**Application for new or updated approval to initiate administration or supply of Scheduled 3 and 4 medicines by a vaccination provider.**

**Section 254 of the *Medicines, Poisons and Therapeutic Goods Act* 2012**

**Please Note: This application is considered by the Chief Health Officer**

|  |  |  |  |
| --- | --- | --- | --- |
| **Application Details** | | | |
| **Name of service organisation** | | | **ACN /ABN** |
| **Full street address of organisation** | | | |
| **Postal address** | | | |
| **Name of contact person** | | | |
| **Phone number** | | **Fax number** | |
| **Mobile number** | | **Email address** | |
| **Name of principal clinician / manager:**  **📎 Attach AHPRA registration**  **📎 Attach a covering letter from principal clinician seeking approval of specified vaccines, specified S3 and**  **S4 medicines** | | | |
| **Details of offsite services (e.g. mobile service, school vaccines, workplaces)** | | | |
| **Previous or existing approvals**  **📎** Attach authorisation or gazette notice | | | |
| **Reason for application / Benefits of proposal:** | | | |
| **Indicate the vaccination program/s your organisation is planning to offer:** | | | |
| **Requested date of commencement** | **End date (if known)** | | |
| **Plan for educating, training and / or informing staff:** | | | |
| **Client population to be covered by approval**  Workplaces General population Other (please specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Estimate target population / workplace numbers:** | | | |
| **Health practitioner group / individual health practitioner to which the approval will apply**  **Note: Additional information on staff credentialing and training may be requested.**  Aboriginal Health Practitioner Midwife Nurse Paramedic Pharmacist   If a sole practitioner, individual’s name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| **Governance** | | | |
| **📎** Attach documents detailing the organisations clinical governance, structure and processes for approving this protocol, for example:   * Clinical governance committee details * Development and review of medicines list and protocols * Reporting of incidents * Review process | | | |
| **📎** Attach an imprest list for specific medicines and quantities approved by principal clinician via governance process. | | | |
| **📎 Attach standard operating procedures or policies which cover the following:**   * Medicine storage and handling according to **Medicines, Poisons and Therapeutic Goods Regulations (MPTGR) - Regulation 26. 📎** Include photographs of medicine storage * Cold chain management of vaccines and temperature sensitive stock **(National Vaccine Storage Guidelines “Strive for 5”**) * Pre-vaccination screening, including the consent process * Patient exclusion and referral to a general practitioner or other National Immunisation Program (NIP) service * Anaphylaxis response kit * Managing anaphylaxis * Adverse events management and reporting * Vaccination documentation, including reporting to the Australian Immunisation Register * Maintaining infection control including management of needle stick injury and exposure to blood or body fluids * Sharps and clinical waste disposal * Medication documentation and record keeping as per **MPTGR – Regulation 73 to Regulation 77**. * An exit strategy covering site closure and staff absences * Staff training and credentialing including the appropriate and legal use of SSTP protocols | | | |
| **📎** Attach a Scheduled substance treatment protocol for each medication to be initiated under protocol that meets requirements under Section 70B and Regulation 17C. See template attached as a guide. For published existing protocols  **📎** Attach a list of publications titles including publication date and publisher. | | | |
| **Name** | | | |
| **Signature** | **Date** | | |
| **Position Title** | | | |

\*\*\*Insert company logo\*\*\*

Scheduled Substance Treatment Protocol (SSTP) Template

|  |
| --- |
| SSTP |

|  |  |  |  |
| --- | --- | --- | --- |
| [Drug Name] For [Indication] Scheduled Substance Treatment Protocol (SSTP) | | | |
| **Areas Applicable** | [Insert relevant area and patient population] | | |
| **Drug** | [Active ingredient name, strength, form] | | |
| **Indication** | [Specify indication(s)] | | |
| **Contraindications and/or Exclusions\*** | [E.g. patients who are pregnant or breastfeeding] | | |
| **Dose and Route\*** |  | | |
| **Dose Frequency\*** | [E.g. single dose] | | |
| **Administration\*** | [E.g. IV bolus injection over 2-5 minutes] | | |
| **Drug Interactions\*** |  | | |
| **Monitoring requirements\*** | [May include baseline assessment, patient observations, laboratory monitoring etc] | | |
| **Nursing Accreditation Requirements** | [Eg Registered Nurses in ward X with a minimum of X months/years experience in (eg type of nursing) and approved by the Clinical Nurse Educator/completed education package/course] | | |
| **Documentation** *(including necessary information to the patient)* | [Patients who receive [Insert name of scheduled substance] must have this documented in the medication section of the patient’s record \*please specify for applicable department area (e.g. NIMC, ED chart, eMMa, Medical Director long term drug summary sheet etc)] | | |
| **Related Documents** | [Include related protocol/guideline or other document(s) that may be applicable] | | |
| **Chair**  **Clinical Governance Committee (or eqv.) (remove if not needed)** | **Signature** | **Name** | **Date** |
|  |  | /     / |
| **Chief Medical Officer** | **Signature** | **Name** | **Date** |
|  |  | /     / |
| **Date for Review** | X years from date approved (maximum 2 years) | | |
| **References:**  **\*** *The drug information provided is to act as a guide only, for further information reference should be made to the full manufacturer’s product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration* | | | |