visual and audible privacy and be of sufficient size to accommodate the patient (including space to manage an adverse event), an accompanying person and the authorised immuniser.
- Must ensure that in addition to the authorised immuniser, that one other staff member who holds current first aid and cardiopulmonary resuscitation (CPR) qualification is present when the vaccines are administered and during the post-vaccination period.
- Must ensure that patients are monitored during the post-vaccination period in line of sight of the AI or other first aid and CPR trained staff member for a minimum of 15 minutes post-vaccination.
- Must ensure that an emergency response protocol and an anaphylaxis response kit which complies with the recommendations of the *AIH* is accessible during sessions.
- Pharmacist Interns may only provide vaccination under the direct supervision of an approved person as stipulated in the *Tasmanian Authorised Pharmacist Immuniser Application Guidelines*.
- Must ensure robust clinical documentation, including that all vaccines administered are recorded on the AIR.

2.6 Equipment

All equipment should comply with the recommendations contained in the *AIH* and *Strive for 5* documents, and should include:

- an anaphylaxis response kit

- a purpose-built vaccine refrigerator with an automated temperature data logger (refrigerator may also be used for the storage of medicines requiring cold storage)
- coolers, data loggers, ice packs and insulation materials suitable for off-site vaccination clinics or for transporting vaccines
- all necessary consumables required for vaccine administration
- a sharps container suitable for the disposal of clinical waste, including used syringes and needles.

2.6.1 Anaphylaxis Response Kit

APIs and vaccinating Pharmacies must have an anaphylaxis response kit accessible when administering vaccines. All equipment should comply with the recommendations in the online version of the *AIH*, and include:

- adrenaline 1:1000 (minimum of three ampoules). Expiry dates are regularly checked; discard and replace expired stock and replenish stock after use
- a minimum of three 1 mL syringes and 25 mm length needles for intramuscular injection
- a pen, paper and stopwatch to record time of administration of adrenaline; alternatively, time of vaccine administrated may be documented and provided to the client
- a laminated copy of table 'Doses of intramuscular 1:1000 adrenaline for anaphylaxis'[15] as per the current edition of the *AIH*, noting weight and age-specific doses required
- a laminated copy of 'Recognition and treatment of anaphylaxis'[16]
- an emergency response protocol (preferably laminated and on display) identifying assigned roles and responsibilities. All clinical and non-clinical pharmacy staff should be aware of the emergency response protocol, and their roles and responsibilities in the event of an emergency.

Where adrenaline ampoules are unavailable, an adrenaline autoinjector may be kept in an anaphylaxis response kit, however, this is not preferred noting that autoinjectors are single use only, do not allow for dose variation or repeated doses and generally have a short expiry (12-24 months). Pharmacists should refer to guidance in the *AIH* regarding the use of autoinjectors in vaccination services[17].

2.7 Insurance

Responsible Officers and APIs are required to hold appropriate insurance for the administration of vaccines and provision of a vaccination service. APIs should consult with their insurance provider regarding insurance appropriate to their circumstances, which includes the provision of vaccination services outside of pharmacy premises (if applicable).

3. Authorised Immuniser Requirements

The *Tasmanian Authorised Pharmacist Immuniser Application Guidelines* outline the process for pharmacists to apply for and renew immuniser authorisation in Tasmania. For further detail, including the minimum requirements to authorise with the department, please refer to those guidelines.

[15] Available at: immunisationhandbook.health.gov.au/resources/tables/table-doses-of-intramuscular-11000-adrenaline-for-anaphylaxis

[16] Available at: immunisationhandbook.health.gov.au/resources/tables/table-recognition-and-treatment-of-anaphylaxis

[17] Available at: immunisationhandbook.health.gov.au/contents/vaccination-procedures/after-vaccination

From 1 January 2024: *all* APIs authorised prior to 1 January 2024 are required to complete additional immunisation training to be competent to administer **all** vaccines within the expanded scope. To administer a vaccine, the API must have completed the specific module relevant to that vaccine (e.g. to administer Meningococcal ACWY vaccines, the Immuniser must have successfully completed a meningococcal vaccine module).

Responsible Officers of vaccination programs must ensure all APIs working under the pharmacy's program have completed these additional requirements. A declaration confirming completion of all necessary vaccine training modules should be received for all API(s) employed under the pharmacy's vaccination program.

Completion of the additional training is a condition of administering the expanded scope of vaccines *and* for renewal of all API authorisations from 1 January 2025.

In 2024, APIs may continue to independently prescribe and administer COVID-19, influenza, MMR and dTpa vaccines to approved age cohorts, and may continue to administer age-appropriate, privately purchased vaccines prescribed by a medical or nurse practitioner without completing additional training up to (and including) 31 December 2024.

From 1 January 2025: *all* pharmacists that have not completed the additional training requirements will be unable to practice as APIs in Tasmania and, will have their authorisation revoked.

3.1 Paediatric Authorisation

APIs are not permitted to administer vaccines to children between 5 and 10 years of age except:

- where the API and pharmacy have received the appropriate paediatric approval from the department to independently provide COVID-19 and/or influenza vaccines, and the child is aged ≥5 years.
- where a vaccine has been prescribed by a medical or nurse practitioner, and the API and pharmacy have received the appropriate paediatric approval from the department, and the child is aged ≥5 years.

It is the responsibility of the Responsible Officer to ensure that all AIs employed are appropriately trained and competent to vaccinate children. This includes identification and management of adverse events following immunisation (AEFI) for this age group.

The Responsible Officer of the vaccination program must ensure all APIs administering vaccines to children from age 5 years have paediatric approval, and that the pharmacy's vaccination program enables vaccination of this cohort.

It is essential that pharmacists administering vaccines to children are familiar with the additional clinical and communication skills required to administer vaccines to younger children. As such it is **strongly recommended** that APIs access additional training opportunities, such as those available from the Melbourne Vaccine Education Centre[18], Health Ed[19] and the National Centre for Immunisation Research and Surveillance[20].

[18] Available from education-mvec.mcri.edu.au/

[19] Available from www.healthed.com.au/learning-modules/

[20] Available from ncirs.org.au/education

4. Scope of Vaccination Practice

The scope of vaccines APIs are authorised to administer, and the circumstances in which pharmacists may administer these vaccines, are outlined in these guidelines in Tables 1 & 2.

4.1 Vaccine Funding

- Vaccines that APIs administer may be NIP-funded, Commonwealth funded (COVID-19), State Government funded (e.g. Hepatitis B, MMR) or privately funded.
- An assessment of eligibility for funding source should be undertaken in the pre-vaccination assessment.
- Table 2A must be reviewed in conjunction with the National Immunisation Program Schedule[21] and Funded Immunisation Schedule Tasmania[22] when considering eligibility for funded vaccine(s).

4.2 Scope of Vaccination Practice

In relation to API scope of practice, there are **three classes of vaccines**:

1. Independent-initiated vaccines (no prescription required)
2. Prescription-initiated
3. Out of scope: must not be administered by an Authorised Pharmacist Immuniser
    - Specialised or infant-only vaccines: yellow fever, tuberculosis, smallpox (mpox), Q fever or rotavirus vaccines as listed in Table 1.
    - Vaccinations for travel purposes without a prescription by a medical practitioner.

General considerations

For independently initiated and prescription-initiated vaccines:

- The API must be providing the vaccine within a setting that has a current vaccination program approved by the DPH.
- The API is working within their scope of practice when administering specific vaccines and is familiar with and follows current guidance in the *AIH*, and publications by the Australian Technical Advisory Group on Immunisation (ATAGI) and other evidence-based sources.
- The vaccine is administered in accordance with the clinical recommendations for the specific vaccine specified in the *AIH* and the approved TGA Product Information (PI).
    - Note: where there is variation in advice provided in the *AIH* and the PI, the advice of ATAGI (the *AIH*) should be considered best practice.
- The API conducts a pre-vaccination check of the AIR and reports all vaccination encounters to the AIR. The API must also report provision of the vaccine dose to the prescriber (for prescription-initiated vaccines).
- Vaccine recommendations are continually updated; please refer to *AIH* before vaccine encounters.
- Live vaccines are contraindicated in pregnancy and are used only under specialised medical supervision for immunocompromised individuals.

[21] Available at www.health.gov.au/resources/publications/national-immunisation-program-schedule?language=en

[22] Available at www.health.tas.gov.au/health-topics/immunisation/vaccinations-and-boosters/adult-and-child-immunisation-schedule

- Please be aware of vaccine schedules and the recommended timeframes for administration to ensure efficacy and ensure recalls are in place for multi-dose schedules.

For prescription-initiated vaccines:

  - The vaccine must have been prescribed by a medical or nurse practitioner on or after 6 March 2023 and remains valid (within 12 months of prescribing)
  - It is the responsibility of the API to complete a pre-vaccination screening checklist and consent form immediately before administering any vaccine. Refer to the *AIH* for current contraindications, precautions, and dose intervals.
  - Please refer back to the prescribing medical or nurse practitioner if you have any concerns.
  - Please follow all directions on the prescription.

4.3 Out of Scope

- The following specialised vaccines ***must not*** be administered by an API (either independently initiated or on receipt of prescription): yellow fever, tuberculosis, smallpox (mpox), Q fever or rotavirus vaccines (refer to Table 1).
- The following must be referred to a medical practitioner and include:
  - clients with contraindications or precautions as defined in the *AIH*[23].
  - Including administration of live vaccines to pregnant people or people who are or will soon be immunocompromised (including those prescribed by a medical or nurse practitioner)[24]
  - vaccination for the purposes of upcoming travel, unless prescribed by a medical practitioner following a travel consultation[25]
  - vaccination of people aged under five years of age
  - vaccination of people who are contacts in the event of an outbreak, unless directed by the DPH[26]
  - administration of any immunoglobulin preparation
  - administration of pharmaceuticals for the purposes of clinical trials.
- Pharmacists should understand the risks associated with vaccinating clients in medical risk groups. Where there is uncertainty or incomplete medical information, the client must be referred to their medical practitioner for assessment and/or vaccination.

[23] *Australian Immunisation Handbook*, available at immunisationhandbook.health.gov.au/

[24] If immune status cannot be determined, the patient must be referred to their medical practitioner

[25] Travel medicine is a specialist area and vaccines cannot be independently initiated and administered by APIs.

[26] A case of this vaccine-preventable disease is notifiable to the Communicable Diseases Prevention Unit, Department of Health under the *Public Health Act 1997*. The department will advise on management of the case and contacts.

Table 1. *Vaccines that are **outside of scope** for administration by Authorised Pharmacist Immunisers*	
Vaccine	**Rationale for exclusion from list of vaccines able to be administered by Authorised Pharmacist Immunisers**
Haemophilus influenzae type b	For use in children aged 5 years and under and patients with complex medical conditions requiring specialist review
Q fever	Pre-vaccination skin prick testing and serology are required
Rotavirus (oral)	Not approved for use in infants over 24 weeks (Rotarix) and 32 weeks (RotaTeq)
Tuberculosis	Intradermal administration. Tuberculin skin test pre-vaccination is required following a clinical risk assessment
Yellow Fever	Providers must be accredited by Chief Human Biosecurity Officer in accordance with international requirements, and vaccine must be provided by either a medical practitioner or nurse practitioner (with vaccine included in formulary)
Smallpox (mpox)	Currently constrained supply and specific, targeted program underway to reach eligible cohort

4.4 In Scope

Tables 2A, 2B and 2C outline the vaccines approved for independent initiation by an Authorised Pharmacist Immuniser and conditions of use. For all listed vaccines, providers must follow best practice clinical guidance specific to the vaccine, as outlined by the *AIH*.

Please note Authorised Pharmacist Immunisers with **restricted practice scope** are only permitted to administer the following:

- COVID-19 (Commonwealth funded) and influenza (NIP and privately funded) vaccines
- Diphtheria-tetanus-pertussis (privately purchased) and measles-mumps-rubella (state and privately funded) vaccines.

Restricted scope APIs may also administer privately purchased vaccines upon receipt of a valid prescription, provided these are approved antigens as per Tables 2A, 2B and 2C.

Vaccine Schedules:

Table 2A, NIP and State funded vaccines approved for administration by Authorised Pharmacist Immunisers, column one, includes preparations funded under the NIP and/or state funded programs, which are available for pharmacies to order. These preparations are not deigned to restrict APIs to supplying only these preparations. Alternative preparations may be provided privately, where all antigens within the preparation are suitable for administration by APIs. For example, Boostrix® vaccine may be administered to patients recommended to receive a Diphtheria-Tetanus-Pertussis containing-vaccine who are not funded under the NIP.

Table 2A. NIP and State funded vaccines approved for administration by Authorised Pharmacist Immunisers

Vaccine name Government funded vaccines available to order	**(I)ndependent** **(P)rescription**	**Conditions of use, patient age**	**Vaccine funding and eligible patient group(s)**	**Rationale for limitation(s)**
COVID-19 Comirnaty® Spikevax® Nuvaxovid® Commonwealth funded ✓	(I) ✓ (P) ✓	Vaccine must be administered as per the recommendations within the *AIH* and in accordance with the TGA approved Product Information. Where there are differences in advice, the *AIH* recommendations must be followed. 10 years and older 5 to 10 years old: APIs must have additional paediatric authorisation with the department	Commonwealth funded for: • People aged 5 years and over	
Diphtheria-Tetanus-Pertussis acellular (dTpa) combination Adacel® NIP ✓	(I) ✓ (P) ✓	Excludes vaccination for tetanus prophylaxis related to wound management. See *'Other considerations - Adolescent vaccinations and the School-Based Immunisation Program'* when considering vaccination of this cohort (Section 4.5) 10 years and older APIs with restriced practice scope: 16 years and older, privately funded vaccines only	NIP funded for • Peopled aged 10-19 years for catch-up vaccination • pregnant women (ideally at 20-32 weeks gestation) • people aged 10 years and over, refugee and humanitarian entrants Private funded for: • People aged 10 years and over recommended (not funded) for dTpa vaccination	Tetanus prone wounds require immediate medical review.
Hepatitis B (Hep B) Engerix-B® (adult) HB Vax II® Paediatric HB Vax II® (adult) NIP ✓ State-funded ✓	(I) ✓ (P) ✓	See State Funded Hepatitis B Vaccination program for more information, including eligibility requirements (https://www.health.tas.gov.au/publications/hepatitis-b-vaccine-high-risk-groups) Exclusions include for travel (including to endemic regions) and vaccination for post-exposure prophylaxis (PEP). 10 years and older	NIP funded for • People aged 10-19 years for catch-up vaccination State funded for: • People aged 10 years and over eligible to receive state funded Hep B vaccine Private funded for: People aged 10 years and over recommended (not funded) for Hep B vaccination	Requirement for concurrent medical consultation including clinical assessment and testing

Vaccine name Government funded vaccines available to order	**(I)ndependent** **(P)rescription**	**Conditions of use, patient age**	**Vaccine funding and eligible patient group(s)**	**Rationale for limitation(s)**
Human Papillomavirus (HPV) Gardasil 9® NIP ✓	(I) ✓ (P) ✓	Catch-up vaccination limited to persons requiring a single dose only. See *'Other considerations - Adolescent vaccinations and the School-Based Immunisation Program'* when considering vaccination of this cohort (section 4.5) 10 years and older	NIP funded for • People aged 10-25 years for catch-up vaccination Private funded for: • People aged 10 years and over recommended (not funded) for HPV vaccination	People requiring more than one dose of HPV vaccine may require complex clinical assessment
Influenza Fluad Quad® Afluria Quad® *Note brand change for 2024 influenza season likely NIP ✓	(I) ✓ (P) ✓	10 years and older 5 to 10 years old: APIs must have additional paediatric authorisation with the department	NIP funded for • People aged 5 years and over who are indigenous, pregnant and/or have medical conditions that increase risk of complication to influenza infection. • People aged 65 years and over Private funded for • People 5 to 64 years	
Measles-mumps-rubella combination (MMR) M-M-R-II® Priorix® NIP ✓ State-funded ✓	(I) ✓ (P) ✓	State funded for unvaccinated (no evidence of vaccination) or seronegative people born during or after 1966 (based on rubella serology) Vaccination for catch-up funded under the NIP, including combination products (e.g. MMRV) 10 years and older APIs with restricted practice scope: 16 years and older, private and state funded vaccines only	NIP funded for: • People aged 10-19 years for catch-up vaccination State funded for: • Unvaccinated individuals as per the state funded Measles-Mumps-Rubella vaccination program Private funded for: • People aged 10 years and over recommended (not funded) for MMR vaccination	A live vaccine; unsuitable for administration to some groups (e.g. pregnant women, immunocompromised)
Meningococcal ACWY (Men ACWY) quadrivalent, conjugate vaccines only Nimenrix® NIP ✓	(I) ✓ (P) ✓	Vaccination of individuals funded under the NIP. See *'Other considerations - Adolescent vaccinations and the School-Based Immunisation Program'* when considering vaccination of this cohort (section 4.5) 10 years and older	NIP funded for: • People aged 10-19 years Private funded for: • People aged 10 years and over recommended (not funded) for Men ACWY vaccination	

Vaccine name Government funded vaccines available to order	**(I)ndependent** **(P)rescription**	**Conditions of use, patient age**	**Vaccine funding and eligible patient group(s)**	**Rationale for limitation(s)**
Pneumococcal Prevenar 13® Pneumovax 23® NIP ✓	(I) ✓ (P) ✓	Vaccination of adults recommended to receive pneumococcal vaccine(s). Refer to the Pneumococcal Vaccination Schedule decision tree when considering vaccination (www.health.gov.au/resources/publications/national-immunisation-program-pneumococcal-vaccination-schedule-from-1-july-2020-clinical-decision-tree-for-vaccination-providers?language=en). 10 years and older	NIP funded for: • People 50 years and over (Indigenous adults), NIP funded • People 70-79 years and over (non-Indigenous adults) • People aged 10 years and over with medical risk conditions (see the *AIH*) Private funded for: • People aged 10-69 years and over, recommended (not funded) for pneumococcal vaccination	Healthy children do not require catch-up pneumococcal doses after age 5.
Poliomyelitis (Polio) IPOL® NIP ✓	(I) ✓ (P) ✓	Vaccination for catch-up, including administration as part of a combination product. 10 years and older	NIP funded for: • People aged 10-19 years for catch-up vaccination Private funded for • People aged 10 years and over, recommended (not funded) for polio vaccination	
Varicella Varivax® NIP ✓	(I) ✓ (P) ✓	Vaccination for catch-up funded under the NIP, including as part of a combination vaccine. 10 years and older	NIP funded for: • People aged 10-19 years for catch-up vaccination Private funded for: • People aged 10 years and over, recommended (not funded) for varicella vaccination	A live vaccine; unsuitable for administration to some groups (e.g. pregnant women, immunocompromised)
Zoster (herpes zoster) Shingrix® NIP ✓	(I) ✓ (P) ✓	Vaccination for adults recommended to receive a zoster vaccine (Shingrix only). Zostavax is unsuitable for independent initiation and administration by Authorised Pharmacist Immunisers, however, may be prescribed. 18 years and older	NIP funded (Shingrix only) for: • People 50 years and over (Indigenous adults) • People 65 years and older • Immunocompromised adults aged 18 years and over with haemopoietic stem cell transplant, solid organ transplant, haematological malignancy or advanced or untreated HIV Privately funded for: • People 18 years and over	Zostavax vaccine contains live virus and can be associated with significant morbidity if administered to immunocompromised individuals.

Table 2B. Private funded vaccines approved for independent initiation by Authorised Pharmacist Immunisers				
Vaccine name	**(I)ndependent (P)rescription**	**Conditions of use, patient age**	**Vaccine funding and eligible patient group(s)**	**Rationale for limitation(s)**
Hepatitis A (Hep A)	(I) ✓ (P) ✓	Vaccination for those recommended, but not funded, to receive Hepatitis A vaccination unrelated to travel 10 years and older	Privately funded for • People aged 10 years and over recommended (not funded) for Hep A vaccination	Hep A vaccines are not included on the Funded Immunisation Schedule in Tasmania.
Meningococcal B (MenB)	(I) ✓ (P) ✓	Vaccination for those recommended to receive a Meningococcal B vaccination unrelated to travel, not funded under the NIP. 10 years and older	Privately funded for: • People 10 years and over recommended (not funded) for MenB vaccination	

Table 2C. Prescribed, private funded vaccines approved for administration by an Authorised Pharmacist Immuniser				
Vaccine name	**(I)ndependent (P)rescription**	**Conditions of use, patient age**	**Vaccine funding and eligible patient group(s)**	**Rationale for limitation(s)**
Japanese Encephalitis (JEV)	(I) x (P) ✓	Prescription only 10 years and older	Prescribed, privately funded for: • People aged 10 years and over	No state funded program, due to very low risk of JEV infection in Tasmania. Requires travel consultation
Rabies	(I) x (P) ✓	Prescription only 10 years and older	Prescribed, privately funded for: • People aged 10 years and over	Excludes post-exposure prophylaxis. Requires travel consultation
Typhoid	(I) x (P) ✓	Prescription only 10 years and older	Prescribed, private funded for: • People aged 10 years and over	Requires travel consultation

4.5 Other Considerations: Adolescent Vaccinations and the School-based Immunisation Program

Diphtheria-tetanus-pertussis (acellular), (dTpa) human papillomavirus (HPV) and conjugated meningococcal ACWY vaccines are funded under the NIP and administered to children in school years 7 and 10. In Tasmania, these vaccines are routinely delivered in the School-based Immunisation Program (SBIP) run by local councils.

Pharmacies are well placed for catch-up of adolescents who missed their vaccination at school, or those who prefer not to have their vaccines in the school setting.

Pharmacists must consider the possibility of inadvertent duplicate vaccination in children and adolescents, particularly those in age groups who are likely to be immunised via a SBIP. Routine checking of the AIR prior to vaccine administration should prevent vaccine administration errors, including inadvertent administration of duplicate doses.

It is important that pharmacists discuss the implications with parents if consent form(s) for school vaccination(s) have already been returned to the school for the year ahead. If permission has already been provided, but the adolescent now presents at the pharmacy, the pharmacist should advise the parent to take the necessary steps to withdraw the SBIP consent. Withdrawal of consent must be a written withdrawal via email to the council managing their child's SBIP.

5. Code of Conduct and Professional Practice Standards

APIs are expected to comply with all elements of the Pharmacy Board of Australia's Code of conduct[27], including, but not limited to the following:

- liaising with other health practitioners
- ensuring continuity of care
- recognising and working within the limits of a practitioner's competence and scope of practice
- providing treatment options based on best practice information
- maintaining knowledge and skills to ensure that practitioners continue to work within their competence and scope of practice.

APIs must maintain current knowledge of vaccines and immunisation policies and be able to provide information about vaccines and vaccination services to individuals.

Where information gathered during the pre-vaccination assessment identifies health concerns or uncertainties in relation to health conditions (including vaccine precautions), pharmacists should refer the individual to their medical practitioner for vaccination or advice.

APIs and pharmacies are expected to comply with the following documents:

- the PSA's *Professional Practice Standards 2023*[28]
- the PSA's *Practice Guidelines for pharmacists providing immunisation services* (current edition)

[27] Pharmacy Board Code of Conduct available from: www.pharmacyboard.gov.au/Codes-Guidelines/Code-of-conduct.aspx

[28] Pharmaceutical Society of Australia, 2023. Professional Practice Standards 2023 (version 6). Available at www.psa.org.au/practice-support-industry/pps/

- The Pharmacy Guild of Australia's *Guidelines for Conducting Pharmacist Initiated and Administered Vaccinations Service with a Community Pharmacy* (NSW Edition), February 2020

6. Clinical Governance and Risk Management

Pharmacies providing a vaccination service(s) must have documented policies and/or procedures in place for all the following to support safe, high quality vaccination services, including:

- Checking of anaphylaxis response kit
- Monitoring of vaccine storage systems
- Managing the transport of vaccines when providing clinics off site
- Respond to a cold chain breach
- Back-up plan for vaccine storage during power failures
- Pre-screening assessment process
- Consent process
- When and how to seek further advice following outcome of screening process
- Routine immediate post-vaccination observation and management
- Responding to a needle stick injury
- Responding to adverse event reports
- Managing anaphylaxis and vasovagal (syncope) episodes
- Documentation and record keeping including general practitioner notification and reporting of vaccination on the AIR
- Disposal of infectious and non-clinical waste

When pharmacists are conducting a pre-vaccination assessment and administering vaccines, they must not engage in any other activity, including dispensing.

All pharmacy staff (including clinical and non-clinical staff) should be familiar with the vaccination service(s) being provided, and be aware of their roles and responsibilities, particularly in relation to managing an AEFI and ensuring continuity of care (including for off-site vaccinations).

Many of these policies are also covered in accreditation processes (such as via the Quality Care Pharmacy Program) and should be in place in accredited immunising pharmacies. It is therefore **strongly recommended** that pharmacies performing vaccination services be accredited via a quality assurance program.

6.1 Professional Publications Supporting Clinical Governance:

The Pharmaceutical Society of Australia's Competency Standards Framework for Pharmacists[29]

The PSA's Clinical Governance Principles for Pharmacy Services[30]

[29] Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia 2016, published 2017. Available at: www.psa.org.au/practice-support-industry/national-competency-standards/

[30] Pharmaceutical Society of Australia. Clinical Governance Principles for Pharmacy Services, 2018. Available at: www.psa.org.au/wp-content/uploads/2019/05/PSAClinicalGovernancePrinciples2018_FINAL.pdf

7. Protocols and Processes

APIs must have a process to ensure they remain current with the *AIH* and *Strive for 5*[31] to inform their practice. Additionally, pharmacies must ensure they practice within the *TPA Pharmacy Guidelines*[32], these guidelines, and any other key resources.

7.1 Emergency Response Protocol

An emergency response protocol must be kept as part of the anaphylaxis response kit (preferably laminated and on display or easily accessible during off-site vaccination clinics). The protocol should identify assigned roles and responsibilities of staff members. Staff involved in vaccination sessions must be aware of their roles and responsibilities, including for after-care or emergency response.

The emergency response protocol should be checked and available prior to each vaccination session and pharmacists should ensure that:

- systems are in place to regularly review the anaphylaxis response kit and emergency response protocol;
- all APIs have current CPR and first aid certification;
- a suitably qualified staff member with a current CPR (updated annually) and first aid certification (updated every three years) is on duty during vaccination sessions and can monitor vaccinees for at least 15 minutes after vaccine administration;
- all APIs maintain recency of practice and continuing professional development in the management of AEFI.

7.2 Maintaining Cold Chain

All vaccination providers must follow the principles of safe vaccine storage and cold-chain maintenance to ensure clients receive the most effective and potent vaccines possible.

Vaccination providers are required to maintain vaccines in a manner that is consistent with the recommendations in *Strive for 5,* noting this is a condition to receiving program approval. This also includes for any off-site vaccination clinics.

- The optimal storage temperature for vaccines is +5 degrees Celsius – which is where the title *'Strive for 5'* arises.

A cold chain breaches occurs when vaccine:

- storage temperatures move outside the recommended range of +2°C to +8°C.
- is exposed to light where removed from the original packet and a glass fridge door allows light to penetrate.

[31] Available at www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5_0.pdf

[32] The Tasmanian Pharmacy Authority Guidelines available at: www.pharmacyauthority.tas.gov.au/guidelines/

7.3 Reporting a Cold Chain Breach

- Cold chain breaches involving government funded vaccines must be reported to the Immunisation team, CDPU as soon as possible.
- Cold chain breaches involving COVID-19 vaccines must be reported to the Vaccine Operations Centre (VOC) on 1800 318 208.

Vaccine temperatures recorded **below +2°C or above +8°C must be reported** to the Immunisation team immediately. This does not include temperature deviations or excursions in which the temperature reaches a maximum of up to +12°C for ≤15 minutes.

Any vaccine impacted by a cold chain breach should be immediately isolated and retained within a monitored vaccine refrigerator and be clearly labelled with "**do not use**" until a thorough assessment has been conducted by a member of the Immunisation team; do not use or discard any vaccine(s) without an assessment first being conducted.

The CDPU Immunisation team can be contacted via the Public Health Hotline on 1800 671 738.

In the event of a cold chain breach related to privately purchased vaccine stock (i.e. non-NIP vaccines), the pharmacist should contact the vaccine manufacturer for advice.

7.4 Pre-vaccination Assessment and Consent

An API **must** obtain valid consent from any individual being vaccinated and/or their parent/guardian. As part of informed consent, a pre-vaccination screening must be completed prior to administering a vaccine to identify if contraindications or precautions to vaccination exist.

A pre-vaccination screening checklist is included in the *AIH* and must be completed prior to **all** vaccinations[33]. It is recommended that the AIR is routinely checked as part of pre-vaccination screening to avoid vaccination administration errors (e.g. incorrect dose intervals or dose numbers being administered).

Prior to obtaining consent, the individual or the parent/guardian of the individual being vaccinated, should be:

- supplied information (preferably written) which includes the risks and benefits relating to the vaccine, and the vaccination procedure and what to do in the event of side effects following vaccination. This should include the name and contact details of the API (and the Pharmacy if different);
- provided with information of any fees that will be charged to the individual or the individual's parent/ guardian for the vaccine and the service;
- notified that the individual's vaccination record will be reported to the AIR.

APIs should have a process to obtain and document individual consent, and to ensure that individual privacy and confidentiality are always upheld.

[33] Available at immunisationhandbook.health.gov.au/contents/vaccination-procedures/preparing-for-vaccination

Where an AI is requested to attend a RACF to provide a vaccination service, consent must be obtained from the resident or medical power of attorney. It is recommended that the AIR is routinely checked as part of pre-vaccination screening. To support robust clinical documentation and communication, the AI must inform the resident's general practitioner of the vaccination encounter and must report provision of that vaccine to the AIR in a timely fashion.

Pharmacists should understand the potential risks associated with vaccinating residents of RACFs and should seek advice from the resident's general practitioner where there is uncertainty or incomplete medical information. The client should be referred to their general practitioner for assessment and/or vaccination if any uncertainty remains or the client cannot provide consent.

7.5 Consent on Behalf of a Child or Adolescent

In general, a parent or legal guardian of a child or adolescent has the authority to consent to that individual being vaccinated[34].

Some Australian states and territories have legislation that addresses the issue of a child's consent to medical treatment. The common law applies in the states and territories that do not have specific legislation relating to children's consent to medical treatment. This common-law position is often referred to as Mature Minor or Gillick Competence.

For certain procedures, including vaccination, a child or adolescent may be determined to be mature enough to understand the proposed procedure, and the risks and benefits associated with it. These young people may have the capacity to consent under certain circumstances.

As outlined in the *AIH*, where the parent and/or guardian of the individual being vaccinated is not present, pharmacists must assess whether the individual is mature enough and has the capacity and sufficient maturity to understand the advice and implications of the vaccine and consent to the procedure.

Pharmacists who elect not to administer a vaccine based on their assessment of the individual's maturity and understanding should refer the individual back to their medical practitioner.

If a child or adolescent refuses a vaccination that a parent and/or guardian has provided consent for, respect the child/adolescent's wishes. Do not vaccinate and inform the parent or guardian.

7.6 Post-vaccination Observation

The API must advise the individual or the individual and their parent and/or guardian to remain on the premises (i.e. within the pharmacy) for a **minimum of 15 minutes** post-vaccination, to allow for immediate assistance in the event of an AEFI.

Seating is to be made available post-vaccination in a position that allows the vaccinee to remain within the line of sight of the pharmacist or person qualified in first aid for the entirety of the post-vaccination monitoring period. This should either be close to the dispensary or close to the vaccination area.

[34] Australian Government Department of Health. Australian Immunisation Handbook. Available at immunisationhandbook.health.gov.au/vaccination-procedures/preparing-for-vaccination

Individuals who have been vaccinated should be provided with identifiers (such as a sticker with the time of vaccination) to enable quick identification of an individual who has received a vaccination, in the instance that they require assistance. Documenting a time of vaccine administration on an identifier will also allow the individual to know when the minimum 15-minute wait time has occurred.

The API must inform the individual or the parent/guardian of the person being vaccinated of the potential risks associated with leaving during the post-vaccination period and put a note in the record of vaccination if the individual chooses to do so.

If a vaccinated person begins to display signs and symptoms of anaphylaxis, typically within 15 minutes of receiving a vaccine, a dose of adrenaline should be administered as soon as possible, and an ambulance called. The risk of death due to anaphylaxis is far greater than the risk posed by administering a dose of adrenaline.

7.7 Adverse Events Following Immunisation (AEFI)

Equipment and poisons necessary for the management of anaphylaxis and protocols, including the emergency response protocol, should be checked and available before each vaccination session, regardless of the setting (including mobile or off-site vaccination services). Staff involved in vaccination sessions must be aware of their roles and responsibilities, including after-care or emergency response.

Individuals (or their parent and/or guardian) must be informed about the potential side effects of vaccination as a component of obtaining informed consent, including how to manage them, and who to notify of delayed adverse events that may occur once they have left the premises.

7.8 Reporting Adverse Events and Vaccine Administration Errors

APIs and pharmacies must report any AEFI to the Immunisation team, CDPU. This also includes any vaccine administration errors (VAE), for example giving expired vaccines, incorrect intervals between vaccines, incorrect age for vaccine etc. The requirements and forms for reporting an AEFI or VAE are available on the DoH Immunisation webpage[35]; completed AEFI forms must be returned via email to **tas.aefi@health.tas.gov.au**.

AEFI surveillance is managed by the CDPU and the TGA to establish vaccine safety in Australia. CDPU helps providers report and look after individuals who have experienced an AEFI. Providing information about an AEFI to CDPU will help detect potential problems with vaccines or systems as early as possible and, will help to deliver safe vaccination program in Tasmania.

[35] Available at www.health.tas.gov.au/health-topics/immunisation/immunisation-providers#how-to-report-an-adverse-event-following-immunisation

7.9 Record Keeping

Pharmacies must retain consent forms and vaccination records in a form that can be recovered and printed for a minimum of seven years, or longer. These documents should be stored in a format and location that allows timely access, easy retrieval and protects individual confidentiality. Records must be retained and provided in accordance with the relevant legislation and regulations.

All Tasmanian AIs are required to comply with the record-keeping requirements, relevant legislation, and the recommendations of the *AIH*[36]. They must record the following details for each vaccine administered:

- Time and date of the vaccination
- name, form, and strength of the vaccine, including brand name, batch number and dose number
- name, date of birth and address of persons to whom the vaccine is administered
- name and contact details of the API carrying out the administration
- name and contact details of the pharmacy
- injection site and route
- date the next vaccination is due (if applicable)
- any adverse events observed or reported (including delayed responses).

7.10 NIP Vaccine Reporting

All vaccination providers (including pharmacies) are required to report on NIP vaccine use and stock on hand prior to ordering additional vaccines, which includes vaccine wastage (i.e. expired stock) and leakage (vaccines given to non-eligible patients). This is to ensure Tasmania meets the national reporting requirements as part of the NIP agreement. The CDPU is the custodian for NIP vaccines in Tasmania.

All NIP vaccine providers are subject to random audits, including for vaccine use, orders, and wastage.

7.11 Immunisation Registers

The AIR is a national register that records vaccinations given to people of all ages in Australia.

Pharmacies must register with the AIR as part of the requirements to provide a vaccination service in Tasmania.-Pharmacies can apply as a business to register with the AIR to obtain login details which enables the reporting of all vaccinations administered to the AIR. An AIR provider number is required to enable automated uploads to the AIR from your pharmacy's software. Registration forms are available from the Australian Government Services Australia webpage[37].

- It is mandatory to report all NIP funded, influenza and COVID-19 vaccine encounters to the AIR. It is strongly recommended that all private and state funded vaccine encounters are uploaded to the AIR.

[36] Available at immunisationhandbook.health.gov.au/

[37] Available at www.servicesaustralia.gov.au/im004

7.12 Complaints

The Department reserves the right to revoke or terminate authorisation of any AIs or pharmacy who engages in unsatisfactory conduct. Where necessary, serious deviations from acceptable professional standards may be reportable to the appropriate organisation.

APIs and pharmacies should develop a process for complaints regarding vaccination services. All individuals and providers who receive vaccination services should be aware that:

- Complaints relating to the pharmacist's professional practice should be directed to the AHPRA by phoning 1300 419 495 or visiting the AHPRA website at **www.ahpra.gov.au**.
- Complaints relating to the pharmacy premises should be directed to the Tasmanian Pharmacy Authority at **registrar@pharmacyauthority.tas.gov.au**.
- Complaints relating to the vaccination setting (non-pharmacy setting) should be directed to the Immunisation team, Tasmanian DoH by email at **immunisation@health.tas.gov.au** or via phone 6166 0632.
- Individuals may also bring a complaint against a pharmacy to the Pharmaceutical Services Branch on 6166 0400 or **pharmserv@health.tas.gov.au**.

7.13 Fees

APIs may charge a service fee for the administration of vaccines to people who are eligible for government-funded vaccines or state-funded vaccination programs. Prior to doing so, the immuniser must advise the recipient (vaccinee) about the availability of funded vaccines and free vaccination services through general practitioners and council vaccination clinics, prior to administering the vaccine.

From 1 January 2024, pharmacies who opt-in to the NIP Vaccination in Pharmacy (NIPVIP) Program may either:

- receive payment for the administration of NIP vaccines from the Australian government, **OR**
- charge the patient a service fee for the administration of that vaccine.

Vaccinating pharmacies are unable to receive concurrent payments for the administration of NIP vaccines (i.e. both NIP and private remuneration) and cannot charge patients for the administration of NIP funded vaccines. Refer to the NIPVIP program webpage for more information[38].

For those persons who are **not** eligible for government-funded vaccines, the pharmacist may charge for the cost of the vaccine plus an administration fee.

8 Contact Us

If you have any questions regarding these guidelines or for clinical guidance, please contact the Immunisation team, CDPU, via email: **immunisation@health.tas.gov.au** or via phone on 6166 0632.

9 Attachments

Attachment 1: Approved Pharmacy Program Independently Initiated Vaccines Flowchart

[38] Available at: https://www.ppaonline.com.au/programs/national-immunisation-program-vaccinations-in-pharmacy-program

Attachment 1: Approved Pharmacy Program Independently Initiated Vaccines Flowchart