

Community Pharmacy Provision of COVID – 19 Vaccine in Tasmania Guidelines and Application Process

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Version 12

About the Guidelines and Application Process

These guidelines have been developed by Public Health Services, Department of Health (DoH) Tasmania to provide guidance to organisations that are approved to provide immunisation programs in Tasmania on the additional application process to be recognised as a 'community pharmacy' administering COVID – 19 vaccines.

The guidelines may be revised from time to time. For the most recent version of the guidelines visit [DoH Immunisation website](#)¹

These guidelines are to be used in conjunction with the professional standards and guidelines that apply to each health discipline.

Contact Details

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Community Pharmacy Definition

Community Pharmacy Agreements between the Commonwealth and the Pharmacy Guild of Australia have been in place since 1991, with their key purpose being to provide for the timely and equitable supply of Pharmaceutical Benefit Scheme (PBS) medicines across Australia.

Community pharmacies dispense prescriptions, provide advice on drug selection and usage to doctors and other health professionals, primary health care advice and support, and educating customers on health promotion, disease prevention and the proper use of medicines.

¹ www.health.tas.gov.au/publichealth/communicable_diseases_prevention_unit/immunisation

Contents

Background.....	1
Application Process	1
Assessment Criteria	1
Conditions of Expanded Scope.....	2
Additional Clinical Considerations.....	2
Clinical Guidance - COVID-19 Vaccines 5-11 Years Old	3
Opt-In to Provide COVID-19 Vaccine to 5-11 Years Old	4
Off-Site COVID-19 Vaccination Service Requirements	5
Appendix A: Expansion of Scope-COVID-19 Vaccines	7
Appendix B: Expansion of Scope-5 Years Old and Older	10

Background

Selected community pharmacies will be involved in the National COVID -19 vaccination rollout. An expression of interest (EOI) was conducted by the Australian Government to identify individual community pharmacies capable of participating from Phase 2 of the national rollout onwards. Tasmanian community pharmacies lodged a total of 103 EOIs in response to the Australian Government's request.

Expanding existing Tasmanian immunisation program approvals to include selected COVID - 19 vaccines is at the discretion of the Tasmanian Director of Public Health. Introduction of community pharmacies to deliver COVID - 19 vaccine in Tasmania will occur as a graduated program.

Application Process

A community pharmacy that has submitted an EOI to the Australian Government may apply to have its existing program approval with Public Health Services Tasmania expanded to include the relevant COVID - 19 vaccine by completing and submitting the Application Form for Expansion of Scope of Approved Vaccination Program to include COVID – 19 Vaccines including the Executive Declaration provided as Appendix A.

Public Health Services' Communicable Diseases Prevention Unit's (CDPU) immunisation team will assess each application based on whether it meets the requirements as outlined below. The Director of Public Health approves applications that meet these requirements.

Assessment Criteria

Each application to be assessed for approval as a community pharmacy delivering a COVID – 19 vaccine service must meet all aspects of the following criteria:

- The pharmacy is recognised as eligible through the Australian Government's EOI process.
- The pharmacy has an existing program approval granted by the Tasmanian Director of Public Health.
- The pharmacy site has been assessed by the Tasmanian Pharmacy Authority (TPA) and deemed an appropriate vaccination site.
- The application demonstrates that the listed Authorised Immunisers have successfully completed the mandatory COVID - 19 vaccine training, including the relevant vaccine-specific modules, and updates provided by the Australian Government Department of Health.
- If a pharmacy opts in to provide COVID-19 vaccine to the 5 to 11 year old cohort, it must ensure that all administering pharmacist immunisers have individually applied, and are authorised, to administer vaccine in this age group.
- The executive declaration component of the application form has been completed and signed. The declaration is to confirm that the community pharmacy still complies with the Australian Government's EOI minimum requirements and is compliant with other minimum expectations (available here: [Community pharmacy COVID-19 vaccine rollout from phase 2A²](#))

² www.health.gov.au/sites/default/files/documents/2021/01/community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-may-2021-onwards.pdf

Conditions of Expanded Scope

Community pharmacies that meet the aforementioned criteria will be recommended for sign-off for expanded scope by the Tasmanian Director of Public Health or his delegate outlining the conditions of the expanded scope. Conditions on the expanded scope to include COVID-19 vaccines include:

1. Expiry date of approval is 30 June 2022 from the date of approval letter, unless otherwise revoked.
2. Adhere to Australian Technical Advisory Group on Immunisation (ATAGI) clinical guidance and TGA approval.
3. Program approvals are for administration of COVID-19 vaccine to those aged 12 years and older.
4. Responsible Officers of programs may apply to 'opt-in' for an expanded scope enabling administration of COVID-19 vaccine to children aged 5 years and older. Under these approved programs, pharmacist immunisers must also have individual approval to vaccinate individuals under 12 years of age (see 'Minimum requirements to apply to 'opt-in' for provision of COVID-19 vaccine to children aged 5 to <12 years old')
5. **For all COVID-19 vaccines:**
 - Ensure the recommended time interval between doses, including the primary course and boosters, is adhered to as per the ATAGI's current clinical guidance; link refers: [ATAGI clinical guidance](#).
 - Individuals with a relative or absolute contraindications, or precautionary conditions to a vaccine must be referred to their general practitioner (GP) or specialist for vaccination.
 - Steps should be taken to minimise vaccine wastage through booking processes. Major wastage should be reported to the Australian Government Department of Health's Vaccine Operations Centre as per the centre's requirements.
 - The Australian Immunisation Register (AIR) should be checked prior to **EVERY** vaccine administration to avoid inadvertent mixed schedules and to ensure the interval is correct.
 - Wherever possible, a two-person vaccine draw-up procedure is best practice to minimise error in vaccine preparation.
 - Ensure that authorised immunisers have successfully completed the mandatory COVID-19 vaccine training provided by the Australian Government Department of Health, including all the relevant vaccine-specific modules for vaccines available through the pharmacy's program.
6. Off-site vaccination is authorised if the requirements of an off-site COVID-19 vaccination service are met, as outlined below under the heading 'Requirements of an Off-site COVID-19 Vaccination Service'.
7. Intern Pharmacists may administer COVID-19 vaccines under the supervision of an authorised pharmacist immuniser if the intern holds a Statement of Attainment from either the Tasmanian branch of the Pharmaceutical Society of Australia (PSA) or the Pharmacy Guild of Australia and has completed the Practicum as per the *Tasmanian Immunisation Program Guidelines*, and
8. The Responsible Officer of the approved program is compliant with the expectations outlined in the Executive Declaration.

Additional Clinical Considerations

Pharmacist Immunisers are recommended to take additional precaution to ensure that a mixed dose schedule is not inadvertently administered, for example AstraZeneca and Moderna.

Based on current evidence, ATAGI recommends using the same COVID-19 vaccine for the two doses of the primary course. In special circumstances, an alternative brand could be considered for dose 2 at the recommendation of a medical practitioner. It is recommended that the immunisation history of the

individual is checked on the AIR prior to administration of a COVID-19 vaccine to ensure the right brand and timing of vaccination is completed.

Please note that as many pharmacies will have more than one COVID-19 vaccine brand in its pharmacy, procedures should be in place to minimise risks. This includes ensuring that the correct vaccine is administered as per the relevant eligibility criteria and considering the differing age recommendations, precautionary conditions, contraindications, dose intervals, dose preparation and cold chain requirements. Vials should be kept in the original carton if unopened, and clearly labelled and stored separately once opened. Pharmacists may consider running dedicated sessions for specific COVID-19 vaccine brands to mitigate these risks.

Clinical Guidance - COVID-19 Vaccines 5-11 Years Old

COVID-19 vaccines can only be administered to those aged 5 to 11 years old in:

1. approved pharmacies, and
2. by Authorised Pharmacist Immunisers who have applied, and are authorised, to administer vaccine for this age group. See 'minimum requirements to apply to 'opt-in' for provision of COVID-19 vaccine to children aged 5 to <12 years old).

Please ensure Pharmacist Immunisers are familiar with the specific clinical guidance pertaining to the Paediatric Pfizer formulation and Moderna in this cohort. In particular, please note the following important differences:

Formulation:

- A specific Paediatric Pfizer formulation is recommended for use in those aged 5 to 11 years old (orange cap). This formulation is different to that for the 12 year old and older cohort (purple cap).
- Primary course:
 - For children aged 5 to <12 years old: ATAGI recommends the use of the specific Pfizer COVID-19 vaccine paediatric formulation (orange cap): 0.2ml (10 µg) *
 - For individuals aged 12 years and older: Pfizer (purple cap): 0.3ml (30 µg)
- For boosters:
 - be administered to those aged 16 years and older.
- The Moderna vaccine used for the those aged 6 to 11 years old is the same vaccine product used for the older cohort (>12 years), however the dose is different (below).
- Primary course:
 - For children aged 6 to 11 years: 0.25 mL (50 µg)
 - For children 12 years and older: 0.50 mL (100 µg)
- Booster dose for adults 18 years and older: 0.25 mL (50 µg)

Age groups:

- Paediatric Pfizer is recommended for those aged 5 to 11 years old.
- Moderna has been approved for use in those aged 6 to 11 years old. The recommended dosage for this age group is half the dose (0.25mL) of that recommended for those aged 12 and older (0.5mL).

Opt-In to Provide COVID-19 Vaccine to 5-11 Years Old

The minimum requirements to apply to 'opt-in' for provision of COVID-19 vaccine to children aged 5 to 11 years old are:

Responsible officers: Pharmacies may apply to 'opt in' to administer COVID-19 vaccine to children aged from 5 to 11 years old by submitting the application form to expand their Program Approval. The form at Appendix B needs to be completed and submitted to the authorised immuniser email address given at the bottom of the form.

Pharmacist immunisers: Individual pharmacist immunisers must also individually apply for approval to administer COVID-19 vaccine to children aged from 5 to 11 years old. To apply for an expanded scope to include children, pharmacists need to renew their Immunisation Authorisation by completing an 'Authorised Immuniser Renewal Application Form' and indicate that they have completed all requirements and would like to expand their scope of practice.

Minimum requirements to apply for expansion of approval to enable administration of COVID-19 vaccine to children aged 5 to 11 years old include:

All Authorised Immunisers participating in the program must:

- a) Have completed a relevant childhood training module from the PSA or Guild.
 - Note: all Authorised Pharmacist Immunisers who completed their training through the Guild from 2019 and the PSA from September 2019 will have completed the childhood module as part of their baseline training. Authorised Pharmacist Immunisers who completed their immunisation training prior to this will need to complete an additional childhood training module as above.
 - Pharmacists wishing to expand their scope can choose to complete the Guild Module which is available here: <https://guilded.guild.org.au/>
or alternatively the PSA Immunisation Refresher course which can be accessed here:
[Immuniser Online Refresher Course](#)
- b) Be current with baseline continuing professional development expectations of APIs, namely basic life support and anaphylaxis management in the last 12 months
- c) have successfully completed the specific paediatric COVID-19 modules for Pfizer and Moderna, and updates, provided by the Commonwealth.
- d) Additional professional development opportunities are strongly encouraged, including:
 - Attendance at a State Government 5 to 11 year old COVID-19 vaccination clinic and
 - Completion of the Melbourne Vaccine Education Centre Immunising Children and Infants Webinar, available here: [MVEC Webinar](#)
 - Authorised Immunisers are also strongly encouraged to attend a PSA refresher course.

Authorised Immunisers considering expansion of their program to include children aged 5 to 11 years old must be aware and competent with the additional clinical considerations concerning this cohort, including:

- Recognition of adverse events following immunisation and how it may present in a paediatric population
- The different adrenaline dose recommendations that span this age group
- Identifying anatomical landmarks and correct administration sites for children
- Strategies to manage difficult immunisation encounters
- Age-appropriate positioning for safe vaccination
- Distraction techniques for different age groups
- Communication and consent.

Off-Site COVID-19 Vaccination Service Requirements

In order for an Authorised Immuniser to administer approved COVID-19 vaccines off-site, the service provider must meet the following conditions:

1. The service must be linked to a community pharmacy with an existing program approval from the Tasmanian Director of Public Health to administer COVID-19 vaccines and have site approval by the TPA.
2. Must meet all of the requirements outlined in the *Tasmanian Immunisation Program Guidelines*.
3. Must meet all of the requirements outlined in the *Community Pharmacy Provision of COVID-19 Vaccine in Tasmania Guidelines and Application Process*.
4. Must ensure they have appropriate insurance for the administration of vaccines and provision of vaccination service.
5. Must ensure they are accredited through an appropriate quality assurance program.
6. Must adhere to the requirements of the *Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines – Strive for 5*, including equipment requirements.
7. 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.
8. Must ensure that patients are monitored during the post-vaccination period in line of sight of the pharmacist immuniser or other qualified staff member* for the recommended time
9. Must ensure that in addition to the authorised immuniser, that one other staff member who holds current first aid and cardiopulmonary resuscitation qualification is present when the vaccines are administered and during the post-vaccination period.
10. Must ensure that an emergency response protocol is accessible and an accessible anaphylaxis response kit which complies with the recommendations of the Australian Immunisation Handbook.
11. Must adhere to the site requirements concerning the physical environment, workforce requirements, cold chain management, multidose vial administration, record keeping, waste disposal, personal protective and other equipment, accreditation, accessibility and cultural safety and equipment as outlined by the Australian Government 'Community Pharmacy COVID-19 vaccine rollout from phase 2A': [Community pharmacy COVID-19 vaccine rollout from phase 2A](#)³
12. Must comply with any additional conditions of off-site vaccination as stipulated by the Commonwealth Australian Government Department of Health
13. Pharmacist Interns must only provide vaccination under the direct supervision of an Authorised Pharmacist Immuniser

* A qualified staff member is defined as a member of staff who has current first aid certificate and cardiopulmonary resuscitation certificate

Exclusions:

- Off-site vaccination activities in the following settings are not currently authorised:
 - educational settings (early learning, primary and secondary schools) and
 - residents of residential aged care facilities unless specifically requested by the resident's GP.
 - The residential aged care facility Nurse Manager must contact the resident's GP to discuss provision of vaccination by an Authorised Pharmacist Immuniser. If unable to contact the resident's GP despite reasonable attempts, the Nurse Manager may ask an Authorised

³ www.health.gov.au/sites/default/files/documents/2021/01/community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-may-2021-onwards.pdf

Pharmacist Immuniser to enter the RACF to administer COVID-19 vaccine to the resident, subject to the consent of the resident or their medical power of attorney.

- Clear documentation of communication (or attempts at communication) with the GP, the individual's vaccination history, consent and fact of administration of the vaccine is recommended.
- A letter to the GP advising of the vaccination encounter is recommended as part of good clinical documentation.
- It is recommended that the AIR is checked by the Immuniser prior to vaccination to ensure the appropriate schedule is followed to prevent vaccine administration errors.
- Uploading all vaccination encounters to the AIR is mandatory.

Appendix A: Expansion of Scope-COVID-19 Vaccines

To apply for an expansion of Scope of Approved Vaccination Program to include COVID-19 Vaccines, please complete the below application form (three pages).

Expansion of Scope of Approved Vaccination Program to include COVID - 19 Vaccines – Application Form

Organisation Details	
Organisation Name:	
Postal Address:	
Suburb:	Postcode:
Phone:	
Email:	
Does your organisation operate from multiple sites? No <input type="checkbox"/> If, Yes <input type="checkbox"/> (Please complete this form for each site)	
Are you applying to administer COVID-19 vaccines to children aged 5 to <12 years old? No <input type="checkbox"/> If, Yes <input type="checkbox"/> (If Yes, please complete form in Appendix B)	

In your program who do you intend to employ?
<input type="checkbox"/> A Registered Nurse/s who is an Authorised Immuniser (AI)
<input type="checkbox"/> A Registered Pharmacist/s who is an AI
<input type="checkbox"/> Other AI, describe:

Names and AHPRA numbers for the AIs you employ	Authorised Pharmacist Immuniser (API)/ Authorised Nurse Immuniser (ANI)	AHPRA Number	Completion of all COVID - 19 modules and updates?
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>

Executive Declaration

I,

(print full name)

The Principal Officer of the organisation / company:

.....

(company name)

Declare that:

- I have read and understood the information in the attached guidelines
- The information I have provided in this application is true and correct
- The immunisation program will be administered in accordance with the latest editions of the NHMRC *Australian Immunisation Handbook*, the *National Vaccine Storage Guidelines Strive for 5* and the *Tasmanian Immunisation Program Guidelines*
- I am aware that I will be subject to random audits of the immunisation service and may be required to submit copies of my organisation's policies and procedures, as well as qualifications of authorised immunisers
- I have provided a copy of this completed application form and the guidelines to each individual involved in the delivery of the immunisation program
- I have received approval from the TPA for the vaccination area within the pharmacy
- The pharmacy has a current Immunisation Program Approval with DoH Tasmania
- All immunisers have completed the mandatory COVID - 19 vaccine modules provided by the Australian Government, and all available updates and other professional development requirements as an authorised immuniser remain current
- I confirm that our site remains compliant with requirements specified by the Australian Government
- I understand that authorised immunisers that will deliver COVID - 19 vaccine are strongly encouraged to participate in training opportunities facilitated by the Tasmanian Vaccination Emergency Operations Centre.

Signature:

Date:

Return this completed application form to:

- Email: authorisedimmuniser@health.tas.gov.au
- Mail: GPO Box 125 Hobart 7000
- Enquiries: 1800 671 738 or (03) 6166 0632

Appendix B: Expansion of Scope-5 Years Old and Older

To apply for an expansion of Scope of Approved Vaccination Program to include Children 5 years old and older, please complete the below application form (three pages).

Expansion of Scope of Approved COVID-19 Vaccination Program to Include Children Aged 5 Years Old and Older– Application Form

Organisation Details	
Organisation Name:	
Postal Address:	
Suburb:	Postcode:
Phone:	
Email:	
Does your organisation operate from multiple sites? No <input type="checkbox"/> If, Yes <input type="checkbox"/> (Please complete this form for each site)	
Are you applying to administer COVID-19 vaccines to children aged 5 to <12 years old? No <input type="checkbox"/> Yes <input type="checkbox"/>	

In your program who do you intend to employ?
<input type="checkbox"/> A Registered Nurse/s who is an Authorised Immuniser (AI)
<input type="checkbox"/> A Registered Pharmacist/s who is an AI
<input type="checkbox"/> Other AI, describe:
Overleaf - Please provide details of the Authorised Pharmacist Immunisers who will be administering vaccine to children aged 5 years to <12 years

Name of the AI	Authorised Pharmacist Immuniser (API)/ Authorised Nurse Immuniser (ANI)	AHPRA Number	Completion of all COVID - 19 modules & updates inc. the Paediatric Pfizer and Moderna 6 to 11 years vaccine module?	Pharmacist Immuniser Childhood Module Completed
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/> Paediatric Pfizer Module? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderna (6-11 years vaccine) module? Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> If PSA courses completed before September 2019 and Guild courses completed before 2019, please attach evidence of completion of childhood specific module
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/> Paediatric Pfizer Module? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderna (6-11 years vaccine) module? Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> If PSA courses completed before September 2019 and Guild courses completed before 2019, please attach evidence of completion of childhood specific module
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/> Paediatric Pfizer Module? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderna (6-11 years vaccine) module? Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> If PSA courses completed before September 2019 and Guild courses completed before 2019, please attach evidence of completion of childhood specific module
Name:	API <input type="checkbox"/> ANI <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/> Paediatric Pfizer Module? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderna (6-11 years vaccine) module? Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> If PSA courses completed before September 2019 and Guild courses completed before 2019, please attach evidence of completion of childhood specific module

Executive Declaration

I,

(print full name)

The Principal Officer of the organisation / company:

.....

(company name)

Declare that:

- I have read and understood the information in the attached guidelines
- Specific to the 5 to 11 year old program, I have read the minimum requirements to participate in this part of the program, are aware of the additional clinical considerations required to safely vaccinate this younger cohort, and affirm that all participating Authorised Immunisers meet these criteria.
- I understand that all Authorised Immunisers need to have individually applied through an 'Authorised Immuniser Renewal Application Form' and are authorised to administer vaccine in this age group.
- The information I have provided in this application is true and correct
- The immunisation program will be administered in accordance with the latest editions of the NHMRC *Australian Immunisation Handbook*, the *National Vaccine Storage Guidelines Strive for 5* and the *Tasmanian Immunisation Program Guidelines*
- I am aware that I will be subject to random audits of the immunisation service and may be required to submit copies of my organisation's policies and procedures, and pharmacist immuniser certificates if requested
- I have provided a copy of this completed application form and the guidelines to each individual involved in the delivery of the immunisation program
- I have received approval from the TPA for the vaccination area within the pharmacy
- The pharmacy has a current Immunisation Program Approval with DoH Tasmania
- All immunisers have completed the mandatory COVID - 19 vaccine modules provided by the Australian Government, and all available updates and other professional development requirements as an authorised immuniser remain current
- I confirm that our site remains compliant with requirements specified by the Australian Government
- I understand that authorised immunisers that will deliver COVID - 19 vaccine are strongly encouraged to participate in training opportunities facilitated by the Tasmanian Vaccination Emergency Operations Centre.

Signature:

Date:

Return this completed application form to:

- Email: authorisedimmuniser@health.tas.gov.au
 - Mail: GPO Box 125 Hobart 7000
- Enquiries: 1800 671 738 or (03) 6166 0632