Victorian Pharmacy Authority

Level 2, 15-31 Pelham St
Carlton Vic 3053

Tel: 03 9653 1700 **Fax: 03 9653 1750** **Email: applications@pharmacy.vic.gov.au**

Form VP22

APPLICATION FOR REGISTRATION OF PHARMACY DEPARTMENT PREMISES

SECTION 44 OF THE *PHARMACY REGULATION ACT 2010*

Application notes:

i. *This form applies only to the registration of pharmacy department premises. It does not cover applications from agencies, hospitals, or health centres seeking a licence to carry on a pharmacy department. A separate licence is required to establish a pharmacy department in new premises. Forms to apply for a* ***licence to carry on a pharmacy department*** *may be obtained from the Authority's offices or website:* ***http://www.pharmacy.vic.gov.au***

ii. *An application fee is required for all applications made using this form. The application fee covers the assessment of the application including a site inspection of the premises. The fee does not cover the statutory annual registration fee.*

iii. *This application comprises two parts. Part A requires the applicant to provide details of the proposed premises. Part B requires the applicant to state if the proposed premises will conform to statutory requirements and the Victorian Pharmacy Authority Guidelines . The Authority requires both parts to be completed in full so that the application may be processed in accordance with its delegated approval procedure.*

iv. *Applications that conform to the Victorian Pharmacy Authority Guidelines may be determined by the Authority's delegate.*

v. *Applications that do not conform to the Victorian Pharmacy Authority Guidelines must be determined by the Authority. As far as is practicable the Authority will consider such applications in detail at its meeting in the month after the application is lodged. For example, applications lodged in May will be considered by the Authority at its June meeting.*

vi. *Applicants who seek a variation to the Victorian Pharmacy Authority Guidelines should attach a written submission demonstrating any special circumstances. For example an answer of "no" to any of the questions in part B would require such a submission. The submission should demonstrate why the proposal meets or exceeds the intent of the Victorian Pharmacy Authority Guidelines, or if it doesn't, why the proposal is consistent with safe storage and dispensing and in the community interest. Applicants may request an appointment to attend a meeting of the Authority to discuss the application.*

vii. *Incomplete applications forms may be returned to the applicant for completion.*

viii. *The Authority must not register a pharmacy department in a registered funded agency unless it has first consulted with the Secretary on the Department of Health and Human Services.*

ix. *Parts of the Pharmacy Regulation Act 2010, Victorian Pharmacy Authority Guidelines and the Drugs, Poisons and Controlled Substances Regulations 2017 have been quoted in the application form. Applicants may view these and related documents at:*

Pharmacy Regulation Act 2010
http://www.legislation.vic.gov.au [click on Victorian Law Today]

Victorian Pharmacy Authority Guidelines
http://www.pharmacy.vic.gov.au

Drugs, Poisons and Controlled Substances Act 1981:
http://www.legislation.vic.gov.au [click on Victorian Law Today]

Drugs, Poisons and Controlled Substances Regulations 2017: http://www.legislation.vic.gov.au [click on Victorian Law Today]

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SEND TO:

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PART A – Application details

1. **Name and address of applicant** (ie name of Registered funded agency, Registered Community Health Centre, Private hospital, Privately-operated hospital)

   Name: .....

   Address: .....

   .....

   .....

   P/Code: .....

2. **Eligibility class of applicant** (eg Registered funded agency, Registered Community Health Centre, Private hospital, Privately-operated hospital)

   .....

3. **Name, position and contact details of the person completing this application** (all correspondence relating to the application will be sent to this person unless otherwise requested)**.**

Name & Position:

Address:

P/Code:

Phone: **Fax:**

E-mail:

4. **Name and address of the hospital/agency/centre where the pharmacy department will be located:**

Postcode:

Phone: **Fax:**

Email:

5. **Indicate the reason for the application:**

Eg You require: (*Please tick* ☑ as applicable)

- ☐ Registration of New pharmacy department premises (for a new pharmacy department).
- ☐ Registration of New (relocated) pharmacy department premises (relocating an existing pharmacy department).
- ☐ Approval of Alterations to existing approved pharmacy department premises.
- ☐ Approval of Alterations and extension of existing approved pharmacy department premises.
- ☐ Other

If other please specify:

6. If relocating an existing pharmacy department into new premises, state the address of the *existing* pharmacy department premises which will be vacated.

.....

.....

P/Code .....

Important Note:
A person must not establish or carry on a pharmacy department until licenced to do so by the Authority. A person seeking a licence to carry on a pharmacy department must lodge a separate and different application using form VP17. Form VP17 can be obtained from the Authority's offices or website [**www.pharmacy.vic.gov.au].**

7. Indicate the level of service to be provided by the pharmacy department in accordance with the NSW Guide to the Role Delineation of Health Services Please CIRCLE the level that most closely describes the level of service to be provided.

Level	Description
Level 1	Drugs supplied on individual prescription from community pharmacy, or drugs from a networked public hospital. No pharmacist employed but regular visits from pharmacists associated with provision of the service. Visiting pharmacist may participate in Drug and Therapeutics Committee or equivalent. Quality assurance activities.
Level 2	As Level 1 plus pharmacist employed on part-time or sessional basis. Co-ordination of drug distribution from community pharmacy or networked source. Limited clinical service. May provide patient and staff education. May participate in ward meetings or rounds. Has an established and regularly updated formulary.
Level 3	As Level 2 with at least one pharmacist employed full-time. May also have support staff. Pharmacy controlled drug distribution to inpatients. Clinical service includes drug information, drug monitoring, drug utilisation review, adverse drug reaction reporting. Has limited participation in ward meetings and rounds and provides patient and staff education programs. May have limited manufacturing services. Formal quality assurance program. May be involved in domiciliary/community care. May provide outpatient service.
Level 4	As Level 3 plus more than one permanent full-time pharmacist employed plus support staff. Pharmacist on-call for emergency advice. Director of Pharmacy involved in Drug and Therapeutics Committee. Non-sterile manufacturing services with facilities provided to Standards Association of Australia (SAA) requirements. May have sterile manufacturing, which follows Good Manufacturing Practice (GMP) or equivalent Standards (see Note). May provide pre-registration training.
Level 5	As Level 4 plus provides regular drug information service and bulletins. Participation in ward rounds or meetings. Must have outpatient service. Has staff development and training program for pharmacy staff. Sterile manufacturing and IV admixture service including cytotoxic drugs if clinical unit is present in hospital. Facilities to standard of SAA. Code of GMP or equivalent followed. May supply to other networked hospitals. Clinical trial support for research activities in hospital.
Level 6	As Level 5 plus extensive involvement in research, clinical trials, clinical review. Provides pre-and post-graduate pharmacy training. Has pharmacist on call 24 hours.

8. Will the department supply medicine directly to patients at the pharmacy department eg an out-patients dispensary;

YES	NO
☐	☐

9. Floor Plan and Elevation Drawings

9.1 Enclose a floor plan of the pharmacy department and any satellites, drawn to scale, showing:-

i) Perimeter and total area of pharmacy department including satellites;

ii) location of work areas eg in-patient dispensing, out-patient dispensing, cytotoxic, sterile, non-sterile preparations, drug information, clerical. research, drug storage, management and, if supplying medicines directly to the patients, client waiting areas and prescription reception / patient counselling areas;

iii) location and dimensions of work benches;

iv) location of stainless steel sink and reticulated hot and cold water;

v) locations of drugs of addiction safe and drug refrigerator;

vi) location(s) of dispensing stations;

vii) location and proposed use of shelving in the department dispensary – eg bulk storage shelving, inpatient dispensary shelving, outpatient dispensary shelving;

viii) location of storage area for dispensed medicines awaiting collection by patients or delivery to wards

ix) location of staff lockers and tea & meal areas, if located in the department;

x) location of doors and windows;

9.2 Enclose an elevation drawing showing walls and screens which provide privacy at prescription reception and counselling areas if medicines will be supplied directly to the public.

9.3 Enclose a location plan, showing the position of the department within the hospital.

This is the end of Part A. Go to Part B.

PART B STATEMENT OF CONFORMITY

DISPENSARY:

The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients' records. Lighting, ventilation and temperature control are essential to maintaining the integrity of the medicines and for personal comfort. The dispensary is to be supplied with hot and cold running water and refrigeration, and provide a sufficient area for equipment and free working space.

10. Is the dispensary area of the department designed in a way that prevents persons other than pharmacy staff members from entering except under the direct supervision of a pharmacist?

YES ☐ NO ☐

11. Will the department include a specific inwards goods unpacking and sorting area?

YES ☐ NO ☐

12. Will the dispensary area of the department include a hot and cold water sink with drainer?

YES ☐ NO ☐

13. Will the dispensary area of the department include a specific bench or bench area located near to a sink for the compounding or preparation of medicines and for the storage for compounding equipment?

YES ☐ NO ☐

14. Will the dispensary area of the department include a bench area for dispensing pharmacists to use to research drug information relevant to prescriptions being dispensed?

YES ☐ NO ☐

15. If the department provides pharmacotherapy to 20 or more persons per day will the dispensary area of the department include a specific bench or bench area of at least 0.6m^2 dedicated to the pharmacotherapy program that is not accessible to the public and provides for the secure storage of "in use" S8 medicines?

YES ☐ NO ☐ N/A ☐

(Tick N/A if < 20 DAAs/week)

16. If the department regularly fills dose administration aids (DAAs) for 15 or more persons per week will the dispensary area of the department include a specific bench or bench area of at least 1 m² dedicated to the filling of DAAs; and secure storage for dispensed medicines?

YES	NO	N/A
☐	☐	☐

(Tick N/A if < 15 DAAs/week)

DISPENSING STATIONS

A dispensary in a pharmacy department is to include one dispensing station for each 150 prescription items or part thereof dispensed on a typical day between 9am and 6pm.

A dispensing station is to include a dispensing bench of at least 0.6m² (e.g. 1000mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, and a dedicated printer for label. Each station must be convenient to a printer that prints Consumer Medicine Information (CMI). The CMI printer may be located at or away from the dispensing station and may service multiple dispensing stations.

17. Will the dispensary area of the department include one dispensing station for each 150 prescription items or part thereof dispensed on a typical day between 9 am and 6 pm?

YES	NO
☐	☐

18. Will each dispensing station include a dispensing bench of at least 0.6 m² (e.g. 1000 mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, and a dedicated printer for labels?

YES	NO
☐	☐

19. Will each dispensing station include or be convenient to a printer that prints Consumer Medicine Information (CMI)? *(The CMI printer may serve multiple dispensing stations).*

YES	NO
☐	☐

DEPARTMENT DISPENSARY SIZE

The area set aside for each of the functional areas in a pharmacy department should be keeping with the level of service to be provided by the department and the needs of the hospital in which it operates.

In considering the area required for a pharmacy department, the Authority has regard to:

1. the level classifications described in the New South Wales Department of Health's Guide to the Role Delineation of Health Services;
2. the Australasian Health Facility Guidelines Part B Health Facility Briefing and Planning 0560 Pharmacy Unit : https://healthfacilityguidelines.com.au/health-planning-units
3. the Authority's experience; and
4. the relevant parallels with community pharmacies.

The Authority requires appropriate space to be allocated to all functional areas such as the dispensing area, offices, staff amenities, bulk storage, clinical trials, drug information, intravenous and/or cytotoxic preparation areas.

Based on 1-4 (above), the minimum dispensary area (i.e. the area allocated for dispensing only) as appropriate to departments fitting the levels described in Appendix 3 are:

Level 3:	45 m^2
Level 4:	85 m^2
Levels 5 and 6:	180 m^2

The Authority, at its discretion may approve a smaller dispensary area provided the hospital can demonstrate to the Authority's satisfaction that it is appropriate for the needs of the hospital and in the public interest. Conversely, the Authority may decline to approve an area meeting the minimum requirements if it considers that they are insufficient for the range or type of services required.

20. Will the dispensary area of the department occupy at least (Refer question 7 - mark one box only):

- **45m^2 if the service provided is classified as level 3**

YES ☐ **NO** ☐

Or

- **85m^2 if the service provided is classified as level 4**

YES ☐ **NO** ☐

Or

- **180 m^2 if the service provided is classified as level 5 or 6**

YES ☐ **NO** ☐

COUNSELLING AREA

A distinct area is required that permits the pharmacist to discuss any matter with a member of the public on a private and confidential basis. The area must be positioned such that any conversations are out of the hearing of other persons. Care must also be exercised in ensuring that third parties do not see a patient's medicines, the packaging of which is indicative of the medicines' identity and potentially its purposes.
Dedicated prescription reception and counselling points fitted with opaque privacy screens that rise to at least 600 mm above the bench to form a booth or that are otherwise arranged or located to provide privacy are required. There should be as many counselling points as there are dispensing stations. They should be designed to encourage routine use for all prescription transactions. A password- protected screen and keyboard is recommended in each.A separate room or office may also be used for the above purposes and for the provision of extended services such as disease screening, prolonged consultations or structured patient programs that, to be effective require privacy and freedom from interruptions. Pharmacists should determine if a level of privacy, as achieved in a counselling room, is required to undertake the more extensive professional activities, compared with the level of privacy that can be achieved at a screened counter for the more routine patient interactions.

21. Will there be a dedicated prescriptions reception and counselling point for each dispensing station used to dispense prescriptions for clients who attend the pharmacy department to collect their medicine?

YES	NO	N/A
☐	☐	☐

(Tick N/A if clients do not attend the pharmacy department)

22. Will the dedicated prescription reception and counselling points be fitted with opaque privacy screens rising not less than 600 mm above the bench to form a privacy booth or be otherwise arranged or situated to provide privacy?

YES	NO	N/A
☐	☐	☐

(Tick N/A if clients do not attend the pharmacy department)

DRUG CABINET - SCHEDULE 8 POISONS – STORAGE

Schedule 8 poisons (Controlled Drugs) are to be stored in accordance with the Drugs, Poisons and Controlled Substances Regulations 2017.

The increased use of Schedule 8 poisons (including substitution therapies) and bulkier packaging indicate the need for installing safes or lockers that are large enough to store all S8 poisons on hand (taking into account future needs) and to facilitate accurate selection of the medicines from the safe or locker. Unwanted or expired stocks of S8 poisons or identifiable returned stock from the public must be stored securely pending their destruction.

Specifications about drug safes or lockers are available from locksmiths and safe manufacturers. The safe or locker must meet at least the minimum standards prescribed under the Drugs, Poisons and Controlled Substances Regulations 2017 and installed in accordance with the Regulations to ensure that it cannot be removed easily.

Bulk quantities of "in use" substitution therapies that are administered to patients attending the pharmacy need to be located so that they are inaccessible to, and preferably out of sight of, the patient.

Keys to the Schedule 8 poisons safe must not be left on the premises overnight, unless they are stored in a safe of at least equivalent security to the Schedule 8 safe and to which pharmacists have exclusive access. In most cases, this will be a safe fitted with a combination lock or a keypad, the codes to which will be limited to pharmacists.

Expert advice received by the Department indicates that the requirement to be securely attached is satisfied by –

a) HARD CORE WALL: The cabinet to be secured by use of four (4) Loxin or Dyna Bolts, each 10mm by 50mm minimum.

b) STUD AND PLASTER OR HOLLOW BLOCK: The cabinet to be secured by use of four (4) 10mm coach bolts through wall and through 3mm mild steel backing plate. This backing plate must, at minimum, be the same size as the back of the drug cabinet.

23. Will the dispensary area of the department include a drug safe for the storage of S8 poisons that facilitates the accurate selection of medicines?

YES ☐ NO ☐

24. Will the drug cabinet be attached in accordance with the Drugs, Poisons & Controlled Substances Regulation 2017?

YES ☐ NO ☐

CONTROLLED TEMPERATURE STORAGE

Guideline
Pharmacies and pharmacy departments are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range.
Temperatures in a pharmacy or pharmacy department should not exceed 25ºC; to this end, thermostatically controlled air conditioning or cooling by other means is necessary unless the premises are so situated or constructed as not to allow this temperature to be exceeded. Air conditioners should be set to maintain temperatures not exceeding 25ºC during periods when the pharmacy is not open for business.
Temperatures may vary considerably between different parts of a refrigerator.

A continuously reading thermometer is required with the sensor (known as a data logger) connected to the computer (or functionally similar arrangements) to alert staff to any malfunction when the premises are unoccupied and provide sufficient information to allow the effect of the malfunction on the integrity of the medicines to be assessed.

Refrigerators used to store medicines should be dedicated to this purpose.

Due regard must be paid to maintaining the integrity of the "cold chain" when stock is received and before it is supplied. It follows that the patient or agent should be informed of the storage conditions both verbally and by labelling.

25. Will all medicine storage areas be serviced by a thermostatically controlled air-conditioner able to maintain storage temperatures not exceeding 25ºC at all times?

YES ☐ NO ☐

26. Will the dispensary area of the department be equipped with a refrigerator dedicated to the storage of medicines?

YES ☐ NO ☐

27. Will the refrigerator dedicated to the storage of medicines be fitted with a continuously reading thermometer connected to a computer (or functionally similar arrangements) to alert staff to any refrigerator malfunction?

YES ☐ NO ☐

SECURITY

Pharmacy department are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls and ceilings.

28. Will an electronic intruder alarm be fitted that conforms to Australian Standard 2201: Intruder Alarm Systems?

YES ☐ NO ☐

29. Will the electronic alarm sensors cover the perimeter of the pharmacy department and all areas where medicines are kept including the department, Schedule 8 cabinet or safe, rooms used to store dispensed medicine for packing into dose administration aids, the professional service area and storerooms?

YES ☐ NO ☐

30. Will the electronic alarm be control room monitored by central agency or dedicated hospital security staff on a 24 hours 7 days a week basis?

YES ☐ NO ☐

31. If the alarm is monitored by an external agency, will the agency hold a security firm licence?

YES ☐ NO ☐

32. If the alarm is monitored by an external agency, will the agency have facilities that conform to Australian Standard 2201.2 Intruder Alarm Systems – Monitoring Centres Grade 1, 2 or 3?

YES ☐ NO ☐

33. If the building permit permits, will each perimeter door be fitted with a lock that prevents the door from being opened by hand from the inside when the premises are not lawfully occupied, OR if such locks are not permitted, will other measures be in place to prevent entry through roofs or ceilings such as floor to roof walls or ceiling space alarm sensors?

YES ☐ NO ☐

34. Will perimeter doors which open to secluded or non-public areas be roller shutters or be constructed of solid core and fitted with heavy gauge metal sheeting or protected by a substantial metal security grille door?

YES ☐ NO ☐ N/A ☐

35. Will perimeter windows to secluded or non-public areas be fitted with bars or security grilles or otherwise secured eg by the use of 'security or bullet proof glass'.

YES ☐ NO ☐ N/A ☐

36. Will skylights be fitted with bars or security grilles?

YES ☐ NO ☐ N/A ☐

SALES COUNTERS

Pharmacy Regulation Act 2010 Schedule para 9(h):
Adequate arrangements are to be in place to ensure that the identity of a medicine being supplied or dispensed to a client of a pharmacy cannot be known by another person present in the pharmacy who is not a person carrying on the pharmacy business or a member of staff of the business

.

37. If prescription medicine is collected at a public counter is the counter arranged to ensure that the identity of a medicine being collected cannot be known by another client at the counter?

YES ☐ NO ☐ N/A ☐

(Tick N/A if clients do not attend the pharmacy department)

DISPLAY OF NAMES

The name of the pharmacist who is regularly and usually in charge of the pharmacy department is to be displayed at the place where medicines are usually collected by the public (if the department supplies medicine directly to patients).

38. Will the Director of Pharmacy's name be clearly displayed at all public interfaces with the department?

YES	NO	N/A
☐	☐	☐

STATUTORY FEE

A statutory **fee** is required to accompany this application.

DECLARATION:

I hereby declare that the information provided in this application for Registration of Pharmacy Premises is true and correct -

Signature: .....

Position: .....

Dated: ..... / / .....

PAYMENT DETAILS

A **fee** of **$525.00** is required to accompany this application. This fee amount is valid for the period **1 May 2019 to 30 April 2020**.

Payment method (*Please tick* ☑)

CHEQUE ☐ Payable to **Victorian Pharmacy Authority**

MONEY ORDER ☐

CREDIT CARD (CC) ☐

VISA OR MASTERCARD ONLY – COMPLETE DETAILS:

VISA or MASTERCARD (Please circle)

Name on credit card ……..…

Credit Card Number:

☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

EXPIRY DATE ☐☐ / ☐☐

CVV ☐☐☐

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