

Victorian Pharmacy Authority applications – frequently asked questions

APPLICATIONS (GENERAL)

Where can I find more information on application processes?

The Victorian Pharmacy Authority (the “Authority”) Guidelines contain information on the application process. The Guidelines are available on the Authority website [here](#). Further detailed information can be found within the application forms themselves. The flow charts accompanying these frequently asked questions provide general guidance to assist applicants to understand the Authority’s application processes.

Will I have to wait for my application to be considered by the Authority at its next monthly meeting?

Authority pharmacists have delegation to issue an agreement in principle to applications that clearly meet the requirements of both the *Pharmacy Regulation Act 2010* (the “Act”) and the Victorian Pharmacy Authority Guidelines.

Authority pharmacists will contact you shortly after receiving your application to request additional information or clarification as necessary, or to advise you about the progress of your application.

If an application does not meet the requirements of the Act or the Guidelines it will be referred to the Authority for a decision at its next meeting. The Authority meets monthly on the second Tuesday of each month.

How long will it take for my application to be processed?

The Authority has set service standards for processing applications. The Authority aims to carry out an initial assessment within five working days of receipt of a complete application.

For applications within delegation of Authority officers processing should be completed within a further three working days, following receipt of any outstanding information.

For applications outside delegation processing should be completed within three working days following a decision of the next monthly meeting of Authority Members, or within three working days of receipt of any further required information.

ESTABLISHING A NEW PHARMACY BUSINESS OR RELOCATING AN EXISTING PHARMACY BUSINESS

What approvals are required?

There are two separate approvals required. An application for *registration* of the pharmacy premises and an application for a *licence* to carry on a pharmacy business must be lodged with the Authority.

The premises must be registered. The owner must be licensed to carry on a pharmacy business at the registered premises.

Licence application forms can be found [here](#).

Registration application forms can be found [here](#).

You may NOT carry on a pharmacy business in the premises UNTIL the Authority has registered the premises AND licensed you to do so.

Note: Applying for PBS approval is a separate process through Medicare and the Australian Community Pharmacy Authority.

Is a separate licence required for each owner when there is more than one owner?

Yes. Separate licences are required when there is more than one owner. A pharmacy business may be owned by (i) a partnership of registered pharmacists, or (ii) a partnership of registered pharmacist(s) and one or more eligible companies, or a partnership of eligible companies. In these cases each partner (whether a natural person or company) is required to hold a licence.

If the owner is a single eligible company formed by registered pharmacists then the company is the legal owner of the business and a single corporate licence is required.

Can the application for a licence be submitted at the same time as the application for registration of the premises?

Yes. Most applicants submit the licence application along with the application for registration.

An application for registration of a pharmacy premises will be considered in the absence of a licence application, however you must first be granted a licence to before you can carry on a pharmacy business at a registered premises.

Do I need to obtain a pharmacy business licence and premises registration from the Authority before I submit an application to Medicare for PBS approval?

The Authority's application process is entirely independent of Medicare's application process. An applicant may choose to apply for PBS approval prior to seeking VPA approval or at the same time. However, Medicare will require evidence of VPA approval prior to issuing PBS approval.

When will Medicare be notified of the status of my application?

The Authority copies correspondence relating to applications to Medicare Australia at each stage of the approval process e.g. agreement in principle, issue of conditional registration, and removal of conditions on registration.

When can I begin to stock the premises with scheduled medicines?

You must have conditional registration BEFORE you stock the new premises with scheduled medicines and BEFORE you open the pharmacy for business.

When the premises have been completed in accordance with the agreed plans, the Authority will use your notification of completion form as the basis of its decision to grant or refuse conditional registration.

DO NOT stock the new premises with scheduled medicines OR open the pharmacy for business UNTIL the Authority has granted Conditional Registration.
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What is "conditional" registration?

When an applicant completes construction of a new pharmacy premises, they are required to self-certify that construction has been completed according to the plans, specifications and information contained in the application and the Victorian Pharmacy Authority Guidelines.

When conditional registration is granted an officer of the Authority will then conduct a site inspection. The registration is conditional on satisfactory inspection.

When can I open a new/relocated pharmacy premises?

A new pharmacy premises may be opened for business only when the Authority has granted conditional registration of the premises and issued conditional licence(s) to carry on a pharmacy business at the registered premises.

DO NOT stock the new premises with scheduled medicines OR open the pharmacy for business UNTIL the Authority has granted a Conditional Licence and Registration.
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When the Authority assesses applications and is satisfied that they meet all the requirements of the Act and Guidelines, it approves licence applications *in principle*, and agrees *in principle* to applications for premises registration. These *in principle* approvals allow the applicant to go ahead and construct the pharmacy. Conditional licences and registration are not issued until the applicant notifies the Authority that premises have been completed according to the approved plans. Applicants must also pay their registration and licence fees using the appropriate notification forms.

When will an Authority pharmacist conduct an inspection of the premises?

The Authority aims to conduct inspections within three months of establishment of a new or relocated pharmacy (or following a change of ownership or completion of alterations to the pharmacy).

ESTABLISHING A NEW PHARMACY DEPARTMENT OR RELOCATING AN EXISTING PHARMACY DEPARTMENT

What approvals are required?

There are two separate approvals required. An application for *registration* of the pharmacy department premises and an application for a *licence* to carry on a pharmacy department must be lodged with the Authority.

The premises must be registered. The owner must be licensed to carry on a pharmacy department at the registered premises.

Licence application forms can be found [here](#).

Registration application forms can be found [here](#).

You may NOT carry on a pharmacy department at the premises UNTIL the Authority has registered the premises AND licensed you to do so.

Can the application for a licence be submitted at the same time as the application for registration of the premises?

Yes. Most applicants submit the licence application along with the application for registration.

An application for registration of a pharmacy department premises will be considered in the absence of a licence application, however you must first be granted a licence before you can carry on a pharmacy department at a registered premises.

When can I begin to stock the premises with scheduled medicines?

You must have conditional registration BEFORE you stock the new premises with scheduled medicines and BEFORE you open the pharmacy department.

When the premises have been completed in accordance with the agreed plans, the Authority will use your notification of completion form as the basis of its decision to grant or refuse *conditional registration*.

DO NOT stock the new premises with scheduled medicines OR open the pharmacy department UNTIL the Authority has granted Conditional Registration.

What is "conditional" registration?

When an applicant completes construction of a new pharmacy premises, they are required to self-certify that construction has been completed according to the plans, specifications and information contained in the application and the Victorian Pharmacy Authority Guidelines.

When conditional registration is granted an officer of the Authority will then conduct a site inspection. The registration is conditional on satisfactory inspection.

When can I open a new/relocated pharmacy department premises?

A new pharmacy department premises may be opened for business only when the Authority has granted conditional registration of the premises and issued conditional licence(s) to carry on a pharmacy department at the registered premises.

DO NOT stock the new premises with scheduled medicines OR open the pharmacy department UNTIL the Authority has granted a Conditional Licence and Registration.

When the Authority assesses applications and is satisfied that they meet all the requirements of the Act and Guidelines, it approves licence applications *in principle*, and agrees *in principle* to applications for premises registration. These *in principle* approvals allow the applicant to go ahead and construct the pharmacy department. Conditional licences and registration are not issued until the applicant notifies the Authority that premises have been completed according to the approved plans. Applicants must also pay their registration and licence fees using the appropriate notification forms.

Is the Authority required to consult with the Department of Health and Human Services prior to registering a pharmacy department?

Yes. When the premises is part of a registered funded agency, the Authority must consult with the Secretary prior to registering the premises.

When will an Authority pharmacist conduct an inspection of the premises?

The Authority aims to conduct inspections within three months of establishment of a new or relocated pharmacy department (or following a change of ownership or completion of alterations). An Authority pharmacist will contact the Director of Pharmacy to arrange a time to conduct the inspection.

Is a new licence application required if relocating a pharmacy department within the hospital?

Provided the relocation is within the grounds of the hospital an application for a new licence to carry on a pharmacy department may not be required. Advice should be sought from the Authority.

ESTABLISHING A PHARMACY DEPOT

Can I establish a pharmacy depot if I am not the owner of a pharmacy or pharmacy department?

No. The Authority can only register a pharmacy depot that is carried on by a person who is licensed to carry on a pharmacy business or a pharmacy department. A pharmacy depot is treated as an extension of an existing pharmacy service.

If a new pharmacy is established in the vicinity of an existing pharmacy depot, must the depot close?

No. There is nothing in the Act requiring a pharmacy depot to close in the event that a pharmacy is established.

PURCHASING OR BUYING INTO AN EXISTING PHARMACY BUSINESS

What approvals are required?

An application for a pharmacy business licence must be lodged with the Authority.

Each proprietor, whether a natural person, eligible company or friendly society, must be licensed to carry on a pharmacy business.

Licence application forms can be found [here](#).

As the premises are already registered, the new owner or partner does not need to seek separate registration.

The Authority will approve your licence application when it is satisfied that the application meets the requirements of the Act. The Authority will grant you a conditional licence when you have notified it that you have settled the purchase of the business and paid the statutory annual licence fee. The conditional licence will allow you to carry on the business while the Authority conducts an on-site assessment of the pharmacy business at the premises.

You may NOT carry on a pharmacy business in the premises UNTIL the Authority has licensed you to do so.

APPROVAL OF ALTERATIONS TO EXISTING PHARMACY PREMISES

When is an application required?

An application for alterations to an existing registered premises must be approved by the Authority prior to making significant alterations to a pharmacy.

Significant alterations include any of the following:

- Alterations to the perimeter or perimeter security of the premises;
- Alterations affecting public access to the premises;
- Alterations to the dispensary including changes to floor area and access to the dispensary;
- Addition of a compounding room or dose administration aid filling room separate from the dispensary;
- Alterations to counselling areas.

This list is not exhaustive. If clarification is required applicants are advised to speak to an Authority officer for advice.

Applications for approval of alterations to registered premises can be found [here](#).

APPROVAL OF ALTERATIONS TO EXISTING PHARMACY DEPARTMENT PREMISES

When is an application required?

An application for alterations to an existing registered premises must be approved by the Authority prior to making significant alterations to a pharmacy.

Significant alterations include any of the following:

- Alterations to the perimeter or perimeter security of the premises;
- Alterations to the pharmacy department including changes to floor area, Schedule 8 drug vaults or access to the department;
- Addition of a sterile suite or facilities for sterile compounding;
- Alterations to existing facilities for sterile compounding;
- Alterations to counselling areas.

This list is not exhaustive. If clarification is required applicants are advised to speak to an Authority officer for advice.

Applications for approval of alterations to registered premises can be found [here](#).

APPROVAL TO DISPENSE MEDICINES IN SPECIAL CIRCUMSTANCES

What special circumstances does section 29(1)(b) of the Act provide for?

A registered pharmacist must not supply, compound or dispense medicines except:

- (a) from a pharmacy or pharmacy department that is approved by the Authority; or
- (b) in any other special circumstances that are approved by the Authority in a particular case.

The majority of pharmacists who supply, compound or dispense medicines in Victoria do so from registered pharmacy premises or pharmacy departments. There are however circumstances in which a pharmacist may be approved to supply, compound or dispense medicines on a case by case basis from premises that are not registered. Examples include:

- Dispensing from a ward in a hospital to provide timely discharge medicines;
- Dispensing from a pharmacy room for the period of major events such as the Commonwealth Games or Scout Jamboree;
- Dispensing from a pharmacy room in a hospital that does not have a pharmacy department;
- Dispensing from a pharmacy area or room in specialty outpatient clinics.

Applications for approval involve consideration of the proposed location to supply, compound or dispense medicines and why the service cannot be provided from a pharmacy or pharmacy department. Other factors include access, security, the type of service and intended clients. When seeking re-approval, applicants are required to complete an annual declaration stating that circumstances relating to the location, layout, equipment and security of the work area are substantially unchanged from those previously approved.

The special circumstances provision is not to be construed as a substitute for the registration of premises.

Application forms for approval to dispense medicines in special circumstances can be found [here](#).

When is an application not required?

Authority approval is not required if practice is restricted to clinical or administrative activities that do not involve the supply, compounding or dispensing of medicines. These include conducting home medication reviews or lecturing. Pharmacists are encouraged to contact the Authority if clarification is required.

RENEWAL OF LICENCES FOR OWNERS AND REGISTRATION OF PREMISES

What is the process for renewal of owner licenses and premises registration?

It is the responsibility of licensees to ensure their premises registration and pharmacy business licence(s) are renewed by 30 June each year as required by the *Pharmacy Regulation Act 2010*.

All renewal invoices are sent by email to the email address notified to the Authority for the registered premises. Email is now the primary mode of communication for the Authority. Consequently it is important to notify the Authority when email addresses change.

There is no provision in the Pharmacy Regulation Act 2010 for late payments. If a licence or registration lapses there may be serious professional and/or legal obligations for licensees and pharmacists practising in unregistered premises.

OTHER APPROVALS

Is Authority approval required to provide other services or carry on another business within the pharmacy?

If the business is carried on by a person other than the owner of the pharmacy business, Authority approval is required. The business must be compatible with the pharmacy business. Please refer to the Guidelines for further information. Application form VP43 can be found on the Authority website [here](#).

ON-LINE PHARMACIES

Do on-line pharmacies need to be registered?

Yes. In accordance with the *Pharmacy Regulation Act 2010*, the owners of a pharmacy business must be licensed and the premises registered. Authority staff are sometimes asked if there are separate

requirements for pharmacies from which medicines and other goods are supplied on-line or by telephone. The short answer is no. The premises must meet all of the security, equipping and temperature control requirements and be open to the public.

On-line pharmacy businesses must be operated from a registered pharmacy premises and the supply of any medicines must take place from the same registered pharmacy premises.

The Pharmacy Board of Australia's Guideline "Internet, mail-order dispensing and other indirect supply of medicines" states, in part: "The Board views the indirect supply of medicines, such as internet and mail-order dispensing, as less than the optimal way of delivering pharmacy services because communication may be compromised".

DISASTERS SUCH AS FIRE OR FLOOD

Please contact the Authority for advice about registered premises affected by natural disasters.

FURTHER QUESTIONS

If you have any further questions regarding applications please contact the Authority offices by phone on (03) 9653 1700 or email enquiries@pharmacy.vic.gov.au.

An Authority pharmacist is available during office hours to provide assistance and advice to applicants, licensees, pharmacists and the general public by telephone or email.