Pharmacy Vaccination Program

Tasmanian Authorised Pharmacist Immuniser Application Guidelines

Effective 3 January 2024

Version I.0



Contents

Int	ro	oduction	3
I	S	Scope of Practice	3
2	٦	Fraining Requirements	3
2	2.1	Continuing Professional Development (CPD)	3
2	2.2	Immunisation Education Courses Accepted by the Director of Public Health in Tasmania	4
3	A	Application Process	5
	3.1	Applying for Authorisation for the First Time	5
:	3.2	Annual Renewal Process	6
	3.3	Pharmacists who Completed a Training Program in Another State or Territory	7
4	F	Paediatric Authorisation	7
5	F	Pharmacist Immunisers in Training (PIIT)	8
6	S	kills Assessment (Practicum)	9
7	(Grievance Procedure	10
8	L	apsed Authorisation Policy	10
9	lı	nformation Support and Questions	10
10	F	Resources	10
П	A	Attachments	11
At	tac	hment 1: Skills Assessment Record	12
At	tac	hment 2: Approved Pharmacy Program Independently Initiated Vaccines Flowchart	17

Introduction

In accordance with Tasmanian legislation a registered health professional other than a medical practitioner or nurse practitioner must be authorised by the Department of Health (DoH) to vaccinate independently in Tasmania.

An Authorised Pharmacist Immuniser (API) is a pharmacist who holds general registration with the Pharmacy Board of Australia (AHPRA) and has completed an approved educational program of study in immunisation, and who:

- has met certain clinical practice requirements in order to become an Authorised Immuniser (AI) in Tasmania, pursuant to Regulation 82(1)(d) of the Poisons Regulations 2018
- has been approved by the Secretary, under the Tasmanian Poisons Act 1971, 38 (1) (i) and Poisons Regulations 2018 Regulation 82 (d) to administer vaccines (as listed in Schedule 4 to the Poisons List) to another person independently of a medical or nurse practitioner
- practices in accordance with a vaccination program approved by the Director of Public Health (DPH).

When APIs apply to renew their authorisation, they will reflect on their practice and declare they are competent to practice safely in accordance with their scope and context of practice.

To maintain safe and effective immunisation practices, APIs will accept responsibility for their personal competence and professional accountability. The requirement for authorisation to practice as an API and the process for annual authorisation are outlined in this document.

I Scope of Practice

A registered pharmacist's scope of professional practice is set by legislation and professional standards such as competency, practice standards, and codes of ethics, as well as public requirements, demands, and expectations. The *Tasmanian Pharmacist Immunisation Program Guidelines* provide information on API practice scope and lists the vaccines that are suitable for administration by APIs.

APIs may administer vaccines within their scope of practice, provided they are operating under a DoH approved vaccination program. Vaccine administration must be in accordance with all recommendations for that vaccine as listed in the Australian Immunisation Handbook (AIH), and/or publications from the Australian Technical Advisory Group on Immunisation (ATAGI) and other relevant evidence-based sources.

2 Training Requirements

2.1 Continuing Professional Development (CPD)

APIs must obtain eight (8) CPD - (8 x Group I or 8 x Group 2) credits specific to immunisation each year, plus their CPR update. CPD should cover the following topics:

 Annual Cardiopulmonary Resuscitation (CPR) theory and practicum, including infant and paediatric CPR.

- APIs must also hold a certificate of competency in First Aid, completed within the last three (3) years, delivered by a Registered Training Organisation.
- Maintaining clinical knowledge of anaphylaxis.
 - APIs are required to complete annual ASCIA anaphylaxis e-training where anaphylaxis content is not covered in the annual CPR assessment¹.
- Knowledge and understanding of any legislation which affects immunisation practice.
- The annual influenza composition and any vaccine or administration changes.
- Any Commonwealth announcements or changes relating to immunisation, new vaccines introduced onto the schedule and current recommendations.
- Remain current with the AIH, including for any changes or updates, and the National Immunisation Program (NIP) Schedule.
- Any other identified learning requirement(s) following a self-assessment of competence.

Other training requirements include:

- Remain current with the Australian Government Department of Health and Aged Care's COVID-19
 vaccination reference guide relating to storage, handling and the administration of COVID-19 vaccines.
 This also includes content on preparing doses from multi-dose vials (MDV) and frozen vaccine
 handling².
- Review and remain current with the clinical recommendations for COVID-19 vaccines as per the AIH (online version), and COVID-19 Vaccination Training Program (CVTP) reference document³.
 - The Resources for COVID-19 vaccine providers should also be accessed to assist providers in developing and maintaining their knowledge of COVID-19 vaccines⁴.

APIs are encouraged to access immunisation education opportunities to support best practice and professional development, such as the National Centre for Immunisation Research and Surveillance's (NCIRS) Australian Immunisation Professionals weekly update⁵.

2.2 Immunisation Education Courses Accepted by the Director of Public Health in Tasmania

From I January 2024, pharmacists wishing to practice as Als in Tasmania must have completed a training program that has been accredited by Health Education Services Australia (HESA). HESA independently accredits immunisation education programs offered by education providers against the *National Immunisation*

² Available at: <u>www.health.gov.au/resources/publications/covid-19-vaccine-reference-guide?language=en</u>

Available at: www.allergy.org.au/hp/hp-e-training

 $^{^3 \} A vailable \ at: \underline{www.health.gov.au/resources/publications/covid-19-vaccination-training-program-cvtp?language=en}$

⁴ Available at: <u>www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/resources</u>

 $^{^{\}scriptscriptstyle 5}$ Available at: $\underline{\text{ncirs.org.au/health-professionals/ncirs-newsletters}}$

Education Framework for Health Professionals (the 'Framework')6. Assessment against nationally agreed program standards will assist in leading to mutual recognition of immunisation education programs across states and territories.

A list of recognised, accredited immunisation training programs suitable for completion by registered pharmacists, intern pharmacists and pharmacy students is available at HESA Accredited Programs⁷.

From I January 2024, immunisation training programs unaccredited by HESA will no longer be accepted in Tasmania. This includes programs completed prior to the HESA accreditation date. APIs with current or previous authorisation will be required to complete a HESA accredited course where their authorisation has lapsed for ≥ 3 years.

Application Process

3.1 Applying for Authorisation for the First Time

Pharmacists who have met the educational requirements listed in section 2 of these guidelines and wish to apply for authorisation in Tasmania can apply by:

- Completing an initial Authorised Immuniser Application on the Immunisation Provider Portal, or;
- Completing an initial Authorised Immuniser Application form and emailing this to authorisedimmuniser@health.tas.gov.au8

The following documentation is required and must be submitted with the initial authorisation application:

- A certificate of general registration, which includes registration number with the Pharmacy Board of Australia (AHPRA)9
- A certificate of competence in adult and paediatric CPR as per Australian Resuscitation Council (ARC) guidelines, issued within the previous 12 months.
- A certificate of competency in First Aid, completed within the last three (3) years, delivered by a Registered Training Organisation.
- A certificate of completion of a HESA accredited immunisation training program, undertaken within the last three (3) years.
- A Skills Assessment Record Practicum (defined in section 6) with evidence of ten (10) individual vaccination encounters.

Please note that authorisation as Pharmacist Immuniser in one jurisdiction may not always be transferable to another state. The pharmacist immuniser's training must meet the Tasmanian requirements to enable authorisation. If uncertain, please contact the Communicable Diseases Prevention Unit (CDPU) directly.

⁶ Available at: <u>www.health.gov.au/resources/publications/national-immunisation-education-framework-for-health-</u> professionals

⁷ Available at: <u>hesa.com.au/accredited-programs/</u>

⁸ Available at: www.health.tas.gov.au/health-topics/immunisation

⁹ Excludes limited registration, provisional registration, non-practising registration, or student registration.

APIs must operate under an approved vaccination program which has policies and procedures in place to provide a safe and efficient vaccination service.

3.2 Annual Renewal Process

APIs must complete their annual renewal by:

- Completing an Authorised Immuniser Renewal Application on the Immunisation Provider Portal, or;
- Completing an Authorised Immuniser Renewal Application form and emailing this to authorisedimmuniser@health.tas.gov.au¹⁰.

The renewal includes an annual statement and is supported by a declaration. APIs must ensure they are compliant with the CPD requirements in section 2.1.

- Confirmation of authorisation to practice will be available before I March each year. The confirmation letter will be available for download from the portal.
- Automated reminder emails for expiring authorisation will be sent where renewal has not been completed. Applicants are encouraged to keep their details up to date to ensure they receive all communication from the Immunisation team and retain access to their account.

From I January 2024: All Pharmacist Immunisers authorised prior to I January 2024 are required to complete additional immunisation training to be considered competent to administer all vaccines listed in Tables 2A, 2B and 2C of the Tasmanian Pharmacist Immunisation Program Guidelines. This can be achieved by:

- Completing training modules for all Vaccine Preventable Diseases (VPD) listed in the declaration from a recognised training provider (either the Pharmaceutical Society of Australia or the Pharmacy Guild of Australia), or:
- Completing a HESA accredited immunisation training program and a declaration confirming
 completion of all relevant modules must be submitted to
 authorisedimmuniser@health.tas.gov.au prior to administering any vaccines within the
 expanded scope; this must be provided before I January 2025. A copy of this declaration should also
 be provided to the Responsible Officer of the vaccination program(s) you are employed under.
- Please note that as part of this declaration all APIs will be subject to random audits of training and are encouraged to maintain a copy of all completed training.

Completion of the additional training is a condition of administering the expanded scope of vaccines and for renewal of authorisation for 2025.

APIs not wishing to access vaccines in the expanded scope, and, who wish to renew their authorisation for 2024 can still apply for annual renewal. APIs may continue to independently prescribe and administer COVID-19, influenza, MMR and dTpa vaccines to approved age cohorts, and may administer age-appropriate, privately purchased vaccines prescribed by a medical or nurse practitioner without completing additional training up to (and including) 31 December 2024.

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¹⁰ Available at: <u>www.health.tas.gov.au/health-topics/immunisation</u>

From I January 2025: All pharmacists that have not completed the additional training, as listed above, will be unable to practice as APIs in Tasmania and, will have their authorisation revoked.

3.3 Pharmacists who Completed a Training Program in Another State or Territory

Pharmacists who completed immunisation training outside of Tasmania are not permitted to administer vaccines until they meet all requirements listed in these guidelines and have been authorised by the DPH.

To obtain authorisation in Tasmania a pharmacist must:

- Have successfully completed an immunisation training program accredited by HESA against the
 Framework, or a program which is considered equivalent to that studied by APIs in Tasmania. Please
 note all interstate trained Pharmacist Immunisers must also have completed the Tasmanian regulatory
 module to practice as an API in Tasmania.
 - A declaration of vaccination training must be submitted to the CDPU Immunisation team.
 Evidence of completing a recognised immunisation training program may also be required.
- Have been practicing as a Pharmacist Immuniser and have administered vaccines in another state or territory within the previous 12 months.
- Meet recency of practice requirements as outlined by the Pharmacy Board of Australia, including for Continuous Professional Development (CPD).
- Hold General Registration as a pharmacist with the Pharmacy Board of Australia (AHPRA).

4 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 all APIs to ensure they are appropriately trained and competent to vaccinate children. This includes the ability to identify and manage adverse events following immunisation (AEFI) in this age group.

Please ensure the Responsible Officer of the vaccination program(s) you work under is aware of your practice scope and has a copy of any training and/or relevant authorisation documents.

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[&]quot;Excludes limited registration, provisional registration, non-practising registration or student registration.

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. It is **strongly recommended** that APIs access additional training opportunities, such as those available from the Melbourne Vaccine Education Centre¹², Health Ed¹³ and the National Centre for Immunisation Research and Surveillance (NCIRS)¹⁴.

5 Pharmacist Immunisers in Training (PIIT)

Pharmacist Immunisers in Training (PIIT, e.g., Intern pharmacists with provisional registration, or pharmacists with general registration undertaking initial immunisation training) are permitted to administer a vaccine(s) only when undertaking clinical practice following the completion of a recognised immunisation training program. PIITs must only administer vaccines under the direct supervision of 'a preceptor,' defined as either:

- A Medical Practitioner or Nurse Practitioner who has a minimum of two years recent and regular experience administering NIP vaccines, to all age groups (infants, children and adults).
- An Authorised Nurse Immuniser (ANI) compliant under Regulation 82 (1)(e) of the Poisons Regulations 2018. The ANI must have a minimum of two years recent clinical experience administering NIP vaccines, to all age groups (infants, children and adults) and be working under a DoH approved vaccination program.
- An API compliant with Regulation 82(1)(f) of the *Poisons Regulations 2018*. The API must have a minimum of two years recent clinical experience in the administration of vaccines and must be compliant with all training requirements as listed in these guidelines. Additionally, the API must be working under a DoH approved vaccination program.

Intern pharmacists are not permitted to administer vaccines unsupervised until they hold general registration with the Pharmacy Board of Australia and have received written confirmation to practice as an API from the DPH.

Pharmacists with general registration may only administer vaccines unsupervised once they have received written confirmation to practice as an API from the DPH.

Pharmacy students may complete the theoretical and simulated practical components of immunisation training, however, are unable to participate in a clinical practice component (e.g., supervised vaccinations or skills assessment practicum) that includes the administration of vaccines until they hold provisional registration with the Pharmacy Board of Australia (AHPRA).

Applications for authorisation from pharmacists or PIIT who do not hold general registration with the Pharmacy Board of Australia will not be accepted.

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¹² Available at education-mvec.mcri.edu.au/

¹³ Available at <u>www.healthed.com.au/learning-modules/</u>

¹⁴ Available at ncirs.org.au/education

6 Skills Assessment (Practicum)

A PIIT must undertake supervised clinical practice to become an API in Tasmania. As part of this practice, the PIIT is required to conduct ten (10) individual encounters under the supervision of a preceptor as defined above.

Preceptors will assess the PIIT's clinical performance according to recommendations in the current edition of the AIH^{15} and the relevant National and State immunisation schedules.

The assessment and judgement of competence in the clinical practice setting will include clinical observation, questioning, and review of documentation to assess skills, knowledge and attitudes.

Preceptors will observe and assess the PIIT, provide appropriate feedback, and complete the Skills Assessment Record (Attachment 1). The preceptor will indicate if the PIIT demonstrates overall competence in the provision of vaccinations according to the performance criteria in the essential immunisation practice standards, or whether the PIIT requires additional practice to further develop their clinical knowledge and skills.

The key areas include:

- availability of an in-date Anaphylaxis Response Kit before each immunisation session
- knowledge and maintenance of cold chain requirements during the immunisation sessions
- completion of the pre-vaccination assessment and ensuring valid consent.
- selection of the appropriate vaccine(s)
- following occupational health and safety guidelines for hygiene to minimise the risk of needle stick injury
- correct administration of the vaccine(s)
- providing immediate after care
- knowledge of common Adverse Events Following Immunisation (AEFI) and the process for documentation and reporting an AEFI in Tasmania
- documentation including reporting of vaccinations to registers as appropriate.
- PIIT with provisional registration may complete a skills assessment (practicum), however, are unable
 to practice unsupervised until they hold general registration with the Pharmacy Board of Australia and
 have received written confirmation to practice as an API from the DPH.

¹⁵ Available at: immunisationhandbook.health.gov.au/

7 Grievance Procedure

If an applicant has a grievance because authorisation to practice has not been granted, the Al Grievance Procedure will be implemented.

The applicant must consider the feedback provided and if wanting to continue with a grievance, lodge a formal appeal to the DPH within 14 days from receipt of the initial contact made with the CDPU.

The formal appeal against the decision must be made to The Director of Public Health, GPO BOX 125, Hobart 7001 detailing all necessary information and documentation, including contact details.

The applicant will be **informed in writing** of the DPH's decision within 14 days of the receipt of the application.

8 Lapsed Authorisation Policy

An API's authority to practice lapses if they fail to complete their online authorisation renewal application.

While the health professional will be notified via email that their authorisation has lapsed and that they are no longer authorised to practice as an API in Tasmania, it should be noted that health professionals who practice without current authorisation will be operating outside the legal framework.

APIs found to be practicing without authorisation will be reported to the Australian Health Practitioner Regulation Agency (AHPRA).

If an API's authority to practice has lapsed for a period of greater than three (3) years, they will be required to provide further educational evidence before being re-authorised. Please contact the Immunisation Unit, CDPU for further information.

9 Information Support and Questions

Providers are encouraged to contact the Immunisation Unit, CDPU for immunisation support or for any queries relating to the authorisation process on 1800 671 738 or via email at **authorisedimmuniser@health.tas.gov.au**.

10 Resources

The following resources will provide guidance and points of reference to assist the Als to meet the standards of competency required for renewal of authorisation to practice.

- Australian Resuscitation Council Website¹⁶
- ASCIA e-training for health professionals¹⁷

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¹⁶ resus.org.au/

¹⁷ etraininghp.ascia.org.au/

- Australian Government, Department of Health, Immunise Australia Program¹⁸
- Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018¹⁹
- Australian Technical Advisory Group on Immunisation (ATAGI)²⁰
- Centre for Disease and Control²¹
- National Vaccine Storage Guidelines 'Strive for 5' ²²
- National Centre for Immunisation Research and Surveillance ²³
- World Health Organization²⁴

II Attachments

- Attachment I: Skills Assessment Record (practicum)
- Attachment 2: Approved Pharmacy Program Independently Initiated Vaccines Flowchart

¹⁸ www.health.gov.au/topics/immunisation?language=und

¹⁹ immunisationhandbook.health.gov.au/

²⁰ www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi

²¹ www.cdc.gov/vaccines/

²² www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

²³ www.ncirs.org.au/

²⁴ www.who.int/health-topics/vaccines-and-immunization#tab=tab_I

Attachment I: Skills Assessment Record

Student Name:		Date:		
Preceptor Name:		Practice Venue:		
		Preceptor Assessment		
Essential Immunisation Practice				Comments
I.	Ensure emergency equipment available and operational, including an anaphylaxis response kit before each vaccination session	t is I.I Protocols, Adrenaline 1:1000 (in date) and dose chart available, checked and operational emergency resuscitation equipment readily available		
2.	Implement the National Vac	ine 2.1 Is able to state correct vaccine temperature range of between +2°C to +8°C		
	Storage Guidelines: Strive for 5 when storing, handling, or transporting vaccines	2.2 Checks temperature log and administers vaccine that has been transported and stored at the correct cold chain temperature		
		2.3 Describes and complies with national guideline requirements for vaccine storage, handling and transportation and their importance in maximising the potency and efficacy of each vaccine. This includes understanding the importance of twice daily temperature checks in addition to data logger management.		
		2.4 Explain actions taken to report and manage a cold chain breach or other events that may compromise vaccine integrity		
3.	Perform pre-vaccination screening to assess and determine the person's med fitness for vaccination, contraindications or precaut to vaccination			

Essential Immunisation Practice			Comments
4. Decide on the appropriate vaccine (s) to be administered	4.1 Reviews the documented vaccination history on the Australian Immunisation Register (AIR)and correctly identifies the correct vaccine(s) due 4.2 Identifies the correct vaccine brand to be administered according to the patient details		
5. Obtain valid consent	5.1 The vaccinator obtains informed consent to immunise and communicates information effectively and in a culturally appropriate manner		
	5.2 Delivers clear, concise messages about the risks of vaccine-preventable diseases and the benefits and risks of vaccines		
	5.3 Advises the person to be vaccinated of the incidence of common adverse events that may occur following vaccination		
	5.4 Provides current and suitable health education resources as appropriate to support communication		
	5.5 Provides adequate time to answer questions and ensure client understanding of the vaccination process		
6. Follow standard occupational health and safety guidelines for	6.1 Performs hand hygiene as per the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)		
hygiene and minimises the risk of needle-stick injury throughout the entire vaccination procedure	6.2 Demonstrates awareness of minimising the risk of needle-stick injury and locates sharps containers safely away from children's reach		
7. Prepare the site and equipment and administer vaccines correctly	7.1 Reconstitutes the vaccine if required as per the product advice. Checks each individual dose to see that the expiry date has not lapsed and that there is no particulate matter or colour change in the vaccine		
	7.2 Locate the correct injection site, uncovering the appropriate limb		
	7.3 Does not swab the skin (unless visibly dirty)		

			Preceptor Assessment	
	Essentia	Is the pharmacist competent? yes no	Comments	
8.	Provide immediate after-care	8.1 Demonstrates safe disposal of used needles, syringes, and vaccine vials/ampoules in accordance with the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)		
		8.2 Cover the puncture wound quickly.		
		8.3 Use comfort and distraction measures to alleviate any distress and pain (pre, during and after vaccination)		
	Anticipate, identify, and manage common and adverse events following immunisation, as appropriate to the practice	9.1 Remind the vaccinated person about the common and rare adverse events following immunisation, what to expect, how to report and how to manage them in both verbal and written form; and provide contact advice in case of a significant adverse event occurring within 24 to 48 hours of the vaccination		
	setting	9.2 Articulates the difference between a vasovagal episode and anaphylaxis		
		9.3 Discusses the management of a vasovagal episode		
		9.4 Discusses the management of anaphylaxis		
	Document information relevant to each immunisation encounter in accordance with practice policy	I 0.1 Explains rationale and demonstrates the importance of accurate documentation of vaccine type (name), dose, batch number, expiry date, injection site, date of administration and name of immuniser		
		I 0.2 Uploads the vaccine administered to the Australian Immunisation Register (AIR)		
	I. Advise and ensure the vaccinated person remains in the nearby area for a minimum of 15 minutes post	II.I Advises and directs person to designated waiting area and instructs them to wait for a minimum of 15 minutes for post vaccination monitoring		
	vaccination and is aware of prompt reporting of any significant adverse event following immunisation	I 1.2 Describes the procedure for documenting and reporting an AEFI in Tasmania		

			Preceptor Assessment			
Essentia	Is the pharmacist competent? yes no	Comments				
12. Act in accordance with legal and	12.1 Maintains client confidentiality and privacy					
ethical standards in all aspects of immunisation practice	12.2 Identifies his/her own professional scope of practice and ethical principles relating to immunisation					
	12.3 Ensures health facility policies/protocols are followed					
13. Completes required vaccination experience under supervision of nominated preceptor in a clinical practice setting	13.1 Successfully completes a minimum of ten (10) client vaccination encounters					
	Record details of vaccinations given by:(PIIT)					
under the supervision of:	(Preceptor)					

Vaccinations given					
Vaccine name	Route	Site	Date administered	Age of client/recipient	

accine name		Route	Site	Date administered	Age of client/recipient
	· l · · · · · · · · · · · · · · · · · ·				1.12
	,		•	nowledge, skills and attitude neces standards in the Skills Assessment	•
	clare that:	6			
	I am a Medical Practitioner children and adults)	with a minimum of 2 years	recent clinical experience	administering NIP vaccines, to all a	ge groups (infants,
OR					
	•	•		ve a minimum of 2 years recent cling under a current DoH Approved '	•
OR					
	I am an experienced Pharm administering vaccines wor		•	nd have a minimum of 2 years recer gram	nt clinical experience
	rmacist Immuniser-in-Tra EASE TICK	ining (PIIT) name			
☐ Is Competent to administer vaccines independently.					
	☐ Requires further pr	actice and direction.			
Pred	ceptor name		_ Preceptor signa	ture	
	PIIT signature		Date		

Attachment 2: Approved Pharmacy Program Independently Initiated Vaccines Flowchart

Approved Pharmacy Program Independently Initiated Vaccines

Pathways to Vaccination



