Structured Administration and Supply Arrangement (SASA)

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| **TITLE:** | **Administration of COVID-19 vaccines by Aboriginal Health Practitioners** |

1. **Authority:**

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

1. **Scope:**

This authorises Aboriginal Health Practitioners 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:** | Aboriginal Health Practitioners who satisfy all of the following:   1. have completed approved training and have the competencies in accordance with Appendix 1 2. are employed by, or contracted to provide services to:  * WA Health; * Department of Justice; or * a health service that is a member of the Aboriginal Health Council of WA. |
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| **Practice setting:** | Places or premises in Western Australia that comply with Appendix 2. |
| **Approved activity:** | Administration. |
| **Approved medicines:** | Therapeutic Goods Administration (TGA) registered SARS-COV-2 (COVID-19) VACCINE products. |
| **Medical conditions:** | Immunisation against COVID-19 infection in the Western Australian population, in accordance with the current Australian Technical Advisory Group on Immunisation (ATAGI) recommendations. |

1. **Conditions:**

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

* 1. where the place or premises at which COVID-19 vaccines are administered is operated by WA Health, the place or premises must be operated in compliance with any relevant Department of Health mandatory policies;
  2. the Aboriginal Health Practitioner 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 Aboriginal Health Practitioner must ensure a record of vaccine administration is included in the Australian Immunisation Register (AIR);
  6. all adverse events occurring following immunisation are notified to the Western Australian Vaccine Safety Surveillance (WAVSS) system and in accordance with any other adverse event surveillance requirements of TGA 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. Advice for COVID-19 vaccine providers and administrators. Available at: <https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers>
3. ATAGI clinical guidance for COVID-19 vaccine providers. Available at: <https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance>
4. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health and Aged Care, Canberra, 2022. Available at: <https://immunisationhandbook.health.gov.au/>
5. *National Vaccine Storage Guidelines: 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. *Adverse event following immunisation (AEFI).* Available at: <https://www.health.wa.gov.au/articles/a_e/adverse-event-following-immunisation-aefi>
7. *Australian Immunisation Register.* Available at <https://www.servicesaustralia.gov.au/individuals/services/medicare/australian-immunisation-register>
8. **Issued by:**

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| **Name:** | Dr Andrew Robertson |
| **Position:** | Chief Health Officer, Delegate of the CEO |
| **Date:** | 18 March 2024 |

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| Enquiries to: | Medicines and Poisons Regulation Branch | Number: | 036/1-2024 |
|  | MPRB@health.wa.gov.au | Date: | 18 March 2024 |

**APPENDIX 1**

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| **Approved Training and Required Competencies** |

All Aboriginal Health Practitioners administering COVID-19 vaccine in accordance with this SASA must have completed:

1. A general immunisation course:

* approved by the Chief Executive Officer of the Western Australian Department of Health or a Department of Health in another Australian State or Territory; or
* accredited by Health Education Services Australia (HESA); or
* an equivalent course relating to the vaccines being administered provided by a Registered Training Organisation (RTO) or a university; and
* must maintain their competency 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 (NHMRC) Immunisation Guidelines;
5. diagnosis and management of anaphylaxis; and
6. documentation of vaccination and critical incidents.

and

1. 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.
7. All Aboriginal Health Practitioners administering a COVID-19 vaccine in accordance with this SASA must be:
   1. competent in cardiopulmonary resuscitation (CPR); and
   2. maintain CPR competency by completing an annual refresher course in CPR.

**APPENDIX 2**

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| **Approved Setting** |

Aboriginal Health Practitioners 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 for 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 flat in the event of a severe adverse event or anaphylactic reaction;
  + 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 and 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*.
  + Up-to-date, written procedures, covering provision of immunisation services.