

Checklist: Application for Authority to Possess and/or Supply Schedule 8 or Schedule 9 substances, or Prohibited Drugs/Plants for the Purpose of Research, Instruction or Analysis, or for the Treatment of an Animal

This checklist is provided to assist you in ensuring that all the required information has been included in your application for an authority.

- Section 1 : Applicant details.** The applicant is a suitably qualified person in charge of a laboratory or department involved in the research, instruction, analysis or study in which the substance is to be used. The applicant may also be the Chief Investigator named in the Ethics Approval. In the case of an application for the treatment of an animal, the applicant must be a Veterinary Practitioner. In the case of a request for authority to supply, the applicant must be the accountable person of the entity. The address wherein the substance is to be stored and/or used is provided.
- Section 2 : Purpose.** A brief description has been provided, including the purpose for which the possession of the substance is sought. Copies of any associated ethics approvals are attached. In the case of a request for authority to supply, a copy of the recipient's authority to possess the substance is attached.
- Section 3 : Substances requiring authority.** The details of the substances are provided. Where there are more than five substances, a separate list is attached. The name of the substance provided is as it appears in Schedule 1 of the *Drug Misuse and Trafficking Act 1985* and if not in this Schedule, as it appears in Schedule 8 or Schedule 9 of the *Poisons Standard* as is in force from time to time. For analogues of substances in Schedule 1, and derivatives of substances in Schedule 8 or Schedule 9, include the name of the listed substance as it appears in the Schedules. *Note: The quantity refers to the maximum quantity to be held at any one time.*
- Section 4 : Authorised supplier.** The names and addresses of the intended suppliers are provided. *Note: The suppliers must be authorised to supply the substances.*
- Section 5 : Storage, Record Keeping and Destruction.** The applicant has confirmed that storage, record keeping and destruction arrangements are in accordance with requirements under the *Poisons and Therapeutic Goods Regulation 2008*. *Note: At a minimum, the substances are to be stored in a safe, cupboard or receptacle that is securely attached to the premises, which should be securely locked when not in immediate use. Access to the substances should be restricted to authorised persons only.*
- Section 6 : Persons with access.** The names and capacity of persons who will have access to the substances are provided. *Note: Persons to have access must be under the supervision of the applicant.*
- Section 7 : Period of authorisation.** The end date of authorisation has been entered where known, otherwise the duration of the authorisation has been provided. *Note: The period of authorisation granted will depend on individual circumstances and in any case will be no longer than three years.*
- Section 8 : Declaration.** A cover letter dated and signed by the applicant is attached. The cover letter is addressed to:

The Director
Pharmaceutical Regulatory Unit
Legal and Regulatory Services Branch
NSW Ministry of Health

Email the completed application and accompanying documents to pharmserv@doh.health.nsw.gov.au

For further information, contact the Duty Pharmaceutical Officer at Pharmaceutical Services during business hours on (02) 9391 9944.