

Department of Health

PHARMACEUTICAL SERVICES BRANCH

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Application for Licence or Renewal of a Licence to Sell or Supply Scheduled Substances as a Wholesale Chemist

Section 16(1)(b) of the *Poisons Act 1971*
Regulation 5 of the *Poisons Regulations 2018*

Licence Information

Section 16(1)(b) of the Tasmanian *Poisons Act 1971* allows the Minister or delegate to issue a licence to carry on business as a wholesale chemist (buying and selling scheduled substances in the ordinary course of wholesale dealing as detailed in the licence) subject to certain conditions.

A licence under this Section is not required for wholesale businesses operating from Australian premises outside of Tasmania if all the following conditions are met:

- The interstate premises hold the necessary licences under relevant poisons legislation in the jurisdiction in which they are located;
- The scheduled substances involved are Schedule 2, 3 or 4 and do not include declared restricted substances (Schedule 4D) or Schedule 8 substances;
- No scheduled substances are stored at premises located in Tasmania (this includes premises of sub-contractors or logistics providers); and
- Supply only occurs directly to Tasmanian customers who are authorised to possess the scheduled substances under the Tasmanian *Poisons Act 1971* and *Poisons Regulations 2018*.

Interstate wholesale businesses wishing to supply Schedule 4D or Schedule 8 substances directly to authorised Tasmanian customers should contact the Branch for licencing advice.

To obtain or renew a licence under Section 16(1)(b) this application form must be completed and returned to Pharmaceutical Services Branch. A fee for this licence is also payable. If you require an invoice please contact the Branch. Please provide evidence of payment along with your completed application.

A Wholesale Chemist Licence is issued for a defined period and expiry will be detailed on the licence.

Before issuing a licence the Department of Health may make any enquiries necessary to establish the bona fides of the applicant and to ascertain if they are a fit and proper person or corporation to hold a licence as per Sections 3A and 3B of the *Poisons Act 1971*.

Applicants must be able to demonstrate compliance with the Commonwealth Department of Health 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8' (the Code) as published by the Therapeutic Goods Administration.

The *Poisons Act 1971* and *Poisons Regulations 2018* are accessible from www.thelaw.tas.gov.au

The latest *Poisons Standard* (the SUSMP) and the Code are available from the Commonwealth Therapeutic Goods Administration webpage www.tga.gov.au

Privacy Statement

The Department of Health provides this form so that you may apply for a licence. The information and documents collected for the purpose of this application may be accessible by authorised departmental persons. The department will not disclose your personal information or supporting documents to third parties without your consent unless required or authorised by law.

Business Details	
Business name:	
Registered office address:	
Premises known as (include address):	
Postal address:	
ABN / ACN:	
Telephone:	
Email address:	
<input type="checkbox"/> I have attached a copy of the current ASIC certificate of registration of business name and / or trading name	

Licence-Holder (Applicant) Details:	
Full legal name:	
Date of birth:	
Position within the organisation:	
<input type="checkbox"/> I have attached a certified copy of photo identification. List of persons who may certify copies is available at: www.justice.tas.gov.au/commissionersfordeclarations/list_of_groups	
Please detail the applicants qualifications and / or experience which make the applicant suitable to hold such a licence: 	

Responsible Officer Details	
<i>The responsible officer should be the person responsible at the licenced premises for compliance with the provisions of the Poisons Act 1971, Poisons Regulations 2018 and licence conditions.</i>	
Is the applicant detailed above also the responsible officer? <input type="checkbox"/> Yes – Go to Section Scheduled Substance Details <input type="checkbox"/> No – Complete responsible officer details below	
Full legal name:	
Date of birth:	
Position within the organisation:	
<input type="checkbox"/> I have attached a certified copy of photo identification.	
Please detail the responsible officer's qualifications and / or experience which make them suitable to be responsible officer for such a licence: 	
I understand I have been listed as the responsible officer on this licence application and agree to abide by the <i>Poisons Act 1971, Poisons Regulations 2018</i> and the conditions of the licence.	
Responsible officer signature:	
Date:	

Scheduled Substance Details

Please indicate the purpose(s) for which a licence is requested:

- Wholesale of human medicines (general)
- Wholesale of human medicines (medical gases only)
- Wholesale of human medicines for specific customers (e.g. shipping supplies, first-aid provision) – **Please provide details:**

- Wholesale of veterinary medicines
- Wholesale of pesticides / agricultural chemicals
- Wholesale of industrial chemicals
- Wholesale of analytical or laboratory standards
- Other – **please specify below:**

Please indicate the schedule(s) of substances for which a licence is requested:

- Schedule 2 Schedule 3 Schedule 4 Schedule 7 Schedule 8

Please list below the scheduled substance(s) you are requesting be included on a licence to sell or supply as a Wholesale Chemist (or provide a list as an Appendix):

Licence Status

Is this a renewal licence application:

- Yes – **please provide previous licence reference number _____ and Go to Section [Declaration](#).**
- No, this is a new business and / or premises application – **please continue below.**

Supplementary Information (New Business or Premises Application Only)

Applicants must be able to demonstrate compliance with the Commonwealth Department of Health 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8' (the Code) as published by the Therapeutic Goods Administration.

Please as an appendix to this application provide documentation to demonstrate how the proposed wholesale business and premises would comply with the Code. This may include but is not limited to copies of relevant poisons control plans, standard operating procedures and policies.

I have included documentation demonstrating planned adherence to the Code with this application.

Please note that during assessment of this application you may be contacted by the assessing delegate to provide further supplementary information.

You may also be contacted to arrange an inspection of the premises by a Poisons Inspector appointed under Section 23 of the *Poisons Act 1971*.

Declaration

I hereby apply for a licence under Section 16(1)(b) of the *Poisons Act 1971* to sell or supply scheduled substances as a Wholesale Chemist, and agree to abide by the *Poisons Act 1971*, *Poisons Regulations 2018* and the conditions of the licence.

In making this application I confirm the compliance of the business with the following:

- The '*Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*' (published by the Therapeutic Goods Administration, Commonwealth Department of Health);
- The *Poisons Act 1971* and *Poisons Regulations 2018*; and
- The *Environmental Management and Pollution Control Act 1994* and subordinate legislation, as amended.

I declare the statements made in this application are true and correct.

Applicant full name:	
Applicant signature:	
Date:	