**Structured Administration and Supply Arrangement (SASA)**

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| **TITLE:** | **COVID-19 Vaccination in Community Pharmacy Program** |

1. **Authority:**

Issued by the Chief Executive Officer of Health under Part 6 of the *Medicines and Poisons Regulations 2016*.

1. **Scope:**

This authorises pharmacists and registered nurses, trained in COVID-19 immunisation, to administer COVID-19 vaccines at a suitably equipped and staffed place or premises in Western Australia.

1. **Criteria:**

This SASA authorises the actions specified in the table below:

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| **Practitioner:** | 1. Registered pharmacists[[1]](#footnote-1).
2. Registered Nurses employed by a pharmacy meeting the ‘practice setting’ requirements of this SASA.

A health practitioner is only approved to administer COVID-19 vaccine under this SASA if they have completed training in accordance with Appendix 1. |
| **Practice setting:** | At a place or premises in Western Australia that complies with Appendix 2.  |
| **Approved activity:** | Administration.  |
| **Approved medicines:** | Therapeutic Goods Administration registered SARS-COV-2 (COVID-19) VACCINE products.  |
| **Medical conditions:** | Immunisation against COVID-19 infection in individuals aged 5 years and above in the Western Australian population, in accordance with the current Australian Technical Advisory Group on Immunisation recommendations.  |

1. **Conditions:**

The administration of approved medicines under this SASA is subject to the conditions that:

* 1. The pharmacist, including a pharmacist with provisional registration, or registered nurse has successfully completed training in accordance with Appendix 1.
	2. A pharmacist with the registration type of ‘provisional’ must be supervised by a pharmacist, who is eligible to administer COVID-19 vaccines in accordance with this SASA.
	3. Premises where vaccination is being conducted meet the requirements of
	Appendix 2: Approved Setting.
	4. Written or documented verbal consent is obtained from the client, or their guardian, before each instance of vaccination.
	5. All vaccines administered must be recorded on the client’s record at the pharmacy, and the administering pharmacist or registered nurse must ensure the administration is entered into the Australian Immunisation Register.
	6. All adverse events occurring following immunisation are notified to the Western Australian Vaccine Safety Surveillance system and in accordance with any other adverse event surveillance requirements determined by the Commonwealth Department of Health as part of approval of the pharmacy as a vaccination site.
	7. Supply and possession of vaccines is conducted by a pharmacy business under the overall authority of the responsible pharmacist in accordance with Section 9 of the *Medicines and Poisons Act 2014*.
	8. Procurement, storage and administration is in accordance with Part 9 of the *Medicines and Poisons Regulations 2016.*
	9. Record keeping is in accordance with Part 12 of the *Medicines and Poisons Regulations 2016*; and
	10. Storage and transport of the vaccines is in accordance with the *National Vaccine Storage Guidelines: Strive for 5* and any requirements of the product information for the vaccine.
1. **References:**
2. *Australian COVID-19 Vaccination Policy available at:* <https://www.health.gov.au/resources/publications/australian-covid-19-vaccination-policy>
3. *Australian Immunisation Handbook available at:*

<https://immunisationhandbook.health.gov.au/>

1. *National Vaccine Storage Guidelines 2019: Strive For 5*. 3rd ed. Canberra: Australian Government, Department of Health and Ageing available at:

<https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>

1. *Western Australian Vaccine Safety Surveillance.* Western Australian Department of Health, 2016 available at: <http://ww2.health.wa.gov.au/Articles/U_Z/Western-Australian-Vaccine-Safety-Surveillance-WAVSS>
2. *Australian Immunisation Register a*vailable at: <https://www.humanservices.gov.au/health-professionals/services/medicare/australian-immunisation-register-health-professionals>
3. **Issued by:**

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| **Name:** | Dr Andrew Robertson  |
| **Position:** | Chief Health Officer, Delegate of the CEO |
| **Date:**  | 3 October 2023 |

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| Enquiries to:  | Medicines and Poisons Regulation Branch | Number: | 024/3-2021 |
|  | MPRB@health.wa.gov.au | Date:  | 03/10/2023 |

**APPENDIX 1**

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| **Approved Training and Required Competencies** |

All registered health practitioners administering COVID-19 vaccine in accordance with this SASA must have completed:

1. Approved general immunisation course delivered by Health Education Services Australia or an equivalent course provided by a Registered Training Organisation, or a university or course approved by the Chief Executive Officer of the Department of Health or equivalent Department of Health in an Australian State or Territory.

Competency must be maintained through yearly updates.

Approved courses must require participants to demonstrate satisfactory knowledge, understanding and minimum competencies in the following areas:

1. storage, transport and handling of vaccines (cold chain);
2. obtaining informed consent for vaccination;
3. indications and contraindications for vaccination;
4. administration of vaccines as per National Health and Medical Research Council Immunisation Guidelines;
5. Cardiopulmonary resuscitation;
6. diagnosis and management of anaphylaxis; and
7. documentation of vaccination and critical incidents.

and

1. COVID-19 training relevant to the COVID-19 vaccines they will be administering delivered by the Commonwealth Government, or an equivalent course approved or recognised by an Australian State or Territory Department of Health.

Approved courses must require participants to demonstrate satisfactory knowledge, understanding and minimum competencies in the following areas:

1. COVID-19 and vaccination against COVID-19;
2. handling and storage;
3. consent;
4. multi-dose vial training;
5. documentation and reporting; and
6. safety and surveillance monitoring and reporting for adverse events following immunisation.

**APPENDIX 2**

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| **Approved Setting** |

Registered health practitioners may only administer COVID-19 vaccine in accordance with this SASA within an approved pharmacy or premises that meets the [Australian Technical Advisory Group on Immunisation (ATAGI) site requirements for COVID-19 vaccination in community pharmacies](https://www.health.gov.au/sites/default/files/documents/2021/02/covid-19-vaccination-site-requirements-for-covid-19-vaccination-in-community-pharmacies.pdf) or [Taskforce requirements for conducting off-site COVID-19 vaccinations](https://www.ppaonline.com.au/wp-content/uploads/2021/09/Taskforce-requirements-for-conducting-off-site-COVID-19-vaccinations.pdf).

The physical environment of the approved pharmacy or premises must have:

* Adequate space for clients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements; and
* a private and quiet space for consultation with clients and vaccinator, including obtaining informed consent, answering client questions and assessment of any conditions that may preclude vaccination or require further assessment and administration of vaccine.
* A dedicated, clean, well-lit space for administration of the vaccine to clients which:
	+ includes a desk and chairs for clients, carers/parents and vaccinator(s);
	+ permits the client to safely lie flat in the event of a severe adverse event or anaphylactic reaction; and
	+ offers unhindered access for emergency staff to attend and perform resuscitation procedures.
* Adequate space for clients to wait and be observed post-vaccination, where physical distancing requirements can be achieved.
* A dedicated area, separate from areas that provide other pharmacy services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration.
* Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available.
* A process in place to safely dispose of unused vaccines, and report wastage of unused vaccines in accordance with the Therapeutic Goods Administration requirements.
* Adequate sharps disposal bins, appropriate for the volume of clients, and securely placed and spaced to mitigate the risk of needle stick injuries.
* Adequate security provisions to ensure no unauthorised access to vaccine doses.
	+ An in-date, complete anaphylaxis response kit.
	+ Access to current editions of the *Australian Immunisation Handbook* and *National Vaccine Storage Guidelines: Strive for 5.*
	+ Up-to-date, written procedures, covering provision of immunisation services.
1. Includes pharmacists with the registration type of ‘provisional’ on the Australian Health Practitioner Regulation Agency Register of Practitioners, who are undertaking their approved supervised practice at a pharmacy meeting the ‘practice setting’ requirements of this Structured Administration and Supply Arrangement. [↑](#footnote-ref-1)