**Application for new or updated approval to initiate administration or supply of Scheduled 3, 4 and 8 medicines in a general health program.**

**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 and specified S3,**  **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** | | | |
| **Requested date of commencement** | **End date (if known)** | | |
| **Plan for educating, training and 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 clinical governance structure and processes   * Clinical governance committee details * Continued medical practitioner oversight * 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 operations procedures covering the following:**   * Medicine storage and handling according to MPTGR 26. **📎** Include photographs of medicine storage * Cold chain monitoring of temperature sensitive stock and vaccines (Strive for 5) * Medication documentation and record keeping as per MPTGR 73 -77 * S8 handling storage and record keeping as per MPTGR 31, 50, 53, 54, 60-65, 67-72 and Vol 2 of the Code of Practice of S8 substance storage and transportation * An exit strategy covering site closure and staff absences * Staff training package to use SSTPs and induction procedures | | | |
| **📎** Attach a Scheduled substance treatment protocol for each medication initiated under protocol (see template)  For published reference protocols  **📎** Attach a list of publications titles including publication date and publisher. | | | |
| **Name** | | | |
| **Signature** | **Date** | | |
| **Position Title** | | | |

**Attachment checklist**

**📎 Principal clinician’s AHPRA registration.**

**📎 Attach a covering letter from principal clinician seeking approval of specified vaccines and specified S3, S4 and S8 scheduled medicines.**

**📎 Attach any relevant current or previous authorisations or gazettal notices.**

**📎 Attach documents detailing clinical governance structure and processes.**

**📎 Attach an imprest list for specific medicines and quantities approved by principal clinician via governance process.**

**📎 Attach relevant standard operating procedures.**

**📎 Attach a Scheduled substance treatment protocol for each medication initiated under protocol (see template).**

**or**

**📎 For published reference protocols, attach a list of publication titles including publication date and publisher.**

\*\*\*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* | | | |