Medicines or Poisons Research & Education Program Licence Applications

This summary has been prepared by ACT Health Protection Service to assist applicants in understanding key application requirements and licensing provisions. Before completing this application form, you are strongly urged to read the *Medicines, Poisons and Therapeutic Goods Act 2008* and *Regulation 2008* (at www.legislation.act.gov.au) to ensure full compliance. Failure to comply with ACT legislation renders a person liable to prosecution.

Please ensure that:

- ☐ All the information on the form is correct;
- ☐ All sections of the form have been completed;
- ☐ All necessary documentation to support the licence application is attached;
- ☐ You have signed the required declarations on the form; and
- ☐ The required fee is being paid.

Cheques should be made payable to ACT Health. GST is not applicable under section 81-5 of the *A New Tax System (Goods and Services Tax) Act 1999* (C'th).

Key legislative provisions:

The key provisions for the application and granting of a research and education program licence are included in the *Medicines, Poisons and Therapeutic Goods Act 2008* Chapter 6 and the *Medicines, Poisons and Therapeutic Goods Regulation 2008* at part 14.2 for controlled medicines, 18.3 for dangerous poisons and 21.2 for prohibited substances. If granted, a licence will confer the following authorisations and responsibilities on the licence holder and to other persons authorised under the licence.

A research and education program licence-holder is authorised to:

- Issue a complying purchase order for the licensed controlled medicine(s) (Canberra Hospital-written requisition), dangerous poison(s), or prohibited substance(s) stated in the licence for the program stated in licence.
- Obtain on a complying purchase order a licensed controlled medicine (Canberra Hospital-written requisition), dangerous poison, or prohibited substance for the program.
- Possess a licensed controlled medicine, dangerous poison, or prohibited substance for the program at the premises to which the licence relates.
- Supply a licensed controlled medicine, dangerous poison, or prohibited substance to anyone taking part in the program for the purposes of the program.

A research and education program supervisor, and anyone taking part in the program, is authorised to:

- Deal with a licensed controlled medicine, dangerous poison, or prohibited substance as authorised by the licence at the premises stated in the licence.

A research and education program licence-holder must:

- Ensure controlled medicines are stored in a locked medicines cabinet, safe, strong room or vault.
- Ensure the security of the lock key or lock combination to the storage receptacle.
- Keep controlled medicines registers at the premises where the controlled medicines are kept. Each page in a controlled medicines register must relate to a single form and strength of a controlled medicine.
- Ensure dangerous poisons are stored in a place where only authorised persons, and not the public, have access.
- Keep dangerous poisons registers at the premises where the dangerous poisons are kept. Each page in a dangerous poisons register must relate to a single form and strength of a dangerous poison.
- Ensure prohibited substances are stored in a locked medicines cabinet, safe, strong room or vault.
- Ensure the security of the lock key or lock combination to the storage receptacle.
- Keep prohibited substances registers at the premises where the prohibited substances are kept. Each page in a prohibited substances register must relate to a single form and strength of a prohibited substance.

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Accessibility

If you have difficulty reading a standard printed document and would like an alternative format, please phone 13 22 81.

If English is not your first language and you need the Translating and Interpreting Service (TIS), please call 13 14 50.

For further accessibility information, visit: www.health.act.gov.au/accessibility

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