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Guide to applying for a Licence or Permit

**Under the Medicines and Poisons Act 2014**

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# When is a licence or permit required?

Many medicines and poisons are classified as ‘scheduled’ substances under the *Medicines and Poisons Act 2014.* There are regulatory controls over ‘scheduled’ substances that vary according the risk of the substance to human health.

The Medicines and Poisons legislation is applicable to the substances listed in the [national Poisons Standard](https://www.tga.gov.au/publication/poisons-standard-susmp), also sometimes referred to as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

One regulatory control is to require businesses intending to supply medicines and poisons to hold a **licence** and for businesses wishing to purchase and use these substances to hold a **permit**.

There are no licence or permit requirements for poisons in Schedule 5 (labelled ‘Caution’) and Schedule 6 (labelled ‘Poison’).

Before a licence or permit is issued, the Department assesses whether the proposed licence or permit holder has sufficient skills and knowledge to safely manage the medicines or poisons. The Department also checks whether the legislated storage, recording, supply and use requirements can be met by the business. The Department also conducts compliance audits at businesses with licences and permits.

A licence or permit issued under the *Medicines and Poisons Act 2014* relates to scheduled medicines and poisons only and not any other business activity of the permit or licence holder.

# What is the difference between a licence and a permit?

A Licence authorises the licensee to *manufacture* and/or *supply* a medicine or poison in accordance with the licence.

A Permit authorises the permit holder to *purchase* a medicine or poison and use the substance in accordance with the purpose listed on the permit.

# Types of applications: Individual, Partnership or Body Corporate

If a licence or permit is issued to an individual on behalf of a business, this person is responsible for ensuring the business complies with the Medicines and Poisons legislation and any conditions on the licence or permit. Correspondence relating to compliance audits or investigations by the Department will be addressed to the individual named on the licence or permit.

Licences or permits issued to a partnership or body corporate mean the responsibility for compliance lies with all partners or all corporate officers, respectively. Partnership or body corporate licences and permits do not include the name of a natural person as the licence or permit holder.

When applying for a partnership or body corporate licence or permit, the following must be submitted:

* A current company extract from the Australian Securities and Investment Commission (ASIC) database showing all corporate officers (all partners, directors and company secretary as applicable).
* Each partner or corporate officer must complete the personal information section of the application form to provide information about themselves.

# What is the difference between a licence/permit holder and a responsible person?

* The licence/permit holder has overall responsibility for ensuring the handling of medicines and poisons by the business is in accordance with both the requirements of the Medicines and Poisons legislation and any conditions on the licence or permit. The licence/permit holder should review any standard operating procedures used by the business, to check they are consistent with the mandatory requirements of the legislation and any licence/permit conditions.
* The licence/permit holder may be a partnership or a corporation or an individual who holds the licence/permit on behalf of the business.
* The ‘responsible person’ is a natural person nominated by the licence/permit holder to manage the medicines and poisons on a ‘day to day’ basis at a premises listed on the licence or permit. The ‘responsible person’ should be someone who routinely works at the premises where the medicines and poisons are stored.
* Where there are multiple premises listed on a licence/permit, there may be a different ‘responsible person’ at each premises.
* If the licence/permit holder is an individual (rather than a partnership or corporation), in most circumstances, they can be the ‘responsible person’.
* Nominating a ‘responsible person’ does not change the responsibility of the licence/permit holder. The licence/permit holder always retains responsibility for the business complying with the law, including any conditions on the licence or permit.

# Who can apply for a licence or permit?

Applicants should determine whether they can meet the requirements of the legislation before applying for a licence or permit.

Individual applicants must have sufficient knowledge of each medicine or poison to which the licence or permit is to apply and the duties and obligations of a licensee or permit holder.

A person can hold more than one licence or permit. However, where a person is named on multiple licences or permits, the Department may ask the person for evidence to show how they are able to adequately fulfil their duties and obligations as a licence or permit holder for all the businesses involved.

If a business is applying for a partnership or corporate licence or permit, the business must employ people who have sufficient knowledge of the medicines or poisons to which the licence or permit will apply.

The information below refers to ‘applicants’. If the application is for a partnership or corporate licence/permit, the business must employ staff who have the same attributes as an individual applicant.

## Wholesaler’s/manufacturer’s licence

Applicants must have either a qualification or experience relevant to the medicines and poisons being manufactured or supplied by wholesale. For applicants with experience only, 5 years working in a wholesaling business that manufactures or sells similar medicines and poisons is considered suitable.

## Indent licence

This licence is intended for businesses that provide sales brokerage services but do not physically take possession of medicines and poisons. The applicant needs to have sufficient knowledge and skills to assess whether a client is authorised to purchase medicines and poisons and be able to comply with record-keeping requirements.

## Schedule 2 retail licence

These licences can be issued to allow a business to sell Schedule 2 medicines to consumers, where there is no pharmacy within 25 km. It is preferable for the applicant to be physically working at the premises to which the licence applies. If the applicant does not work at the premises, a person who does work at the premises should be nominated as the ‘responsible person’.

## Schedule 7 retail licence

This licence allows a business to sell Schedule 7 poisons to end users. Schedule 7 retail licences are most commonly issued to stores selling agricultural pesticides to primary producers. The applicant is expected to have a relevant qualification or at least 5 years of experience working at a business that sells or handles Schedule 7 poisons. Training for agricultural chemical sellers is available via AgSafe.

## Health Service permit

This permit allows health services to purchase medicines for the treatment of patients of the health service. ‘Health service’ is a broad term and includes, but is not limited to, medical practices, dental practices, hospitals, medical businesses servicing mining and industrial sites, ambulance services, immunisation services, residential care facilities and cosmetic procedure clinics.

For medical practices, where a medical practitioner is on site whenever the practice is open, a practice nurse can be nominated as a permit holder. The practice manager can only be nominated as the permit holder if they are a registered nurse.

[Licensed private healthcare facilities](https://ww2.health.wa.gov.au/Articles/J_M/Lists-of-licensed-private-healthcare-facilities) and residential care facilities may nominate a suitable registered nurse, such as the director of nursing, as their permit holder.

For other types of health services, the applicant must be a registered health practitioner with authority to prescribe the medicines listed on the permit (most commonly a medical practitioner). Examples of this type of health service are cosmetic procedure clinics, immunisation services and medical businesses providing healthcare to remote workplaces.

[Specific application forms](https://ww2.health.wa.gov.au/Articles/A_E/Application-forms-for-Licences-and-Permits) are available for different types of health services. A [detailed guideline](https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/Cosmetic%20Procedure%20Clinic%20Guideline.docx) is available for those applying for a permit for cosmetic procedure clinics, including clinics that specialise in cosmetic injections.

## Industrial permit

This permit allows a business to purchase scheduled poisons for use within the business. Commonly this type of permit is issued for specific Schedule 7 poisons such as chlorine gas, cyanide and hydrofluoric acid. The allowable use for the poison must be included on the permit.

The applicant must be able to show they are suitably qualified or experienced (preferably 5 years) to manage the poison(s) on the permit. For example, those wishing to purchase hydrofluoric acid will usually need a suitable trade qualification (such as a welder, boilermaker, or powdercoater) or must have worked with this dangerous acid for at least 5 years before they can apply for their own permit.

Permits for chlorine gas for water treatment (including public swimming pools) can be issued to the Chief Executive Officer for the local government area, provided a suitably trained responsible person is available to handle the chlorine gas on a ‘day to day’ basis.

Due to Australia having ratified the Minamata Convention, industrial permits for mercury will not be issued to artisanal and small-scale mining operations or for manufacturing processes prohibited by the [Environmental Protection Regulations 1987](https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1400_homepage.html).

## Research/education permit

This permit is to purchase medicines and poisons for the purpose of research or education within tertiary institutions, bona fide research organisations, registered training organisations (RTO) or government departments. The applicant is expected to be a research supervisor and hold a relevant qualification.

## Veterinary practice permit

To apply for this type of permit, the applicant must be a WA registered veterinarian. Registered veterinary clinics and hospitals with multiple veterinarians will need a permit. Mobile only veterinary practices also need a permit.

Further information about [who needs a veterinary practice permit](https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/Who-needs-a-veterinary-practice-permit.docx) is available on the WA Health website.

# Why do applicants and responsible persons need to provide information about themselves?

This information is used to determine whether the person can meet the requirements of Section 41 of the *Medicines and Poisons Act 2014*, including being considered a ‘fit and proper’ person and having sufficient knowledge to be a licensee, permit holder or responsible person.

## Certified identification

Before issuing a licence or permit, the Department must be sure of the identity of the applicant and any nominated responsible persons. A certified copy of government issued photographic identification is therefore required as part of all licence and permit applications. It is preferable that documents used are issued by an Australian government.

All application forms include an appendix which lists the categories of people who can certify that a copy of a document is a true copy.

## National Police Clearance (NPC)

A national police clearance is required as part of determining whether an applicant is a ‘fit and proper’ person to hold a licence or permit or be a responsible person in the following circumstances:

* The applicant is not a registered health practitioner or registered veterinary surgeon and
* The application is for a:
  + Manufacturer’s/wholesaler’s licence
  + Indent licence
  + Schedule 7 retail licence
  + Permit which includes medicines and poisons in Schedule 8 or Schedule 9 or
  + Schedule 9 licence.

The NPC provided must have been issued within the preceding 12 months.

If the person has been convicted of any indictable offences or has any pending offences since their NPC was issued (or in the case of a health practitioner or veterinary surgeon since they last renewed their registration), a statutory declaration including full details of the alleged offence must also be submitted.

# Licences and permits at residential premises

In most circumstances, businesses selling or using scheduled medicines and poisons will not operate from residential premises. Because there are risks associated with the storage of quantities of scheduled medicines and poisons, in most cases, domestic premises will not be suitable for this purpose.

If a premises to be listed on a licence or permit is a residential premises, the Department will usually require evidence that your local government has approved you to operate your business at your home or advice that no such approval is required. This is to ensure the Department does not issue a licence or permit inconsistent with local government land use requirements.

For a residential premises to be considered a suitable location, the applicant (licence or permit holder) must have unrestricted access to the premises, such as by being the tenant or the owner occupier.

# Storage of Schedule 8 substances

If the licence or permit will include any medicines in Schedule 8 (controlled drugs), the applicant must provide details of how they will comply with the storage requirements detailed in the Medicines and Poisons Regulations 2016.

Wholesalers require a strong room to store Schedule 8 medicines. Permit holders require either a large safe or a small safe, depending on the quantity and type of Schedule 8 products being stored.

Where larger quantities of Schedule 8 medicines are being stored, continuously monitored alarm systems with motion detectors are also required.

Information about [compliant storage requirements](https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/Safes-for-storing-schedule-8-medicines.docx) is available on the WA Health website.

The Department will only consider an application for alternative storage arrangements in limited circumstances. Applicants must provide advice about why they cannot comply with the usual storage requirements and the Department will use this information to determine whether an application for alternative storage will be accepted.

# Difference between a legal entity and business name

Licence and permit application forms ask you to provide the name of the legal entity with which the licence or permit will be associated. This is the name that appears on official documents and legal papers associated with your business and, depending on your business structure may be your own name if you are a sole trader, the name of a partnership, a proprietary limited company or an incorporated association.

Application forms also ask for your business or trading name. This may be different to the name of the legal entity. There may be multiple business names linked to a single legal entity.

A new licence or permit is required where there is a change in legal entity, such as when the business is sold or where a merger occurs. The *Medicines and Poisons Act 2014* does not allow licences and permits to be transferred from one legal entity to another.

[Further information about business, trading and legal entity names](https://www.abr.business.gov.au/FAQ/Names) is available from the [Australian Business Register](https://www.abr.business.gov.au/)

# Fees

When applying for a new licence or permit, the fee has two components:

* An application fee which is non refundable
* A one year licence/permit fee which can be refunded if the licence or permit is not issued.

Applicants are reminded to ensure any payment details are correct before submitting their application. Any credit card expiry date should be at least one month from the date of submitting the application.

# Signing an application form

* All applications must be signed by the proposed licence or permit holder. This person is signing to confirm that the information provided in the application is true and correct. There are penalties of up to $30,000 for providing false or misleading information in licence and permit applications.
* For partnership applications, at least one of the partners must sign the application.
* For body corporate applications, a corporate officer or the Chief Executive Officer is to sign the application.
* Applicants should check all relevant sections of the application form have been completed and all required attachments included before submitting their application. A ‘check-list’ is provided on application forms to assist applicants with this process.

## Digital signatures

When the application form is completed electronically a ‘digital signature’ may be used instead of printing out the completed document and adding a handwritten (ink/wet) signature.

A digital signature uses encrypted information unique to the signatory to ensure data integrity and provide confidence that the signatory cannot deny its validity.

The Department must be able to verify the validity of any digital signature used on the application form, in the format in which the application is submitted to the Department. For example, a scanned document where the ‘digital signature’ was added before scanning is unlikely to meet this requirement.

A digital signature is not a scan of a handwritten signature. Similarly, simply typing a name into the space for the signature, even if a font resembling handwriting is used, is not acceptable.

# Processing time for applications

* The Department processes applications in order of receipt after payment has been processed by Finance, provided the required fee has been paid., and all the required information is submitted as part of the application. There is no facility for priority processing of applications.
* The most common reason for delays in processing of applications is submission of incomplete applications or failure to provide additional information requested by the Department in a timely manner.
* To avoid delays, read the instructions on the front of the application form, fully complete all required sections of the form and provide all accompanying documents as requested on the application form. Application forms include a check list to help applicants.
* If the Department requests further information, processing of your application will not recommence until you provide this information. Delays in providing requested information may result in the processing time extending beyond the usual service delivery standards.

# Renewing a licence or permit

Licences and permits are valid for 12 months from the date of issue. The expiry date is printed on the licence or permit.

At least two months before a licence or permit expires, a renewal notice will be mailed to the postal address provided on the application. It is the responsibility of the permit/licence holder to inform the Department if the postal address or other contact details have changed, so that renewal notices are posted to the correct address.

To renew a licence or permit:

* Pay the renewal fee using your credit card via [BPoint](https://www.bpoint.com.au/payments/depthealthpharm) or from your transaction account via BPay.
* Arrange for the licence/permit holder to sign the declaration on the renewal form, make a copy of the form for your records (tax invoice) and return the original, signed form to the Department.
* Ensure payment is made and the signed renewal form is returned to the Department at least 28 days prior to the licence/permit expiry date, to allow processing prior to expiry.

If payment and the signed renewal form are received by the Department after the licence/permit has expired, the licence/permit cannot be renewed and a new application will be required.

# More information

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