

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

September 2021

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 www.dhhs.tas.gov.au/peh/immunisation

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

Contact Details

For further information about the guidelines and the approval process please contact:

Clinical Nurse Consultant (Immunisation)

Public Health Services
Department of Health

Telephone: 1800 671 738 or 6166 0632 or authorisedimmuniser@health.tas.gov.au

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.

Contents

About the Guidelines and Application Process	I
Contact Details.....	I
Community Pharmacy Definition	I
Contents.....	I
Background.....	2
Application Process	2
Assessment Criteria	2
Conditions of expanded scope	3
Appendix A.....	34
Application Form for Expansion of Scope of Approved Vaccination Program to include COVID - 19 Vaccines.....	45
Cont'd - Application Form for Expansion of Scope of Approved Vaccination Program to include COVID - 19 Vaccines.....	67

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 vaccines 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. When approval is granted it will include an offer for a familiarisation shift in a Tasmanian Government AstraZeneca vaccine clinic facilitated by the DoH's Tasmanian Vaccination Emergency Operations Centre.

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 site has been assessed by the Tasmanian Pharmacy Authority and deemed an appropriate vaccination site.
- The application demonstrates that the listed Authorised Immunisers have successfully completed the mandatory COVID - 19 vaccine training and updates provided by the Australian Government Department of Health.
- The executive declaration component of the application form 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-2a-community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-may-2021-onwards.pdf](https://www.health.gov.au/media/10111/community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-community-pharmacy-covid-19-vaccine-rollout-from-phase-2a-may-2021-onwards.pdf) ([health.gov.au](https://www.health.gov.au))).

Conditions of expanded scope

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

1. Expiry date of approval one year from the date of approval letter, unless otherwise revoked.
2. For AstraZeneca COVID-19 (Vaxzevria) vaccine: clinical practice must align with ATAGI guidance for non-outbreak settings and TGA provisional approval, i.e.:
 - First dose provision is limited to those aged 60 years and over.
 - Second doses may be given to those aged 18 years and above who received their first dose without a serious adverse event, adhering to the recommended dose interval.
 - Additionally, individuals with a relative or absolute contraindication, or a precautionary condition relevant to AstraZeneca, must be referred to their GP or specialist for vaccination.
3. For Spikevax (Moderna) COVID-19 vaccine: administration must align with ATAGI clinical guidance and TGA provisional approval, i.e.:
 - Be administered to those aged between 12 years and 59 years, or those aged 60 years and older who a precautionary condition, relative contraindication or absolute contraindication to AstraZeneca COVID-19 Vaccine (Vaxzevria) who have been referred by a medical practitioner to your pharmacy for vaccination with Spikevax (Moderna).
 - You must retain and/or document the referral from a medical practitioner requesting provision of Spikevax (Moderna) to those aged 60 years or older.
 - Individuals with a relative or absolute contraindication, or precautionary condition to Spikevax (Moderna) must be referred to their GP or specialist for vaccination.
4. Administration must occur in a pharmacy setting
5. The approval applies to Authorised Immunisers and excludes Intern Pharmacists, and
6. 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 (e.g. AstraZeneca – Moderna). In Australia, mixing of COVID-19 vaccine brands is not routinely recommended and limited to selected medical indications at the recommendation of a specialist. It is recommended that the immunisation history of the individual is checked on the Australian Immunisation Register prior to administration of a COVID-19 vaccine to ensure the right brand and timing of vaccination is completed.

Please note that pharmacies should have strict procedures in place to ensure that the correct vaccine for age group is given to the individual because pharmacies will be storing both COVID-19 Vaccines, AstraZeneca (Vaxzevria) and Spikevax (Moderna), in their fridge. For example, pharmacies with large numbers of bookings may choose to run vaccine-specific clinics. It should also be noted that there are different shelf-life requirements for each, including once the vial is punctured. Vials should be kept in their original carton if unopened, and clearly labelled and stored separately once opened.

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

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)	

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"/>
Cont'd	Authorised Pharmacist	AHPRA Number	Completion of all COVID - 19

[illegible]

Cont'd - Application Form for Expansion of Scope of Approved Vaccination Program to include COVID - 19 Vaccines

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
- 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 the Australian Government's Community pharmacy COVID – 19 vaccine rollout from Phase 2A [Community pharmacy COVID - 19 vaccine rollout from Phase 2A May 2021 onwards](#)
- 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 the Director of Public Health, via:

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