POISON MANUFACTURER'S LICENCES

For the purposes of this section, manufacture includes production, packing or repacking.

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), prohibits any person manufacturing poisons unless licensed to do so. These licensing requirements do not apply to medical practitioners, pharmacists, dentists, or veterinary surgeons who manufacture as part of normal professional practice, or manufacturers who are licensed to manufacture the poisons under the Commonwealth *Therapeutic Goods Act 1989*.

The penalty for manufacturing a poison without a licence is a fine up to $10,000.

A licence may be issued to an individual or a company but will only be issued to a genuine manufacturer.

Licences may be granted for one or more specific poisons or for all poisons in one or more Schedules depending on the manufacturing that is to be undertaken by the applicant if approved by SA Health.

A manufacturer's licence also allows the licensee to sell, by way of wholesale dealing, the poison(s) manufactured by the licensee, however, if he or she also sells poisons they do not manufacture, a wholesale dealers licence will be required also to legally sell those extra poisons.

Any person, whether licensed or exempt from the licencing requirement, who manufactures a poison must ensure that it is correctly packaged and labelled in accordance with the Act and regulations.

Licences will only be issued if the manufacture of poisons will be supervised by a person who

- is a registered medical practitioner;
- is a registered pharmacist;
- holds a degree in science, with a major in chemistry, conferred by a university;
- is a Fellow or Associate of the Royal Australian Chemical Institute;
- holds a diploma in chemistry; or
- is approved by SA Health.

Before issuing a licence SA Health may make any enquiries necessary to establish the bona fides of the applicant or the person(s) who will supervise the manufacture of the poison(s) and to ascertain if they are fit to hold a licence.

Please include the following with your application:

- 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.

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: 1/7/2021 to 30/6/2022

	1 Year	3 Years
Fee ($) for Schedule 8 Poisons	$418.00	$1,254.00
Fee ($) for Schedule 2, 3, 4, or 7 Poisons	$320.00 (each)	$960.00 (each)
Maximum fee ($) payable for Manufacturers Licence ***not*** *including* Schedule 8 poisons	$1,065.00	$3,195.00
Maximum fee ($) payable for Manufacturers Licence ***including*** Schedule 8 poisons	$1,333.00	$3,999.00

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 $1,065.00 where no Schedule 8 poisons are manufactured, or $1,333.00 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 ($320.00) + fee for Schedule 3 ($320.00) + fee for Schedule 4 ($320.00) + fee for Schedule 7 ($320.00) + fee for Schedule 8 ($418.00) = $1,698.00. **However,** the maximum cumulative fee for 1 year where Schedule 8 poisons are included is **$1,333.00**, and this is the amount payable. In this example, the 3 year fee would be $3,999.00

- 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 ($960.00) + fee for Schedule 3 ($960.00) + fee for Schedule 4 ($960.00) + fee for Schedule 7 ($960.00) = $3,840.00. **However**, the maximum cumulative fee for 3 years where Schedule 8 poisons *are not* included is **$3,195.00**, so this is the amount payable. In this example, the 1 year fee would be $1,065.00.

- If applying for a licence to manufacture Schedules **3 & 8**, the **1 year** fee would be $738.00 ($320.00 + $418.00); and the **3 year** fee would be $2,214.00 ($960.00 + $1,254.00). As these amounts are less than the maximum cumulative fees, these would be the amounts payable.

Licence Conditions

After considering all details contained in an application, SA Health sets conditions appropriate for the poisons 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 penalty of 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 records;
- restriction of sale or supply;
- storage;
- compliance with the *Dangerous Substances Act 1979*, and its regulations; and
- security.

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 Manufacturers Licence.

Samples

As a general principle samples can not be given to the public as a means of promoting a poison for therapeutic use, however, manufacturers 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 manufacturer.

(CSA13, 14, 18, 31, 55; PO 9, 39, 40, 45)

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