



WHOLESALE POISON DEALER'S LICENCES

Section 14 of the *Controlled Substances Act, 1984* which applies to all poisons, other than Section 18 which applies to Schedule 4 (Prescription drugs) and Section 31 of the Act which applies to Schedule 8 (controlled drugs), requires any person who sells a poison by way of wholesale dealing to be licensed by SA Health except a pharmacist who is registered under the *Health Practitioner Regulation National Law (South Australia) Act 2010* and sells poisons by way of wholesale dealing as part of normal professional practice at premises registered under the Act. The penalty for selling a poison by wholesale without a licence is a fine up to \$10,000.

Wholesale dealers or manufacturers with no South Australian address do not need to be licensed unless they have representatives based in South Australia or representatives who visit South Australia for the purpose of making sales in this State.

Licences may be issued to an individual or a company but will only be issued to genuine wholesale dealers.

Before issuing a licence SA 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 to hold a licence.

Please include the following with your application:

(except those applicants incorporated under the *Health Care Act 2008*)

- A copy of the current certificate(s) of registration of your company and/or trading names including the names and addresses of the company directors; **or**
- The names of the persons running the business where there is no company name but there is a trading name, and a copy of the current certificate(s) of registration of trading names; **or**
- The names of the persons running the business where there is no company name or trading name.

If you use a trading or company name that is not registered you should make immediate application to the Office of Consumer and Business Affairs or the Australian Securities & Investments Commission respectively.

Term of Licence and Expiry Date

Applicants have the option of applying and paying for a licence that will expire either 1 year or 3 years from the date of issue. The licence will therefore expire on the day before the 1 or 3 year anniversary of the date of issue. Thereafter, if renewed, the licensee will have the option of renewing the licence for a 1 year or 3 year period.

Licence Fees: 1/7/2020 to 30/6/2021

	1 Year	3 Years
Fee (\$) for Schedule 8 Poisons	\$410.00	\$1,230.00
Fee (\$) for Schedule 4, or Schedule 7 Poisons	\$210.00 (each)	\$630.00 (each)
Fee (\$) for Schedule 2, or Schedule 3 Poisons	\$104.00 (each)	\$312.00 (each)
Maximum fee (\$) payable for Manufacturers Licence not including Schedule 8 poisons	\$525.00	\$1,575.00
Maximum fee (\$) payable for Manufacturers Licence including Schedule 8 poisons	\$801.00	\$2,403.00

Fees are cumulative if more than one Schedule of poisons is manufactured (see *below*). For clarification please contact Controlled Substances Licensing.

The maximum cumulative *annual* fee for a manufacturers licence is either \$525.00 where no Schedule 8 poisons are manufactured, or \$801.00 where Schedule 8 products are included in the products to be manufactured.

Applicants may opt to pay licence fees for either a 1 year or 3 year period. All Scheduled poisons manufactured (for which a licence is required) by the applicant at the same location must be included on a single licence and be covered by the same term of licence.

Calculating the fee required

Examples (refer to table above):

- If applying for **1 year** licence to manufacture poisons in Schedules **2, 3, 4, 7 & 8** the fee is calculated as follows:
Fee for Schedule 2 (\$104.00) + fee for Schedule 3 (\$104.00) + fee for Schedule 4 (\$210.00) + fee for Schedule 7 (\$210.00) + fee for Schedule 8 (\$410.00) = \$1,038.00. **However**, the maximum cumulative fee for 1 year where Schedule 8 poisons are included is **\$801.00**, and this is the amount payable. In this example, the 3 year fee would be \$2,403.00
 - If applying for a **3 year** licence to manufacture poisons in Schedules **2, 3, 4 & 7** the fee is calculated as follows:
Fee for Schedule 2 (\$104.00) + fee for Schedule 3 (\$104.00) + fee for Schedule 4 (\$210.00) + fee for Schedule 7 (\$210.00) = \$628.00. **However**, the maximum cumulative fee for 3 years where Schedule 8 poisons *are not* included is \$525.00, so this is the amount payable.
Note: In this example, the 1 year fee would be \$1,575.00.
 - If applying for a licence to manufacture Schedules **3 & 8**, the **1 year** fee would be \$514.00 (\$104.00 + \$410.00); and the **3 year** fee would be \$1,542.00 (\$312.00 + \$1,230.00). As these amounts are less than the maximum cumulative fees, these would be the amounts payable.
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Licence Conditions

After considering all details contained in an application, SA Health sets conditions appropriate for the substance and the purpose for which the licence is required. These conditions are as legally binding on the licensee as the requirements of the Act and relevant regulations. Failure to comply with the conditions is an offence which may result in a fine up to \$5000 and or loss of the licence.

Conditions applying to a licence are part of the licence and may include but are not limited to:

- The keeping of sales records
- Restriction of the sale or supply of the poisons.
- Storage.
- Compliance with the provisions of other Acts or regulations.
- Security.

(CSA 14, 18,31, 55; PO 11)

Representatives

As the employer is held responsible for the acts and omissions of the employee it has been decided that separate licences will not be required by representatives employed by persons or companies who hold a South Australian Wholesale Dealers Licence.

Samples

As a general principle the giving of samples as a means of promoting poisons for therapeutic use is prohibited, however, wholesale dealers are permitted to supply appropriate samples to medical practitioners, dentists, veterinary surgeons, optometrists, dental therapists or pharmacists. Records of such supply must be kept by the wholesale dealer.

(CSA13, 14; PO 35, 40)

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