

MEDICINES POISONS THERAPEUTIC GOODS NEW LICENCE-PERMIT APPLICATION

PURPOSE

This form is to be used to apply for a licence under the *Medicines, Poisons and Therapeutic Goods Act 2008* (the Act). You can access the Act and its regulation at www.legislation.act.gov.au.

PRIVACY

The collection of personal information is required by this form for the purposes of issuing a licence under the Act. The Health Protection Service (HPS) prevents any unreasonable intrusion into a person's privacy in accordance with the *Privacy Act 1988* (Commonwealth).

HEALTH PROTECTION SERVICE CONTACT INFORMATION

Trading Hours: 9.00am – 4.30pm Monday to Friday

Website: www.health.act.gov.au/hps	General Enquires: (02) 6205 1700	Email Address: hps@act.gov.au	Fax Number: (02) 6205 1705
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INSTRUCTIONS FOR COMPLETION & IMPORTANT INFORMATION

The licence may be issued to an applicant for the business, who is the person(s) who will have the overall responsibility for the business, including responsibility for any contraventions of the Act.

Accordingly:

- (1) Trusts will not be licensed. Companies operating as trustees for a trust will be licensed in the company name only.
- (2) Applications listing a partnership as the owner will not be accepted. If your business is operated by a partnership, one or more of the individuals in the partnership will need to be listed.
- (3) Parts B and C of this application form must be separately completed for each individual to be listed as an owner. Extra copies of Parts B and C are available at www.health.act.gov.au/hps or by contacting the HPS.

- The applicant should be familiar with the *Medicines, Poisons and Therapeutic Goods Act 2008* and Regulation 2008.
- Failure to comply with ACT legislation renders a person liable to prosecution.
- Information is collected for licence purposes and will not be provided to other parties without consent, or if otherwise required by law.
- Complete this form using a black or blue pen only.
- **Part D (page 6) provides details of the fee required.**

Is the licence to be issued to a corporation (a Company, Incorporated Association, Government agency or a Registered Charitable Organisation)?

YES **Complete PART A, C, D and (E as required)** of this application. NB: Trusts or Partnerships will not be licenced. Companies operating as trustees for a trust will be registered in the company name only.

NO **Complete PART B, C, D and (E as required)** of this application. Separate details must be completed by each individual listed as an applicant.

Confirmation of identity will need to be produced either:

1. In person at the Health Protection Service office; or
2. By submitting certified copies via post/email/fax to the HPS office

TRANSLATING AND INTERPRETING SERVICE

A language assistance service is available by phoning the Translating and Interpreting Service (TIS) on 13 14 50.

COMPLETED FORMS TO BE RETURNED

In Person: Health Protection Service Howard Florey Centenary House 25 Mulley Street HOLDER ACT 2611	By Post: Health Protection Service Locked Bag 5005 WESTON CREEK ACT 2611	By Fax: (02) 6205 1705	By Email: hps@act.gov.au
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CHECKLIST

If applying as an INDIVIDUAL	
<input type="checkbox"/>	Part B completed and signed: Applicant details for an individual (one copy for each owner)
<input type="checkbox"/>	Part C complete: Proof of identification (one copy for each owner)
<input type="checkbox"/>	One form of current photographic identification (for each signatory) presented in person at the Health Protection Service OR One form of current photographic identification (for each signatory) sighted and certified by an authorised witness for each signatory.
<input type="checkbox"/>	Part E completed: Licence application details
<input type="checkbox"/>	Declaration signed (page 11)
<input type="checkbox"/>	Attached payment (page 13)
If applying as a CORPORATION	
<input type="checkbox"/>	Part A completed and signed: Applicant details of a company
<input type="checkbox"/>	Attached current company extract issued by the Australian Securities and Investment Commission (ASIC)
<input type="checkbox"/>	Part C complete: Proof of identification (for company agent)
<input type="checkbox"/>	One form of current photographic identification presented in person at the Health Protection Service OR One form of current photographic identification sighted and certified by an authorised witness.
<input type="checkbox"/>	Part E completed: Licence application details
<input type="checkbox"/>	Declaration signed (page 11)
<input type="checkbox"/>	Attached payment (page 13)

PART A – DETAILS FOR A COMPANY APPLICANT (Do NOT complete if you are applying as an individual)

COMPANY NAME – A copy of the company's current extract (*issued within the previous 30 days*) from the Australian Securities and Investment Commission (ASIC) **must be attached**

AUSTRALIAN COMPANY NUMBER (A.C.N.) - Leave blank if an Incorporated Association, Government agency or a Registered Charitable Organisation

REGISTERED COMPANY ADDRESS (*Property Name, Unit, Flat Number, Street Number, Street Name*)

CITY / SUBURB / TOWN

STATE / TERRITORY

POSTCODE

POSTAL ADDRESS (*If different to above company address*)

CITY / SUBURB / TOWN

STATE / TERRITORY

POSTCODE

HOME TELEPHONE NUMBER

MOBILE NUMBER

()

WORK TELEPHONE NUMBER

EMAIL ADDRESS

()

COMPANY DECLARATION

I, _____, confirm that the information supplied on this page is true and accurate and understand that the provision of false or misleading information is an offence.

Signature of authorised agent: _____

Position title: _____

Date: / /

PART B – APPLICANT DETAILS FOR AN INDIVIDUAL*(Do NOT complete if you are applying as a company)*

TITLE <i>(Mr, Ms)</i>	GIVEN NAMES	FAMILY NAME	
PROPRIETOR RESIDENTIAL ADDRESS <i>(Property Name, Unit, Flat Number, Street Number, Street Name)</i>			
CITY / SUBURB / TOWN		STATE / TERRITORY	POSTCODE
POSTAL ADDRESS <i>(If different to above address)</i>			
CITY/ SUBURB/ TOWN		STATE / TERRITORY	POSTCODE
HOME TELEPHONE NUMBER		MOBILE TELEPHONE NUMBER	
()			
WORK TELEPHONE NUMBER		EMAIL ADDRESS	
()			
AUSTRALIAN BUSINESS NUMBER (A.B.N.) <i>(If applicable)</i>			

DECLARATION SIGNATURE

I, _____, confirm that the information supplied on this page is true and accurate and understand that the provision of false or misleading information is an offence.

Signature: _____

Date: / /

Note for Multiple Applicants:

(for example partnerships) Copies of Part B are available at www.health.act.gov.au/hps or by contacting the HPS.

PART C – PROOF OF IDENTIFICATION (Must be completed for company (by the registered agent) and individual if applicable)

One form of current photographic identification sighted and certified by an authorised witness must be provided for each signatory in Parts A or B.

A list of authorised witnesses for true and correct copy can be found at:

<http://www.ag.gov.au/Publications/Pages/Statutorydeclarationsignatorylist.aspx>

The witness should include the following text on a certified copy:

EXAMPLE**CERTIFIED TRUE COPY OF THE ORIGINAL**

I certify that this is a true and accurate copy of the original document sighted by me.

Full Name: _____ **Signed:** _____ **Dated:** _____ **Authority to sign:** _____ **Phone:** _____

ACCEPTABLE FORMS OF PHOTOGRAPHIC IDENTIFICATION – Examples below

Driver's licence

Proof of age or identity card issued by a State/Territory

Passport

FORMS OF IDENTIFICATION PROVIDED

Type	Number	Expiry Date	Certified Copy Attached
			<input type="checkbox"/>
			<input type="checkbox"/>

Note for Multiple Applicants: (for example partnerships) Copies of Part C are available at www.health.act.gov.au/hps or by contacting the HPS.

PART D - LICENCES (Please ✓ licence type you are applying for)

- First-aid Kit Licence** – (FK) (\$214 per year) *If you are applying for a FK licence please complete Part E Business Details and Section 1 First-aid Kit.*

REQUIRED INFORMATION

- Qualifications – Evidence to support the qualifications of all persons authorised under the (FK) licence
- Letter of Support – The original letter of support from a registered Medical Practitioner who will provide medical direction and support to the licence holder.
- Copy of approval under the *Emergencies Act 2004* (if applicable).
- Declaration and payment (page 11).

- Research & Education Program Licence** – (R&EP) (\$35 per year) *If you are applying for a R&EP licence please complete Part E Business Details & Section 2 Research & Education Program Section only.*

- Controlled Medicines R&EP Licence* *Dangerous Poisons R&EP Licence* *Prohibited Substances R&EP Licence*

REQUIRED INFORMATION

- Approval of the proposed program by the person in charge of the institution, faculty or division (full name, position held, academic qualifications, statement of approval).
- HREC approval – A copy of the Human Research Ethics Committee approval (HREC) (if applicable).
- Declaration and payment (page 11).

- Medicines Wholesalers Licence** – (MW) (\$357 per year). *If you are applying for a MW licence please complete Part E Business Details & Section 3 Medicines Wholesalers Licence Section only.*

REQUIRED INFORMATION

- Qualifications – Evidence to support the qualifications (in chemistry, pharmacy, or pharmacology or experience appropriate for the sale of medicines) of the person who is to supervise the dealings authorised under the licence.
- Floor Plan – A plan of the premises that shows where the medicines are proposed to be stored and the location and nature of security devices.
- Declaration and payment (page 11).

- Pharmacy Medicines Rural Communities Licence** – (PMRC) (\$120 per year). *If you are applying for a PMRC licence please complete Part E Business Details Section only.*

REQUIRED INFORMATION

- Map - A map showing the location of the proposed business for the licence and the distance to the nearest community pharmacies.
- Declaration and payment (page 11).

- Dangerous Poisons Manufacturers Licence** – (DPM) (\$357 per year) *If you are applying for a DPM licence please complete Part E Business Details & Section 4 Dangerous Poisons Manufacturers Licence Section only.*

REQUIRED INFORMATION

- Plan – A plan of the premises that shows each part of premises where:
- A process in the manufacture of the dangerous poisons is proposed to be carried and the nature of the process.
 - It is proposed to store the dangerous poisons to which the application relates and any other dangerous poisons obtained for the manufacture of those dangerous poisons; and
 - Location and nature of security devices.
- Qualifications - Evidence to support the qualifications of the person who is to supervise the dealings with authorised substances under the licence.
- Declaration and payment (page 11).

- Dangerous Poisons Suppliers Licence** – (DPS) (\$357 per year) *If you are applying for a DPS licence please complete Part E Business Details & Section 5 Dangerous Poisons Suppliers Licence Section only.*

REQUIRED INFORMATION – Attached to application

- Plan – A plan of premises that shows each part of premises where:
- It is proposed to store the dangerous poisons to which the application relates and any other dangerous poisons obtained for the manufacture of those dangerous poisons; and
 - Location and nature of security devices.
- Qualification Compliance - Evidence to support the qualifications of the person who is to supervise the dealings.
- Declaration and payment (page 11).

PART E – LICENCE APPLICATION DETAILS (must be completed)**BUSINESS DETAILS**TRADING NAME – *if applicable***PHYSICAL ADDRESS OF BUSINESS**

NUMBER:

PROPERTY NAME:

STREET NAME:

SUBURB:

STATE:

POSTCODE:

BUSINESS ONSITE CONTACT PERSON

GIVEN NAME:

FAMILY NAME:

BUSINESS PHONE:

MOBILE PHONE:

EMAIL ADDRESS:

FAX:

Is the storage address the same as physical address of business? No Yes (If Yes continue to OPERATIONAL DETAILS)

PROGRAM/STORAGE ADDRESS

NUMBER:

PROPERTY NAME:

STREET NAME:

SUBURB:

STATE:

POSTCODE:

CONTACT NAME:

CONTACT NUMBER:

OPERATIONAL DETAILS (Applicable to all licences unless otherwise stated)**SUBSTANCE DETAILS:**

Name of Substance	Strength	Form of Substance	Maximum Quantity*	Total Quantity*

* *Maximum Quantity*: the quantity that would be possessed under the licence at any one time.

* *Total Quantity*: the quantity that may be possessed during the licence period.

SECURITY ARRANGEMENTS

Please provide information.

SECTION 1 - FIRST-AID KIT (FK)

AUTHORISED PERSON DETAILS

Details of each person proposed to be authorised to deal under the licence. If insufficient space provided to record all details, please attach additional information to this application.

Note: Occupation must be a registered nurse or ambulance paramedic. Ambulance paramedic qualifications must be Associate Diploma Health Science (Ambulance Officer) or equivalent.

Given Names	Family Name	Residential Address	Occupation	Qualifications & Board Registration. No. (if applicable)

DETAILS OF USE

Details of the situations in which the proposed medicines will be used (e.g operational protocols). Details of workplaces and/or community venues at which the relevant medicines are proposed to be administered.

Please ensure that the declaration and payment page are signed on page 10.

SECTION 2 - RESEARCH & EDUCATION PROGRAM (R&EP)

Is the supervisor the same as applicant? No Yes – (if Yes continue to **RESEARCHER DETAILS**)

SUPERVISOR	
GIVEN NAME:	FAMILY NAME:
PHONE NUMBER:	MOBILE:
QUALIFICATIONS*:	

**Supervisor qualifications: for R&EP refers to academic, professional or other relevant experience.*

Is the researcher the same as the supervisor? No Yes – (if Yes continue to **DETAILS OF PROGRAM**)

RESEARCHER DETAILS	
GIVEN NAME:	FAMILY NAME:
PHONE NUMBER:	MOBILE:
QUALIFICATIONS*:	

**Qualifications: for R&E researchers refers to academic, professional or other relevant experience.*

DETAILS OF PROGRAM
PROGRAM/PROJECT TITLE:

DESCRIPTION OF THE PROGRAM/PROJECT: include an explanation of why it cannot be carried out satisfactorily without the use of the proposed regulated substance(s):

If insufficient space provided to record all details, please attach additional information to this application.

PROPOSED SUPERVISION ARRANGEMENTS FOR THE PROGRAM/PROJECT

Please ensure that the declaration and payment page are signed on page 10.

SECTION 3 - MEDICINES WHOLESALERS (MW)

Is the supervisor the same as applicant? Yes No – (if **No** complete below information)

SUPERVISOR	
GIVEN NAME:	FAMILY NAME:
PHONE NUMBER:	MOBILE:
QUALIFICATIONS*:	

*Supervisor’s qualifications: for the MW licence, must be in chemistry, pharmacy or pharmacology or appropriate sales experience.

SECTION 4 - DANGEROUS POISONS MANUFACTURERS (DPM)

Is the supervisor the same as applicant? Yes No – (if **No** complete below information)

SUPERVISOR	
GIVEN NAME:	FAMILY NAME:
PHONE NUMBER:	MOBILE:
QUALIFICATIONS*:	

*Supervisor’s qualifications: for the DPM licence, must be in chemistry, pharmacy or pharmacology or appropriate sales experience.

SECTION 5 - DANGEROUS POISONS SUPPLIERS (DPS) –

Is the supervisor the same as applicant? Yes No – (if **No** complete below information)

SUPERVISOR	
GIVEN NAME:	FAMILY NAME:
PHONE NUMBER:	MOBILE:
QUALIFICATIONS*:	

*Supervisor’s qualifications: for the DPS licence, must be in chemistry, pharmacy or pharmacology or appropriate sales experience.

Please ensure that the declaration and payment page are signed on page 10.

DECLARATION AND PAYMENT (Must be completed)

DECLARATION OF SUITABILITY

I declare that I am a suitable person to hold a licence because:

- I, a close associate or a corporation where I am an executive officer, has not been convicted or found guilty in the 5-year period before the day of application for the licence of an offence against the Act or an offence in Australia or elsewhere in relation to a regulated substance or regulated therapeutic good.
- I, or a close associate, are not an undischarged bankrupt now or were in the 5-year period before application, or have executed a personal insolvency agreement.
- I, or a close associate, were not involved in the management of a corporation in the 5-year period before application that became the subject of a winding-up order or where an administrator was appointed for the corporation.

NAME: _____ **SIGNATURE:** _____

DECLARATION FOR ENTIRE APPLICATION

I declare that I am authorised to supply all the information above; that all the information supplied on this form is true and correct; and that there are necessary records and/or documentation to support this licence application.

I understand that failure to submit all required information and documentation may delay my application and that the provision of false or misleading information may be a criminal offence.

NAME: _____ **POSITION:** _____

SIGNATURE: _____ **DATE:** _____

CREDIT CARD DECLARATION - IF PAYING BY CREDIT CARD

I agree to the credit card (details provided overleaf) being debited the required fee and credit card details destroyed immediately once the transaction is processed.

SIGNATURE: _____ **DATE:** _____

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PAYMENT

How to Pay



Fax: 6205 1705
MasterCard / Visa accepted
(Not accepted where plans are involved)



By Mail: Health Protection Service
Locked Bag 5005 Weston Creek ACT 2611.



In Person: Health Protection Service
25 Mulley Street Holder ACT 2611

Please Note:

1. All paperwork must be completed and signed.
2. Where plans are involved, the originals must be received prior to the granting of your licence/registration certificate.
3. Applications sent by fax should **NOT** also be mailed.

Payment Method

Please Tick (✓)

Cash Cheque Credit Card

Note: Cheque should be made payable to the Health Protection Service.

Contact Person: _____

Type of Credit Card - Please Tick (✓) Visa Master Card

Credit Card No

Expiry Date

 /

Fee \$ _____ Please check Application form for applicable fee (see page 6)
GST is not applicable under section 81-5 of the A New Tax System (Goods and Services Tax) Act 1999.

I agree that the Health Protection Service debit my account the above fee.

Card Holder's Name: _____

Card Holder's Signature: _____ **Date:** _____ / _____ / _____

Daytime Phone No: _____