

ACT Health

MEDICINES POISONS THERAPEUTIC GOODS **NEW LICENCE 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: **General Enquires: Email Address:** Fax Number: www.health.act.gov.au/hps (02) 5124 9700 hps@act.gov.au (02) 5124 5554

INSTRUCTIONS FOR COMPLETION & IMPORTANT INFORMATION

The licence may be issued to the applicant for the licence, who is the person(s) who will have the overall responsibility for the licence, 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 the Medicines, Poisons and Therapeutic Goods 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 provides details of the fee required. Payment details must be supplied on page 11.
- Both declarations on page 10 must be signed.

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 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 of this application. Separate details must be completed by each individual listed as an applicant.

Confirmation of identity will need to be produced either:

- In person at the Health Protection Service office; or
- By submitting photographic identification 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 AND PAYMENT TO BE RETURNED

In Person:

Health Protection Service

25 Mulley Street **HOLDER ACT 2611**

By Post:

Health Protection Service Locked Bag 5005 **WESTON CREEK ACT 2611** Ⅲ By Fax:

Bv Email:

(02) 5124 5554 hps@act.gov.au

If the application is faxed or emailed, please do not post the original.

HPS-00-0331 Page 1 of 11 CHECKLIST

If applying as an INDIVIDUAL				
	Part B completed and signed: Applicant details for an individual (one copy for each owner)			
	Part C complete: Proof of identification (one copy for each owner)			
	One form of current photographic identification (for each signatory)			
	Part E completed: Licence application details			
	Declarations signed (page 10)			
	Attached payment (page 11)			
If applying a	as a CORPORATION			
	Part A completed and signed: Applicant details of a company			
	Attached current company extract issued by the Australian Securities and Investment Commission (ASIC)			
	Part C complete: Proof of identification (for company agent)			
	One form of current photographic identification (for company agent)			
	Part E completed: Licence application details			
	Declarations signed (page 10)			
	Attached payment (page 11)			

HPS-00-0331 Page 2 of 11

PAR	Γ A – A	PPLIC	ANT DE	TAILS	FOR A	COMP	YANY	(Do NO	T complete if you are	applying as an individual)
_	A copy of the Company's current extract (<u>issued within the previous 30</u> days) from the Australian Securities and Investment Commission (ASIC) <u>must be attached.</u>									
COM	IPANY	NAMI	E							
	AUSTRALIAN COMPANY NUMBER (A.C.N.) - Leave blank if an Incorporated Association, Government agency or a Registered Charitable Organisation									
Note		ultiple	e Owne					-		re applying as a company) lable at <u>www.health.act.gov.au/hps</u> or
TITLE	(Mr, M	ls)	GIVEN I	NAMES	,				FAMILY NAME	
			NT ADI						e registered company a	ddress must be provided)
CITY	/ SUBUI	RB / T	OWN			STA	TE / T	ERRITOR	RY	POSTCODE
PAR	Г С - АР	PLICA	ANT PO	STAL A	\DDRE:	SS (If dij	fferent	to above	applicant address)	
CITY	/ SUBUI	RB / T	OWN			STA	TE / TERRITORY			POSTCODE
BUSII	NESS HO	OURS I	PHONE I	NUMBI	ER			MOBILE	NUMBER	
							_			
FAX	NUMBE	R						EMAIL A	DDRESS	
DECL	ARATIC	ON								
Signa	I,									
Date	Date: / /									

HPS-00-0331 Page 3 of 11

PART C – PROOF OF IDENTIFICATION (Must be completed for company (by the registered agent) and individual if applicable)						
One form of current photographic identification must be provided for each signatory in Parts A or B.						
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						
Туре	Number	Expiry Date	Copy Attached			

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.

HPS-00-0331 Page 4 of 11

PART D - LICENCES (Please ✓ licence type you are applying for)
First-aid Kit Licence – (FK) (\$285.30 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 <i>Emergencies Act 2004</i> (if applicable). Declaration and payment (page 10).
Research & Education Program Licence – (R&EP) (\$45.65 per year) If you are applying for a R&EP licence please complete
Part E Business Details and 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 10).
Medicines Wholesalers Licence – (MW) (\$474.15 per year). If you are applying for a MW licence please complete Part E Business Details and Section 3 – Supervisor Details
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 10).
Declaration and payment (page 10). Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 per year). If you are applying for a PMRC licence please complete Part E Business Details Section only.
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 per year). If you are applying for a PMRC licence
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 per year). If you are applying for a PMRC licence please complete Part E Business Details Section only.
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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.
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence – (DPM) (\$474.15 per year) If you are applying for a DPM licence please
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence – (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 – Supervisor Details REQUIRED INFORMATION Plan – A plan of the premises that shows each part of premises where:
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence – (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 – Supervisor Details REQUIRED INFORMATION
Pharmacy Medicines Rural Communities Licence − (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence − (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 − Supervisor Details 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
Pharmacy Medicines Rural Communities Licence − (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence − (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete
Pharmacy Medicines Rural Communities Licence
Pharmacy Medicines Rural Communities Licence – (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence – (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 – Supervisor Details 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 10).
Pharmacy Medicines Rural Communities Licence — (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence — (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 — Supervisor Details 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 10). Dangerous Poisons Suppliers Licence — (DPS) (\$474.15 per year) If you are applying for a DPS licence please complete Part E Business Details and Section 3 — Supervisor Details
Pharmacy Medicines Rural Communities Licence - (PMRC) (\$160.80 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 10). Dangerous Poisons Manufacturers Licence - (DPM) (\$474.15 per year) If you are applying for a DPM licence please complete Part E Business Details and Section 3 - Supervisor Details 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 10). Dangerous Poisons Suppliers Licence - (DPS) (\$474.15 per year) If you are applying for a DPS licence please complete Part E Business Details and Section 3 - Supervisor Details REQUIRED INFORMATION - Attached to application

HPS-00-0331 Page 5 of 11

Medicines	Paisons &	Therapeutic	Goods new	licence	annlication
IVICUICITICS	1 0130113 0	ITICIAPCALIC	GOOGS HEW	11001100	application

Other Medicines. Poisons and T please complete Part E Business De						or an Other licence	
Qualifications – Evidence to support the qualifications (refers to academic, professional or other relevant experience) 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)	10).						
PART E – LICENCE APPLICATION	ON DETAILS (m	nust be co	mpleted)				
TRADING NAME – if applicable							
PHYSICAL ADDRESS OF BUSINESS							
NUMBER:	PROPERTY NAM	IE:					
STREET NAME:		1					
SUBURB:		STATE:			POSTCODE:		
BUSINESS ONSITE CONTACT PERSO	N						
GIVEN NAME:			FAMILY NAME:				
BUSINESS PHONE:			MOBILE PHONE:	;			
EMAIL ADDRESS:				FAX:			
Is the storage address the same as pl	nysical address of	f business?	☐ No ☐ Yes	(If <u>Yes</u> con	tinue to OPERA	ATIONAL DETAILS)	
PROGRAM/STORAGE ADDRESS							
NUMBER:	PROPERTY NAM	IE:					
STREET NAME:							
SUBURB:		STATE:			POSTCODE:		
CONTACT NAME:			CONTACT N	UMBER:			
OPERATIONAL DETAILS (Applicable	to all licences un	nless otherv	vise stated)				
SUBSTANCE DETAILS:						Ι	
Name of Substance	Strength	Form of S	ubstance	Maximum	Quantity*	Total Quantity*	

HPS-00-0331 Page 6 of 11

^{*} $\underline{\textit{Maximum Quantity:}}$ the quantity that would be possessed under the licence at any one time.

^{* &}lt;u>Total Quantity:</u> the quantity that may be possessed during the licence period.

SECURITY ARRANGEN	MENTS			
Please provide inform	ation.			
SECTION 1 - FIRST-AID) KIT (FK)			
Zerion I inoi Alb				
AUTHORISED PERSON	I DETAILS			
Details of each persor	n proposed to be author	ised to deal under the licence. I	f insufficient space pro	ovided to record all details,
	nal information to this a		den e e e e e e e e e e e e e e e e e e	:C:
	st be a registered nurse (ce (Ambulance Officer) c	or ambulance paramedic. Ambu or eauivalent.	ilance parameaic quali	ifications must be Associate
,				Qualifications &
.				Board Registration. No.
Given Names	Family Name	Residential Address	Occupation	(if applicable)
DETAILS OF USE				
		l medicines will be used (e.g ope icines are proposed to be admin		etails of workplaces and/or
ommunity venues at	willch the relevant meal	cines are proposed to be damin	istereu.	

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

Please ensure that both declarations on page 10 are signed and payment details are provided on page 11.

HPS-00-0331 Page 7 of 11

SECTION 2 - RESEARCH & EDUCATION PROGRAM (R&EP)							
Is the supervisor the same as applicant? \square No \square Yes – (if Yes continue to RESEARCHER DETAILS)							
SUPERVISOR							
GIVEN NAME:	FAMILY NAME:						
PHONE NUMBER:	MOBILE:						
QUALIFICATIONS*:							
* <u>Supervisor qualifications</u> : for R&EP refers to academic, professional or other relevant experience.							
Is the researcher the same as the supervisor? \(\subseteq \text{No} \subseteq \text{No} \)	Yes – (if <u>Yes</u> continue to DETAILS OF PROGRAM)						
RESEARCHER DETAILS							
GIVEN NAME:	FAMILY NAME:						
PHONE NUMBER:	MOBILE:						
QUALIFICATIONS*:							
*Qualifications: for R&E researchers refers to academic, profes	ssional or other relevant experience.						
DETAILS OF PROGRAM							
PROGRAM/PROJECT TITLE:							
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 both declarations on page 10 are signed and payment details are provided on page 11.

HPS-00-0331 Page 8 of 11

SECTION 3 - MEDICINES WHOLESALERS (MW) , DANGEROUS POISONS MANUFACTURERS (DPM) & DANGEROUS POISONS SUPPLIERS (DPS)							
Is the supervisor the same as applicant? \square Yes \square No – (if <u>No</u> complete below information)							
SUPERVISOR							
GIVEN NAME:	FAMILY NAME:						
PHONE NUMBER:	MOBILE:						
QUALIFICATIONS*:							
* <u>Supervisor's qualifications</u> for MW, DPM & I sales experience.	DPS licences must be must be in chemistry, pharmacy or pharmacology or approp	riate					
SECTION 4 – OTHER MEDICINES, POISONS	AND THERAPEUTIC GOODS LICENCE (OTHER)						
Is the supervisor the same as applicant?	☐ No ☐ Yes – (if <u>Yes</u> continue to RESEARCHER DETAILS)						
SUPERVISOR							
GIVEN NAME:	FAMILY NAME:						
PHONE NUMBER:	MOBILE:						
QUALIFICATIONS*:							
DETAILS OF USE	refers to academic, professional or other relevant experience.						
Details of the situations in which the propo- community venues at which the relevant m	ed substances will be dealt (e.g. operational protocols). Details of workplaces and edicines are proposed to be dealt.	I/or					
If insufficient space provided to record al	details, please attach additional information to this application.						
If insufficient space provided to record al PROPOSED SUPERVISION ARRANGEMENTS							

Please ensure that both declarations on page 10 are signed and payment details are provided on page 11.

HPS-00-0331 Page 9 of 11

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

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:
IVAIVIE:	
DECLARATION FOR ENTIRE APPLICATION	
1	ormation above; that all the information supplied on this form is true and /or documentation to support this licence application.
I understand that failure to submit all required in of false or misleading information may be a crimin	formation and documentation may delay my application and that the provision nal offence.
NAME:	POSITION:
SIGNATURE:	DATE:

HPS-00-0331 Page 10 of 11

PAYMENT

LICENCE DURATION AND FEE PAYABLE — PLEASE TICK (✓)							
Licence type	1 year	2 years	3 years				
First-aid Kit Licence	\$285.30	\$570.60	\$855.90				
Research & Education Program Licence	\$45.65	\$91.30	\$136.95				
Medicines Wholesalers Licence	\$474.15	\$948.30	\$1422.45				
Pharmacy Medicines Rural Communities Licence	\$160.80	\$321.60	\$482.40				
Dangerous Poisons Manufacturers Licence	\$474.15	\$948.30	\$1422.45				
Dangerous Poisons Suppliers Licence	\$474.15	\$948.30	\$1422.45				

PAYMENT METHOD		
Please tick (✓)		
Cheque (please make payable to the Health Protection Service)		
Credit card (please complete details below)		
CREDIT CARD DETAILS - IF PAYING BY CREDIT CARD		

CREDIT CARD DETAILS - IF PAYING BY CREDIT CARD			
☐ I agree to this credit card being debited the required fee and the credit card details being destroyed once the transaction is processed.			
GST is not applicable under section 81-5 of the A New Tax System (Goods and Services Tax) Act 1999.			
Card Holder's Name:	-		
Card Holder's Signature:	_ Date:/	/	
Daytime Phone No:			
Card Number (Visa or MasterCard only)		Expiry Date	

HPS-00-0331 Page 11 of 11