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

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Version 11

Department of Health

Tasmanian Government

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

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.

[1] https://www.health.tas.gov.au/health-topics/immunisation

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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 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.
- 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[2]

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 is 30 June 2022 from the date of approval letter, unless otherwise revoked.

[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

2. **For AstraZeneca (Vaxzevria) vaccine:** clinical practice must align with ATAGI guidance and TGA provisional approval, i.e.:

- Adults <60 years: Pfizer (Comirnaty) of Moderna (Spikevax) are preferred for people aged < 60 years. This is due to the higher risk of thrombosis with thrombocytopaenia syndrome in people aged <60 years compared with people aged ≥ 60 years.
    - AstraZeneca (Vaxzevria) vaccine can be used in adults aged 18 to <60 years if the person has discussed this with their GP and made an informed decision based on an understanding of the risks and benefits.
- Pfizer (Comirnaty) or Moderna (Spikevax) are also preferred for third doses or booster doses in people of all ages, including people aged >60 years and people who received AstraZeneca (Vaxzevria) for their first two doses.
- AstraZeneca (Vaxzevria) is no longer recommended for use as the booster dose for people who received a primary vaccination course of the AstraZeneca (Vaxzevria). However, it can still be used for this purpose if these individuals decline receiving an mRNA vaccine as a booster dose.
- AstraZeneca (Vaxzevria) is now only recommended as a booster when there are medical contraindications to mRNA vaccines.
- Individuals with a relative or absolute contraindication, or a precautionary condition relevant to AstraZeneca (Vaxzevria), must be referred to their GP or specialist for vaccination.

3. **For Spikevax (Moderna) vaccine:** administration must align with ATAGI clinical guidance and TGA provisional approval, i.e.:

- For a primary course: be administered to those aged 12 years and older.
- For a booster: be administered to those **aged 18 years and older**.
- **Note:** the booster dose is ***different*** to the primary course dose:
    - **Primary course dose:** 0.5 mL (100 µg)
    - **Booster dose**: 0.25 mL (50 µg)
- Individuals with a relative or absolute contraindication, or precautionary condition to Spikevax (Moderna) must be referred to their GP or specialist for vaccination.

4. **For Pfizer (Comirnaty) vaccine:** administration must align with ATAGI clinical guidance and TGA provisional approval, i.e.:

- For a primary course: be administered to those aged 12 years and older.
- For boosters: be administered to those aged **16 years and older.**

5. For Novovax (Nuvaxovid) vaccine: administration must align with ATAGI clinical guidance and TGA provisional approval, i.e.

- **For a primary course:** be administered to those aged 18 years and older.
- Can be used as a booster in those aged 18 years and above if no other COVID-19 vaccine is considered suitable. Novovax has been introduced at a stage of the roll-out when >99% of Tasmanians over the age of 18 years have received a COVID-19 vaccine. As such, prior to administering the first dose of Novavax, it is particularly important to check the AIR and verify immunisation history with the individual to avoid administration errors.

6. For all COVID-19 vaccines:

- The minimum age that approved COVID-19 vaccines can be administered in Tasmania through approved community pharmacies is 12 years old.

- Ensure the recommended time interval between doses, including the primary course and boosters, is adhered to as per current ATAGI clinical guidance.
- Steps should be taken to minimise vaccine wastage through booking processes. Major wastage should be reported to the Commonwealth Vaccine Operations Centre as per their 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 Department of Health, including all the relevant vaccine-specific modules for vaccines available through your program.

6. Off-site vaccination is authorised if the requirements of an off-site COVID-19 vaccination service are met, as outlined below under '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 they hold a Statement of Attainment from the Tasmanian PSA or Pharmacy Guild and have completed their 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 (e.g. AstraZeneca (Vaxzevria) – 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 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 as many pharmacies will have more than one COVID-19 vaccine brand in their 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 their 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.

Boosters and third doses

Authorised Pharmacist Immunisers should be familiar with the differences between boosters and third doses.

Third doses:

ATAGI recommends a third primary dose of COVID-19 vaccine in severely immunocompromised populations to address the risk of suboptimal or non-response to a standard primary course.

- **Age & eligibility:**

- ATAGI recommends that all individuals aged 5 years and over* with certain medical conditions or on therapies leading to severe immunocompromise receive a 3rd primary dose of a COVID-19 vaccine. A list of the eligible conditions is here: ATAGI recommendations on third primary dose of COVID-19 vaccine[3]
- *note: the minimum age that approved COVID-19 vaccines can be administered in Tasmania through approved community pharmacies is 12 years old.
- To assess evidence of eligibility, please follow the guidance provided by the Australian Government: Eligibility guidelines for third primary dose of COVID-19 vaccine[4]
- **Vaccine brand:** An mRNA vaccine (Pfizer (Comirnaty) or Moderna (Spikevax)) is preferred over AstraZeneca (Vaxzevria) for this 3rd dose. AstraZeneca (Vaxzevria) can be used for the 3rd dose for individuals who have received AstraZeneca (Vaxzevria) for their first 2 doses if there are no contraindications or precautions for use, or if a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g. anaphylaxis, myocarditis)

- **Timing**: the recommended interval for the 3rd dose is 2 to 6 months after the 2nd dose of vaccine.
  - A minimum interval of 4 weeks may be considered in exceptional circumstances (e.g. anticipated intensification of immunosuppression; outbreaks).
    People who have received a 2nd dose more than 6 months ago should receive a 3rd dose as soon as feasible.

Booster doses:

ATAGI supports the use of a single booster dose for those **16 years and older**. Note: currently Pfizer (Comirnaty) is the only vaccine registered for use as a booster in people aged 16-17 years.

Latest ATAGI guidance should be adhered to in relation to timing, eligibility, age and brand considerations.

Timing and eligibility

- Booster doses are not currently recommended by ATAGI for those aged under 16 years.
- As of 1 February 2022, the minimum interval between the primary course and booster dose is 3 months.
- Access to boosters should be facilitated for those at greatest risk of COVID-19 as a priority.
- Anyone with a contraindication or precaution to a vaccine, including an adverse event to an earlier dose, should seek specialist review.
- Severely immunocompromised persons aged 16 years and older who have received a third dose as part of their primary COVID-19 vaccine course, booster doses (that is, a fourth dose) are recommended 3 months after the most recent dose in the primary course.

Age and brand considerations:

- **16 to 17 years old:**
  - Pfizer (Comirnaty) vaccine is the only vaccine registered for use as a booster for people aged 16–17 years at present.
  - ATAGI recommends a booster vaccination with the 30 microgram Pfizer (Comirnaty) COVID-19 vaccine, for all adolescents aged 16-17 years who have previously received any

[3] https://www.health.gov.au/sites/default/files/documents/2021/11/atagi-recommendations-on-the-use-of-a-third-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised.pdf
[4] https://www.health.gov.au/sites/default/files/documents/2021/10/covid-19-vaccination-eligibility-declaration-form.pdf

TGA approved or recognised vaccines for their primary vaccine schedule, from 3 months after receiving their last primary dose. This includes those who were aged under 16 years when they received their last primary dose and are now aged 16 years.

- **18 years and older:**
    - Pfizer (Comirnaty) or Spikevax (Moderna): Recommended as a single booster dose, irrespective of the primary COVID-19 vaccine used. **Note:** the recommended dose for a Moderna booster (0.25mL; 50µg) is half the recommended dose of the Moderna vaccine used for the primary course (0.5mL; 100 µg).
    - AstraZeneca (Vaxzevria): although not preferred, can also be used as a booster dose in the following situations:
        - For individuals who have received AstraZeneca (Vaxzevria) for their first two doses if they decline an mRNA booster dose *and* there are no contraindications or precautions for its use.
        - If a significant adverse reaction has occurred after a previous mRNA vaccine dose which contraindicates further doses of mRNA vaccine (e.g., anaphylaxis, myocarditis), and after specialist review.
    - Novovax (Nuvaxovid) can be used as a booster in those aged 18 years and above if no other COVID-19 vaccine is considered suitable.

Requirements of an off-site COVID-19 vaccination service

In order to 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 Director of Public Health to administer COVID-19 vaccines and have site approval by the Tasmanian Pharmacy Authority
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[5]

12. Must comply with any additional conditions of off-site vaccination as stipulated by the Commonwealth
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 General Practitioner (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 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.

[5] 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

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 ☐ If, Yes ☐ (Please complete this form for each site)	

In your program who do you intend to employ?
☐ A Registered Nurse/s who is an Authorised Immuniser (AI)
☐ A Registered Pharmacist/s who is an AI
☐ 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 ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Cont'd **Names and AHPRA numbers for the AIs you employ**	**Authorised Pharmacist Immuniser (API)/**	**AHPRA Number**	**Completion of all COVID - 19**

	Authorised Nurse Immuniser (ANI)		modules and updates?
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐
Name:	API ☐ ANI ☐		Yes ☐ No ☐

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 (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)
- 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