Structured Administration and Supply Arrangement (SASA)

|  |  |
| --- | --- |
| **TITLE:** | **Administration of COVID-19 vaccines by WA Health Pharmacists** |

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, who are staff members of WA Health and trained in COVID-19 immunisation, to administer COVID-19 vaccines at suitably equipped and staffed places or premises in Western Australia.

1. **Criteria:**

This SASA authorises the actions specified in the table below:

| **Practitioner:** | Pharmacists who satisfy both of the following:1. have completed approved training and have the competencies in accordance with Appendix 1; and
2. are staff members of a Health Service Provider.[[1]](#footnote-1)
 |
| --- | --- |
| **Practice setting:** | Places or premises in Western Australia where a vaccination clinic is being operated by WA Health. |
| **Approved activity:** | Administration.  |
| **Approved medicines:** | Therapeutic Goods Administration registered SARS-COV-2 (COVID-19) VACCINE products.  |
| **Medical conditions:** | Immunisation against COVID-19 infection in the Western Australian population, in accordance with the national roll-out strategy. |

1. **Conditions:**

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

* 1. The place or premises must be operated in compliance with any relevant Department of Health mandatory policies;
	2. The Pharmacist has successfully completed training and has the competencies, in accordance with Appendix 1;
	3. Sites where vaccination is being conducted meet the minimum requirements specified in Appendix 2, including being appropriately equipped to treat clients in the event of an anaphylactic reaction;
	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 in the clients’ record, and the Pharmacist must ensure a record of vaccine administration is included in 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 of Therapeutic Goods Administration product registration;
	7. The vaccines are stored at premises named on an appropriate Permit issued under 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. Australia’s COVID-19 vaccine national roll-out strategy. Available at: <https://www.health.gov.au/resources/publications/australias-covid-19-vaccine-national-roll-out-strategy>
3. Australian COVID-19 Vaccination Policy. Available at: <https://www.health.gov.au/resources/publications/australian-covid-19-vaccination-policy>
4. Australian Immunisation Handbook. Available at: <https://immunisationhandbook.health.gov.au/>
5. *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>
6. *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>
7. *Australian Immunisation Register.* Available at: <https://www.humanservices.gov.au/health-professionals/services/medicare/australian-immunisation-register-health-professionals>
8. **Issued by:**

|  |  |
| --- | --- |
| **Name:** | Dr Andrew Robertson  |
| **Position:** | Chief Health Officer, Delegate of the CEO |
| **Date:**  | 30 November 2021 |

|  |  |  |  |
| --- | --- | --- | --- |
| Enquiries to:  | Medicines and Poisons Regulation Branch | Number: | 027/2-2021 |
|  | MPRB@health.wa.gov.au | Date:  | 30 November 2021 |

**APPENDIX 1**

|  |
| --- |
| **Approved Training and Required Competencies** |

All Pharmacists administering COVID-19 vaccine in accordance with this SASA must have completed both:

1. Approved general immunisation training; and
2. COVID-19 vaccine-specific training approved by the Chief Health Officer.

**Required competencies for general immunisation training:**

* Storage, transport and handling of vaccines (cold chain);
* Obtaining informed consent for vaccination;
* Indications and contraindications for vaccination;
* Administration of vaccines as per National Health and Medical Research Council Immunisation Guidelines;
* Cardiopulmonary resuscitation;
* Diagnosis and management of anaphylaxis; and
* Documentation of vaccination and critical incidents.

**Approved general immunisation training:**

Courses delivered by the following organisations are approved:

1. Pharmaceutical Society of Australia (WA Branch);
2. Pharmacy Guild of Australia (WA Branch);
3. University of Western Australia;
4. An equivalent course approved or recognised by another Australian State or Territory Department of Health.

**COVID-19 vaccine-specific training must include:**

* Cold chain management of vaccines, including storage specific to the vaccine in use, such as ultra-low temperature storage;
* Indications and contraindications for COVID-19 vaccines;
* Management of multi-dose vials;
* Documentation of COVID-19 vaccinations to the Australian Immunisation Register and adverse events following immunisation to the Western Australian Vaccine Safety Surveillance System.

**APPENDIX 2**

|  |
| --- |
| **Approved Setting** |

Pharmacists may only administer COVID-19 vaccine in accordance with this SASA at a place or premises that has:

* Adequate space for clients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements;
* A private 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);
* A dedicated, clean, well-lit space for administration of the vaccine to clients which:
	+ includes a desk and chairs for clients and vaccinator(s);
	+ permits the client to safely lie prone in the event of a severe adverse event or anaphylactic reaction; and
	+ offers unhindered access for emergency staff to attend and perform resuscitation procedures.
* A space for clients to wait and be observed post-vaccination, separate from the area for administering the vaccine;
* A dedicated, clean, well-lit area separate from areas that provide other clinical 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;
* Disinfectant wipes to clean stations between clients;
* A process in place to safely dispose of unused vaccines, and report wastage of unused vaccines in accordance with policies issued by the Department of Health;
* Adequate sharps disposal bins, appropriate for the volume of clients, and securely placed and spaced to mitigate the risk of needle stick injuries;
	+ An in-date, complete anaphylaxis response kit;
	+ Access to current editions of the *Australian Immunisation Handbook* and *National Vaccine Storage Guidelines: Strive for 5;* and
	+ Up-to-date, written procedures, covering provision of immunisation services.

1. As established under Section 32 of the *Health Services Act 2016*. [↑](#footnote-ref-1)