PHARMACY BOARD OF VICTORIA

guidelines

for good pharmacy practice

2010

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PART 1
FOREWORD

This document operates from 1 January 2010 and replaces Guidelines for Good Pharmaceutical Practice 2004, as amended.

1.1 HEALTH PROFESSIONS REGISTRATION ACT 2005

The *Health Professions Registration Act 2005* ("the Act") is an Act of the Victorian Parliament replacing individual registration acts that have regulated at least some of the health professions for well over a century. The Act unifies many of the regimes governing registration, the complaints process, investigations, hearings and discipline that, under the former separate enactments, were similar but not the same.

Each Board continues its separate existence and composition as it was established under each of the immediate previous enactments, which in the case of pharmacy, was the *Pharmacy Practice Act 2004*.

Despite the commonality that pervades the Act, Part 6 is devoted to pharmacy with particular emphasis placed on the ownership and operation of pharmacy businesses and pharmacy departments.

This document for the guidance of pharmacists has been written to assist them in complying with the Act and related purposes.

In this document:

- "the Act" means the *Health Professions Registration Act 2005*
- "the Board" means the Pharmacy Board of Victoria.

Section 118(1) of the Act lists the functions of the health registration boards. Among these is "to issue and publish codes for the guidance of registered health practitioners regulated by the board and registered students regulated by the board about standards recommended by the responsible board relating to the provision of regulated health services and about professional performance".

This document advises pharmacists about:

- the Board's interpretation of certain aspects of the Act;
- how the Board exercises its discretion under the Act;
- the Board's determinations of minimum standards of good practice; and
- how the Board expects the duties and responsibilities of pharmacists may be best observed.

The Board recognises that there might be different yet acceptable ways of meeting its guidelines but these may require justification especially if the wellbeing of the public is jeopardised.

1.2 PRACTICE STANDARDS

The Board takes into account the following Guidelines and Standards that are published in the *Australian Pharmaceutical Formulary and Handbook,* 20th and 21st editions.

- Code of Professional Conduct
- Dispensing Practice Guidelines
- Guidelines for Pharmacists on PBS Brand Substitution
- The Professional Role of Pharmacists in Assisting Self-Medication by Consumers
- Guidelines for Pharmacists on Providing Medicines Information to Patients
- Consumer Medicines Information and the Pharmacist
- Guidelines for Pharmacists for Concordance Assessments
- Pharmacists and the Commonwealth Privacy Legislation
- General Practitioners' and Pharmacists' Interprofessional Communication
- Guidelines for Pharmacists on Domiciliary Medication Management Reviews (or Home Management Review); the Framework Document for Domiciliary Medication management Review (or Home Medicines Review); and Occupational Health & Safety Issues When Conducting Home Medicines
- The Provision of Pharmacy Services to Residential Aged Care Facilities
- Comprehensive Medication Reviews in Residential Aged Care Facilities
- Supply of Levonorgestrel as a Pharmacist Only Medicine for Emergency Contraception
- Provision of Oral Fluconazole as a Pharmacist Only Medicine for the Treatment of Vaginal Candidiasis
- Provision of Orlistat as a Pharmacist Only Medicine
- SHPA Standards of Practice for the Provision of Consumer Medicine Information by Pharmacists in Hospitals
- SHPA Standards of Practice for the Community Liaison Pharmacist
- SHPA Guidelines for Self-Administration of Medication in Hospitals and Residential Care Facilities
- SHPA Standards of Practice for Parenteral Therapy in Home Health Care

- SHPA Standards of Practice for the Provision of Clinical Oncology Pharmacy Services
- SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments
- SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments
- Guidelines for Counselling Patients Receiving Drugs Used in the Treatment of Neoplastic Disease
- Australian Guidelines for Drug Donations to Developing Countries
- Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy

The Board also has regard to:

- Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia
- Dose Administration Aids Services – Standards – Pharmaceutical Society of Australia
- Quality Care Standards – The Pharmacy Guild of Australia

PART 2
REGISTRATION

2.1 CATEGORIES OF REGISTRATION

2.1.1 General registration (Section 6)

General registration is required by pharmacists seeking to provide pharmacy services in Victoria. The period of general registration period is up to 12 months and expires 31 December annually. The registration fee structure and procedures for lodging an application are outlined on the 'Application for Registration' form. The information in this section outlines the process for persons lodging their first application for general registration in the State of Victoria, the granting of interim registration status and the process of lodging an application for renewal of general registration.

Qualifications for general registration (Section 5)

To qualify for general registration in Victoria prior to lodging his/her application for registration in Victoria, a person is required to have met the requirements under Section 5 of the Act regarding education, training and competency assessment. The Board may grant initial general registration to persons who obtained the necessary qualifications in Victoria or in other jurisdictions and to pharmacists registered in other jurisdictions or countries.

Policy

To be an eligible candidate for general registration to provide pharmacy services in Victoria, a person (other than a person newly qualified for general registration) must have provided the same pharmacy services within the previous two years in a jurisdiction where mutual recognition applies (within Australia or New Zealand). Pharmacists who do not meet this requirement may be required by the Board to undertake supervised practice and/or education courses and/or assessment to ensure competence to provide pharmacy services in Victoria.

Professional indemnity insurance (Sections 6(3) & 13)

Refer to 2.2.1 of this document for details of the Board's minimum terms and conditions regarding professional indemnity insurance cover for pharmacists seeking registration in Victoria. An applicant for general registration is required to declare on a registration application form that he/she meets the Board's minimum terms and conditions for professional indemnity insurance.

Provision of information (Section 34)

Damages or other compensation paid by pharmacists:

In accordance with section 34(2)(a) of the Act, if a person has claimed damages or compensation from a registered pharmacist for alleged negligence in the course of providing pharmacy services, the pharmacist must provide the Board with information about the amount of damages or other compensation he/she is ordered to pay by a court within 30 days after the order is made, unless the court ordered that the terms of the order should not be disclosed.

Policy

For the purpose of section 34(2)(a), regarding the amount of damages or other compensation a pharmacist is ordered to pay by a court for alleged negligence in the course of providing pharmacy services, pharmacists are required to notify the Board of details of any payment ordered by a court in excess of $10,000, unless the court ordered that the terms of the order should not be disclosed.

Indictable offences

In accordance with section 34(3), if a registered pharmacist has in respect of an indictable offence, been committed for trial or been convicted or found guilty of the offence, the pharmacist must notify the Board within 30 days after the committal for trial, conviction or finding of guilt.

Changing pharmacy services or not providing pharmacy services for a period of more than 2 years

In accordance with section 34(4), a pharmacist (other than a non-practising pharmacist) must as soon as practicable, notify the Board if he or she has not provided pharmacy services for a period of more than two years or if he or she intends to change the type of pharmacy services he or she provides on a regular basis. Details of training which ensures competence must be provided to the Board if a pharmacist intends to provide those pharmacy services during the period of registration.

Note: *One example of changing pharmacy services which obliges a pharmacist to notify the Board under section 34(4) is a pharmacist working in the pharmaceutical industry for more than two years, who intends to return to community or hospital practice. In this case, the pharmacist will not have dispensed medicines, provided primary healthcare and will therefore be required to undertake appropriate training under supervision until he or she is competent to provide these pharmacy services.*

Provision of information – change of personal details

Changes in personal details must be notified to the Board within 14 days. Pharmacists should ensure that up-to-date contact details are provided to the including their address which is recorded on the register.

Types of applicants for general registration:

1. **Applicants who completed their qualifications and are seeking their initial registration as a pharmacist** – Graduates of approved courses in

pharmacy practice who completed the requirements for initial general registration in accordance with the Board's requirements as outlined on the Board's website and in these Guidelines.

2. **Overseas qualified pharmacists from countries other than New Zealand** – To be eligible for general registration in Victoria, applicants must have
   - had their credentials assessed by the Australian Pharmacy Council (APC) as meeting the course of study requirement of section 5(a) of the Act; and
   - completed the APC requirements for registration

as outlined in the APC process for registration.

1. **Pharmacists registered in Australia** – Current registration in another Australian State or Territory entitles a pharmacist to lodge an application for **equivalent** registration under the Mutual Recognition Acts of the Commonwealth, States and Territories of Australia. Applicants must follow the procedures outlined on the 'Application for Registration' form which includes providing a suitable form of identification and evidence of current equivalent registration in Australia. Applicants should also refer to the information regarding recent practice experience under pharmacy services and the above policy regarding eligibility for general registration.
2. **Pharmacists registered in New Zealand** – Current registration in New Zealand entitles a pharmacist to lodge an application for registration under the Trans-Tasman Mutual Recognition Act.

Policy

From 1 September 2007, to be eligible for general registration to provide pharmacy services in Victoria, a person registered as a pharmacist in New Zealand must:

- **hold current registration with the Pharmacy Council of New Zealand**
- **lodge an application for provisional registration and provide certified copies of current photo identification and registration with the Pharmacy Council of New Zealand**
- **undertake at least 152 hours of supervised practice in a community pharmacy or hospital pharmacy department in Victoria under the supervision of a pharmacist approved by the Board**
- **after completion of the period of supervised practice, demonstrate to an Officer of the Board during an interview, that he or she has a practical understanding of the legislation and guidelines affecting the practice of pharmacy in Victoria**

Note:

- *during the period of supervised practice, the applicant must hold provisional registration status*
- *supervised practice must be undertaken in accordance with the conditions of supervised practice as specified by the Board in its policy of supervised practice*
- *the applicant must ensure that the pharmacist with whom it is intended to have that experience and the premises is acceptable to the Board for that purpose*
- *the applicant must provide evidence that he or she has undertaken the period of supervised practice prior to the assessment interview.*

Applicants must follow the procedures outlined on the 'Application for Registration' form which includes providing a suitable form of identification and evidence of current registration with the Pharmacy Council of New Zealand. An applicant must attend the office in person to lodge their application form. Applicants should also refer to the information regarding recent practice experience under pharmacy services and the above policy regarding eligibility for general registration.

Interim registration (Section 10)

Interim registration is granted by the Registrar, to an applicant who has lodged an application for general registration (that entitles the applicant to general registration) who meets the requirement regarding professional indemnity insurance. The Registrar may also impose conditions on the interim registration of a pharmacist. The Registrar may refuse to grant interim registration and refer the application to the Board for its consideration at its next meeting.

A person who is granted interim registration (which is taken to have been granted by the Board) is for all purposes taken to be a registered pharmacist from the date on which interim registration was granted. A person's interim registration is in force until the application has been considered at a meeting of the Board and the applicant has been given notice of the Board's decision. The Board may grant registration or if the Board is of the opinion that the person is no longer entitled to registration, refuse registration and cancel the interim registration. The Board may also notify the person's employer if interim registration is cancelled.

2.1.2 Renewal of registration (Section 18)

An application for renewal of registration is sent to all registered pharmacists. A pharmacist may apply for renewal of registration by returning the application by post or by lodging an application online via the Board's website.

Registration Period

To renew registration until 31 December, a pharmacist must lodge an application for registration with payment of the renewal of registration fee before the existing registration period expires.

Policy

The dates of expiry of the different categories of registration are:

General registration	**31 December annually**
Non-practising registration	**31 December annually**
Specific registration	**Specified by Board for each applicant**
Provisional registration	**Two years from the date the application was received**

Failure to lodge application by the due date – An applicant who fails to apply to renew their existing registration by the due date may apply to have his or her name retained on the register. An applicant must lodge his or her application, with payment of the annual renewal of **registration fee and late payment fee**, no later than three months after the due date. If a pharmacist fails to lodge an application in time, the Board will remove his or her name from the register. If subsequently requiring registration, a person is required to apply to have his or her name restored to the register provided that the eligibility criteria for the type of registration required is met.

Failure of pharmacists (other than non-practising pharmacists) to ensure competence to provide pharmacy services – Pharmacists renewing general registration have a responsibility to ensure they are competent if providing pharmacy services. This is further detailed in 2.2 of this Part.

If a pharmacist cannot provide evidence of competence when applying for renewal of general registration due to a lack of practice experience or training, his or her application to maintain general registration may be approved with conditions imposed or denied.

If the Board's decision to deny an application is not altered upon reviewing its decision at the request of the applicant or upon consideration of a submission from the applicant, to pursue registration, the applicant will be required to follow the procedure outlined under 2.2.6 of this document.

Rejection of an application for renewal of registration / imposing conditions on a pharmacist's registration – A pharmacist whose application for renewal of registration is to be rejected or a pharmacist who is to have conditions imposed on his/her registration will be notified by the Board within 28 days. He or she may:

(i) obtain a review of the decision;

(ii) make a submission to the Board; and / or

(iii) meet with the Board's Registration and Education Committee to have their application assessed for the purpose of determining whether any requirements should be set by the Board before renewing the applicant's registration. This may include completion of courses, supervised

training and/or assessment. An assessment, if conducted will also be at the expense of the applicant.

Note: *Applicants who are not satisfied with the Board's final decision after a review of its decision, may apply to Victorian Civil and Administrative Tribunal (VCAT) within 28 days for a review of the decision.*

2.1.3 Non-practising registration (Section 11)

Qualifications for non-practising registration

A person who previously met the requirements for general registration may apply to register as a non-practising pharmacist.

An applicant for non-practising registration may be:

1. a pharmacist who currently holds or is eligible to hold general registration who will not be providing pharmacy services in Victoria;
2. a pharmacist holding general registration who does not meet the competence requirements to provide pharmacy services; or
3. a person no longer registered as a pharmacist in Victoria or other Australian State or Territory or New Zealand.

An 'Application for Registration' must be lodged in accordance with the procedures outlined on the application form which includes providing a suitable form of identification and evidence of qualification for non-practising registration which may be evidence of current registration in Australia or New Zealand. The registration period is no longer than 12 months and expires on 31 December annually.

Obligations of pharmacists holding non-practising registration

Pharmacists holding non-practising registration have the following obligations:

- to comply with the conditions of non-practising registration outlined in section 11(2) of the Act (not to practise as a pharmacist or provide pharmacy services during the period of registration and any other conditions imposed on the applicant by the Board)
- in the case of proprietors, to comply with the Board's guideline on public liability insurance (see below).

Insurance – A non-practising pharmacist is not required to hold professional indemnity insurance cover although proprietors who are registered as non-practising pharmacists are required to meet the Board's policy regarding public liability insurance cover.

Policy

A proprietor who is registered as a non-practising pharmacist must hold public liability insurance cover with a minimum cover in the amount of $10 million.

Non practising pharmacists seeking to return to practice – A pharmacist who holds non-practising registration may apply for general (practising) registration. To be granted general registration, an applicant must meet the requirements outlined under 2.2.8 of this document.

2.1.4 Specific registration (Section 7)

If a person is not eligible for general registration, he/she may apply for specific registration. An application in writing to the Registrar must be lodged, outlining the reasons why specific registration is required and accompanied by any documentary evidence supporting the application. If specific registration is in the public interest and is granted, the Board will specify the conditions imposed on the pharmacist's specific registration, which remain valid for the period specified by the Board.

The requirement regarding professional indemnity insurance cover outlined under 2.2.1 of this document must be met by an applicant granted specific registration.

2.1.5 Endorsement of registration (Section 26 & 29)

The Board may endorse the registration of a pharmacist to obtain and have in his/her possession, to use, sell or supply (but not prescribe), Schedule 1 poisons within the meaning of the *Drugs, Poisons and Controlled Substances Act 1981*. This is subject to the pharmacist providing evidence of successful completion of a course of study, a period of supervised practice and an examination which in the opinion of the Board qualifies the pharmacist and determines the pharmacist to be competent to possess, to use, sell or supply Schedule 1 poisons.

The Board may impose any condition on endorsement. Endorsement continues for the period of a pharmacist's registration.

Applicants are required to lodge an application form for endorsement of registration (available from the Board's office or on the Board's website) in accordance with the procedure outlined on the application form.

2.1.6 Recognition of additional qualifications (Section 12)

Policy

In addition to the qualification required for registration, the Board recognises the following additional qualifications, considered relevant to the provision of pharmacy services, which registered pharmacists may seek to have noted against their name on the Register:

(i) Graduate Diploma in Community Pharmacy

(ii) Graduate Diploma in Hospital Pharmacy

(iii) Fellowship of the Society of Hospital Pharmacists

(iv) Masters in Clinical Pharmacy

(v) Other post-graduate qualifications provided that the holder of the qualification satisfies the Board that the qualification is relevant to the provision of pharmacy services.

Note: *This list may be periodically updated by the Board. An updated list is available for inspection at the Board's office and is published on the Board's website.*

The applicant is required to lodge an application for registration of additional qualifications (available from the Board's office or on the Board's website) in accordance with the procedure outlined on the application form.

Note: *One application may include a request for recognition of more than one qualification and requires payment of only one fee.*

2.1.7 Registration of Victorian pharmacists in other countries

Victorian registered pharmacists seeking to register in other countries are required to make direct application to the relevant registering authorities. Pharmacist requiring evidence of registration or a letter of good standing from the Board to provide to a registering authority or other body may apply to the Board for a 'Certificate of Identity' by lodging a 'Request for a Certificate of Identity' form (available from the Board's office or on the Board's website) in accordance with the procedures outlined on the form.

2.1.8 Registration of Victorian registered pharmacists in other Australian States or Territories or in New Zealand

A Victorian registered pharmacist may seek registration in other Australian States or Territories or in New Zealand under a Mutual Recognition Act.

Applicants should contact the relevant registering authorities regarding procedures and requirements for seeking registration in other jurisdictions. Evidence of current Victorian registration is provided to registered pharmacists in the form of an annual registration card.

2.2 REQUIREMENTS FOR PRACTICE

2.2.1 Professional indemnity insurance (Section 13)

Requirements for professional indemnity insurance for pharmacists are set out in the *Health Professions Registration Act 2005* (the Act) under sections 4 (3)(d), 6 (2)(h), 6 (2), 6 (3), 13 (1), 13 (2), 7 (5) and 18 (3).

The Board has developed the following guidelines to ensure that, at all times whilst practising as a pharmacist, pharmacists are covered by at least the minimum terms and conditions of professional indemnity insurance determined by the Board.

These guidelines apply to ALL pharmacists registered in the general registration category.

2.2.1.1 Undertakings prior to registration

All applicants for registration are required to provide the Board with the following undertakings before registration will be granted:

c. At all times during practice, the applicant must comply with these **Guidelines for Mandatory Professional Indemnity Insurance**';
AND

d. That:
   – at the time of application, the applicant certifies that he/she will obtain individual professional indemnity insurance approved by the Board within 7 days of applying for registration, and
   – the applicant further certifies that he/she will not commence practice as a pharmacist until his/her professional indemnity insurance is in place;
   AND

e. At all times during practice, the applicant will be covered by an approved level of professional indemnity insurance.

2.2.1.2 Risk & practitioner responsibility

Pharmacists must, in consultation with their insurer/insurance broker, identify the risk exposure associated with their practice, and outcomes linked to long term care factors and ensure that they have cover which at least meets the minimum limit of indemnity specified by the Board.

Pharmacists intending to cease to practise or change insurance provider should also obtain their own advice about how much run off cover they require to ensure they are covered for claims brought against them many years later, i.e. how they are affected by the relevant legal limitation periods within which their former clients may sue them.

It is the responsibility of the pharmacist to:

- Examine the insurance policy to ensure that the cover obtained provides appropriate protection for risks arising from their provision of pharmacy services;
- Ensure that the Schedule describes, if necessary, any activities carried on which are outside the cover described in the policy, for example:
  – Compounding activities not exempt under the *Therapeutic Goods Act 1989*
  – Supply to clients outside of Australia

2.2.1.3 Approved level of cover

All pharmacists are required to:

- hold an individual policy for professional indemnity insurance which at least provides for the minimum level of cover prior to commencing practice as a pharmacist, AND
- maintain an 'approved' level of cover at all times during practice.

'Approved' level of cover

Currently, the Board has determined that the approved level of cover (i.e. the minimum sum insured limit of professional indemnity insurance required by the Board) is:

> *no less than $20 million cover for any single claim (i.e. for each claim) that may be made against the pharmacist.*

The Board reserves the right to vary the approved level of cover at registration renewal. Registrants must be covered by their own professional indemnity insurance policy.

2.2.1.4 Currency of insurance

All registrants must ensure that their professional indemnity insurance is current for their entire period of registration.

On application for renewal of registration, the applicant will be required to certify that they have individual professional indemnity insurance in their name which at least meets the minimum limit of indemnity specified by the Board.

On the request of the Board, the practitioner must provide, within 14 days, the full policy wording to enable the Board to determine whether an applicant has professional indemnity insurance that satisfies the Board's requirements.

2.2.1.5 Run off cover

All pharmacists must ensure appropriate provision for an unlimited number of years of run off cover should they cease to practise or change insurance provider. Some policies have run-off cover incorporated and pharmacists must ensure they meet the requirements for access to the run-off cover at the time they cease practice. In other cases pharmacists may need to maintain ongoing insurance.

2.2.2 Pharmacy services

Types of pharmacy services

The Act provides the following definition:

> "pharmacy services" includes —
> (a) the supply, compounding or dispensing of medicines; and
> (b) advice and counselling on the effective and safe use of medicines;

The Board acknowledges that pharmacists with general registration may provide one or more of the following pharmacy services:

- Promote and contribute to optimal use of medicines
- Dispense medicines
- Prepare pharmaceutical products
- Provide primary health care
- Provide medicines and health information and education

These are derived from and defined in the 'Competency Standards for Pharmacists in Australia 2003.' (Pharmacists are advised refer to this document for further details).

The Board acknowledges that a pharmacist may be able to identify that he or she provides other pharmacy services which the above do not encompass.

When applying for registration or renewal of registration, a pharmacist is required to describe the types of pharmacy services he or she intends to provide and types of pharmacy services he or she provided during the previous two years. A pharmacist may only provide pharmacy services which he or she is competent to provide.

Providing pharmacy services in other jurisdictions

When assessing applications for renewal of general registration, the applicant's practice history during the previous two years is assessed to determining eligibility for general registration in Victoria.

Policy

To be eligible to renew general registration, the applicant must have practised in a jurisdiction where mutual recognition applies, within the previous two years.

Pharmacists who have not practised within Australia or New Zealand during the two years prior to lodging an application for renewal of general registration may be required to undertake requirements outlined under 2.2.6 and 2.2.8 of this document.

When assessing a registration application for general registration under a Mutual Recognition Act, whether or not the applicant has practised within the previous two years in a jurisdiction where mutual recognition applies will be considered to determine his/her eligibility for general registration. If the applicant has not practised within Australia or New Zealand during the two years prior to lodging an application for general registration, the Board may require the applicant to undertake training and/or assessment or to follow the procedures outlined under 2.2.6 of this document.

2.2.3 Competence to provide pharmacy services

Upon entering the profession as an initial registrant, a pharmacist is deemed competent to provide a range of pharmacy services. A pharmacist can maintain competence through continued practice and professional development.

In time, a pharmacist may limit the range of pharmacy services he/she provides, which may be specific to a chosen practice area. Some pharmacy services are specialised services, which require a pharmacist to undertake further training and education to maintain competence.

If a pharmacist does not provide one or more pharmacy services for more than two years, he/she is required to undertake training to ensure competence to provide the pharmacy service(s). Training is also required when new

pharmacy services are provided. In accordance with section 34(4) of the Act, pharmacists are obliged to notify the Board of such circumstances. Procedures for this are outlined under 2.2.6 of this document.

2.2.4 Maintaining competence to provide pharmacy services

The public expects pharmacists to provide pharmacy services as competent professionals. In the public's interest, pharmacists must take the necessary steps and use appropriate tools to maintain competence to provide pharmacy services relevant to their practice. The Board's functions include initiating programs that it considers will improve pharmacists' ability to practise as pharmacists and to protect the public from those pharmacists.

Practising

Practising is one aspect of maintaining competence to provide pharmacy services. The Board's minimum practice requirements for providing pharmacy services, which apply to any pharmacist registered to practise in Victoria (or renewing registration) or a pharmacist seeking to register in Victoria are outlined in its policy below.

Training

In accordance with Section 18 of the Act, a pharmacist seeking renewal of general registration must provide to the Board, information regarding the type of pharmacy services he/she intends to provide, and details of new pharmacy services he/she has been providing in the existing registration period or intend to provide in the ensuing period of registration. In the case of providing new services, the Board requires details of the training undertaken or the proposed training to ensure competence to provide those services.

Undertaking continuing professional development

The Board may also require pharmacists to provide details of any continuing professional development (CPD) undertaken during a period of registration.

Overall, a pharmacist must assess their competence to provide their chosen pharmacy service(s) by assessing their:

(i) recent practice experience;

(ii) individual training needs (which may or may not be required); and

(iii) participation in CPD and the outcomes of their participation in these activities.

If a pharmacist fails to achieve competence to provide a particular pharmacy service and wishes to provide that service, he/she must undertake the procedure outlined below under 2.2.7 'Failure to achieve competence to provide a pharmacy service.'

Policy

To provide a type of pharmacy service, a registered pharmacist should demonstrate competence to provide the service(s) by:

(i) having provided that pharmacy service during the previous two years and/or
(ii) undertaking or having undertaken training to ensure he/she is competent to provide any new pharmacy service and /or
(iii) undertaking continuing professional development.

2.2.5 Loss of competence to provide pharmacy services

The loss of competence to provide a type of pharmacy service commonly involves the pharmacist's absence from practice and/or insufficient professional development as described in the following circumstances:

(i) a pharmacist does not provide pharmacy services for more than two years

(ii) a pharmacist does not maintain involvement in sufficient continuing professional development expected to maintain competence to provide a particular pharmacy service

(iii) a pharmacist moves into a particular practice area, limiting their range of pharmacy services

(iv) a pharmacist ceases to practise and does not renew their registration

(v) a pharmacist's name is removed from the register after a determination of the Board

(vi) a pharmacist elects to register as a non-practising pharmacist

2.2.6 Ensuring competence to provide a pharmacy service in Victoria

Before providing pharmacy services in Victoria, a pharmacist who has not provided one or more pharmacy services for more than two years, is required in accordance with section 34(4) of the Act, to advise the Board of the details of training or proposed training that he/she has or will undertake to ensure competence to provide pharmacy services in Victoria. Similarly, in cases where a pharmacist has practised outside of Australia or New Zealand for more than two years, he/she may also be required to undertake training to ensure competence to provide pharmacy services in Victoria. In cases where details of training undertaken or proposed training are not considered by the Board to be sufficient to ensure competence, a pharmacist is required to follow the procedure outlined below.

Procedure

a) Contact the Board office

b) If directed to do so, make an appointment with the Board's Registration and Education Committee for an interview. At the interview, the committee will take into consideration, the applicant's practice history and any efforts made to keep their pharmaceutical knowledge and knowledge of practice up-to-date, before making a recommendation to the Board regarding the

requirements that must be undertaken before the person may provide the relevant pharmacy service(s). The Board may set requirements to be undertaken by an applicant which may include a period of retraining under the supervision of an approved pharmacist, completion of a course of study and/or an examination.

c) If undertaking a period of retraining, the person may be instructed to:
   (i) Undertake the period of retraining which is conducted in accordance with requirements detailed under 3.2.1 of this document, including lodging an application for approval of preceptor and premises prior to commencement of retraining
   (ii) Provide documentary evidence of completion of retraining in the form of a training record book signed by the preceptor (prior to presenting for assessment / examination).

   Note *A candidate may be accepted to work less than the minimum 90 hours per 3 week period required of candidates seeking initial registration in Victoria.*

d) If undertaking a course of study, the person must provide documentary evidence of satisfactory completion of that course (prior to presenting for assessment / examination).

e) If undertaking an examination / assessment, the person must
   (i) pay any applicable examination / assessment fee to the Board prior to the due date set by the Board for examination / assessment
   (ii) satisfy the examiners that he/she is competent to practise.

   Note: *If the person fails to satisfy the examiners of his/her competence, he/she may be required by the Board to complete additional requirements prior to providing pharmacy services.*

2.2.7 Failure to achieve competence to provide pharmacy services

If a pharmacist does not meet the requirements set by the Board to achieve competency to provide any pharmacy services and does not wish to continue in their pursuit to achieve competence, a pharmacist cannot provide pharmacy services or be granted general registration. The pharmacist may choose one of the following options:

(i) Not seek registration; or

(ii) Apply for registration as a non-practising pharmacist.

2.2.8 Restoration of name to the Pharmacists Register in Victoria / returning to practice in Victoria

A person whose name previously appeared on the Pharmacists Register in Victoria and who failed to or chose not to renew there registration may apply to have his/her name restored to the register with either general

(practising) registration or non-practising registration. The procedures for restoration of name vary depending on the type of registration (general or non-practising) being sought by the applicant and the applicant's particular circumstances (e.g. work history or registration held in other jurisdictions).

Alternatively, a person may be currently registered in Victoria:

(i) having maintained non-practising registration in Victoria and now requires general registration to return to practice in Victoria; or

(ii) having maintained general registration in Victoria and did not practise locally for more than two years.

In the case of applicants requiring general registration to practise in Victoria, the applicant's most recent practice experience is taken into consideration by the Board including the jurisdiction of past practice. The Board may require the applicant to demonstrate competence to provide pharmacy services in Victoria by undertaking training, study and/or assessment. Alternatively, having practised in another jurisdiction may be accepted by the Board as being appropriate to return to practice in Victoria.

The following outlines the different categories of applicants seeking to return to practice in Victoria and the Board's requirements in each case:

Category 1 Applicants who provided pharmacy services during the previous two years anywhere within Australia and New Zealand.

In accordance with the policy outlined under 2.2.2 of this document, pharmacists who have provided pharmacy services in jurisdiction where mutual recognition applies are entitled to return to practice in Victoria. Where appropriate, an 'Application for Registration / Restoration of Name to the Register' should be lodged.

Category 2 Applicants who provided pharmacy services during the previous two years only in the United Kingdom, the Republic of Ireland, the United States of America or Canada.

The following procedure applies to pharmacists who return to practice in Victoria after a period of more than two years of providing pharmacy services in other jurisdictions which the Australian Pharmacy Council (APC):

- acknowledges there is a legislative basis for registration / licensure of pharmacists
- considers the practice of pharmacy is considered to be substantially equivalent to Australia
- considers the level of competency required to practise pharmacy to be substantially equivalent to Australia.

Procedure

An applicant returning to practice in Victoria after practising in the United Kingdom, the Republic or Ireland, the United States of America or Canada for a period of two years or more is required to:

a) arrange a certificate of identity and good standing to be issued by the applicable registration authority within six months of seeking to return to practice in Victoria;

b) attend the office of the Board in person for identification purposes and present another form of photo identification (eg passport or driver licence), after the Board has received the original certificate(s) of identity and good standing;

c) provide details regarding practise as a pharmacist for the previous three years including details of premises and the number of hours worked;

d) undertake 152 hours of practical experience working under the supervision of a pharmacist in Victoria;

Note:

- *the applicant must ensure that the pharmacist with whom it is intended to have that experience and the premises is acceptable to the Board for that purpose;*
- *a lesser or greater period may be set by the Board upon assessment of the information provided)*

e) upon completion of the period of practical experience, attend the office to be interviewed by an officer of the Board;

f) provide evidence that he/she has undertaken the period of practical experience working under the supervision of a pharmacist in Victoria;

g) demonstrate to the interviewing officer that he/she has a practical understanding of the legislation and guidelines affecting the practice of pharmacy in Victoria;

h) if required to lodge an application for registration in accordance with the procedures outlined on the application form; and

i) ensure that he/she is competent to provide their chosen pharmacy services as outlined under 2.2.2 and 2.2.3 of this document.

Note: *For applicants in the above categories, pharmacy services must have been provided as a registered pharmacist in the relevant jurisdiction(s).*

Category 3 **All other applicants**

All other applicants are required to:

(i) Lodge an application for registration (if required) with payment of the required fee and include details of previous Victorian registration; and

(ii) Undertake the procedure outlined in 2.2.6 of this document.

Note: *The requirements set by the Board for restoration of name to the register should be completed within two years from the date of notification by the Board of those requirements. If the person's name is not restored to the Register within this period, the applicant must recommence the process outlined in (ii) above.*

PART 3

INITIAL GENERAL REGISTRATION

3.1 GENERAL INFORMATION

3.1.1 Definitions

For the purpose of Part 3 of this document, the following definitions apply:

Clinical training	Training undertaken by a registered pharmacy student under the supervision of a registered pharmacist, in approved premises as part of an approved course of study in pharmacy practice, for the purpose of meeting the requirement outlined in section 5(a) of the Act
Supervised practice (internship or the specified number of intern training hours required by the Board)	Any hours of approved supervised training undertaken by a provisionally registered person under the supervision of a registered pharmacist, in approved premises for the purpose of meeting the requirement outlined in section 5(b) of the Act.
Registered pharmacy student	A person granted student registration under section 8 of the Act on the basis of being enrolled in an accredited course in pharmacy practice approved by the Board (refer 3.1.6a);
Provisionally registered person	A person granted provisional registration by the Board in accordance with section 9 of the Act on the basis of being either: (i) a graduate of an accredited course in pharmacy practice approved by the Board, undertaking the practical training requirements for initial registration for the purpose of meeting the requirement outlined in section 5(b) of the Act (refer 3.1.6b); or (ii) an overseas trained pharmacist undertaking the APC process for registration for the purpose of meeting the requirement outlined in section 5(b) of the Act (refer 3.1.5); or (iii) a person who previously held general registration who is required by the Board to undertake supervised practice prior to returning to practice.
Intern	A provisionally registered person who has been approved by the Board to undertake supervised practice in premises approved by the Board under the supervision of a preceptor approved by the Board.
Preceptor	A registered pharmacist supervising approved clinical training or supervised practice.

3.1.2 Registration as a pharmacy student (Section 8)

A person must apply for registration as a pharmacy student prior to undertaking supervised training in the State of Victoria. This applies to students undertaking pharmacy courses in Victoria or other jurisdictions.

An 'Application for Registration as a Pharmacy Student,' available from the Board's office or website, must be lodged and approved in accordance with the procedures outlined on the form and approved by the Board. There is no fee payable for student registration. The Board may refuse to grant student registration or apply conditions to student registration in accordance with section 8 of the Act.

Preceptors and premises must be approved by the Board before a registered pharmacy student commences clinical training.

3.1.3 Provisional registration (Section 9)

A person must apply for provisional registration prior to undertaking supervised practice in Victoria. This applies to:

(i) persons seeking to undertake training for the purpose of meeting the requirements of section 5(b) of the Act;

(ii) overseas qualified pharmacists undertaking the Australian Pharmacy Council (APC) process for registration: and

(iii) previously registered pharmacists seeking to have their name restored to the register if required by the Board to undertake supervised training for general registration.

An 'Application for Provisional Registration,' available from the Board's office or website, must be lodged in accordance with the procedures outlined on the form with the applicable fee and be approved by the Board. The Board may refuse to grant provisional registration or apply conditions to provisional registration in accordance with section 9 of the Act.

A provisionally registered person must have all supervised practice periods approved by the Board as outlined in 3.2.1(iv).

3.1.4 Applicants for initial registration

An applicant for initial registration in Victoria is a provisionally registered person who qualifies for general registration under section 5 of the Act and either:

(i) has never registered as a pharmacist or

(ii) was an overseas trained pharmacist who has completed the Australian Pharmacy Council (APC) requirements for registration (refer 3.1.5) but has never registered as a pharmacist within Australia.

Note: *This excludes pharmacists registered with the Pharmacy Council of New Zealand who are required to follow the applicable procedures for registration outlined under 2.1.1.*

3.1.5 The role of the Australian Pharmacy Council (APC)

Policy

Overseas trained pharmacists (other than those registered in New Zealand) who propose to seek initial registration in Victoria are required in the first instance to make an application to the Australian Pharmacy Council (APC).

Note*:*

APC may be contacted as follows:

Australian Pharmacy Council
PO Box 269
Civic Square ACT 2608
Tel (02) 6247 5088
Fax (02) 6247 9611
E-mail apec@pharmacycouncil.org.au
Website www.pharmacycouncil.org.au

Applicants are required to seek details regarding the APC process for registration directly from APC. APC will advise eligible candidates when to contact the Board regarding commencement of supervised training.

Prior to being assessed as eligible to proceed to undertaking supervised training in Victoria as part of the APC process, and being awarded provisional registration status by the Board, overseas trained pharmacists do not have any formal status in Victorian practice and, if employed in a pharmacy or pharmacy department, must not be employed in any professional capacity. They may however, be employed as dispensary assistants as specified in this document subject to completion of a Board approved course and fulfilling the requirements for employing dispensary assistants outlined in this document).

3.1.6 Qualification for general registration – initial registrants

Section 5 of the Act outlines the qualifications for general registration, which all applicants must meet to be eligible for their initial general registration. The following policies outline the requirements of the Board.

a) A course of study in pharmacy practice approved by the Board (Section 5(a))

Policy

To meet the requirement outlined in section 5(a) of the Act and be eligible for general registration, a person must successfully complete a course of study in pharmacy practice approved by the Board such as:

(i) a pharmacy course conducted in Australia or New

Zealand which has been awarded provisional or full accreditation by the Australian Pharmacy Council (APC) prior to lodgement of an application for initial general registration in Victoria; or

(ii) any other pharmacy courses conducted by an overseas course provider, provided that the holder of that qualification has had their qualification assessed and accepted by APC as being equivalent to Australian qualifications, and the holder of that qualification has completed the relevant APC procedure for registration (refer to procedure outlined under 3.1.5).

b) A period of supervised practice approved by the Board (Section 5(b))

Policy

To meet the requirement outlined in section 5(b) of the Act, an applicant for initial registration must have undertaken 1824 supervised practice hours after successful completion of a course in pharmacy practice approved by the Board.

Note*:*

1. *Clinical training placements undertaken as part of a course in pharmacy practice may not be counted as part of the 1824 supervised practice hours required for initial registration in Victoria.*
2. *Overseas qualified pharmacists may be required to undertake less than 1824 supervised practice hours if undertaking the APC process for registration. The number of supervised practice hours allocated to such individuals is determined by the Board on a case-by-case basis. Refer to APC for further information regarding the APC process).*

The 1824 supervised practice hours must be undertaken under the following conditions:

(a) Hours are undertaken in a pharmacy, pharmacy department, school of pharmacy or pharmaceutical manufacturing premises under the supervision of a pharmacist (preceptor) and the premises and preceptor are approved by the Board for each training period prior to commencement of those hours;

(b) Each period of supervised practice hours is undertaken under the direction and / or supervision of the one pharmacist approved by the Board for a minimum period of 114 hours;

(c) During the course of supervised practice hours, hours are undertaken regularly and consistently such that during a three consecutive week period, a minimum of 90 hours are undertaken.

(Note:

1. *During a three consecutive week period, a maximum of 135 hours may be counted as training hours.*
2. *Annual leave may be taken by interns, however, this may not be counted as supervised practice hours.)*

c) An examination (Section 5(c))

Policy

To meet the requirement outlined in section 5(c) of the Act, an applicant for initial registration (other than overseas pharmacists undertaking APC examinations for registration) must have passed the Board's Registration Examination (in accordance with the rules outlined in the Board's 'Registration Examination Candidate Guide') to be judged competent to practise. The Registration Examination comprises the following:

(a) a written examination on pharmacy law and pharmaceutical calculations;

(b) the Australian Competency Assessment Tool (APCAT); and

(c) an oral examination on pharmacy law and pharmacy practice.

Note*:*

1. *The Board conducts each examination up to three times during each calendar year on dates published in its 'Registration Examination Candidate Guide' on its website.*
2. *The Board utilises the document 'Competency Standards for Pharmacists in Australia 2003' in the development of these assessments.*
3. *Interns are expected to be fluent in spoken and written English, sufficient to satisfy the Board at the Registration Examination that they can effectively communicate at professional and lay levels. Interns who believe they need assistance in improving their ability in this area are invited to seek guidance from –*
   - *student counsellors at their School of Pharmacy;*
   - *counsellors at those educational institutions which provide suitable communication courses;*
   - *course providers of Pre-registration Training Program providers approved by the Board; or*
   - *the Board's Education Pharmacist.*

4. *As outlined in 3.1.5 of this document, in the case of overseas qualified pharmacists undertaking the APC process for registration, details regarding the APC examinations must be obtained from APC).*

3.1.7 Eligibility to undertake the registration examination

A candidate for the registration examination is required to have undertaken sufficient and satisfactory supervised practice experience before attempting any component of the Board's registration examination.

Policy

To be eligible to undertake the Registration Examination, a candidate must meet all eligibility criteria published by the Board.

Eligibility criteria. To undertake the oral component of the registration examination, a candidate must have:

a) passed the National Forensic, Ethics and Calculations Examination (NFECE), the Pharmacy Law (Victoria) Examination and the Australian Pharmacy Competency Assessment Tool (APCAT);

Note*:*

1. *A candidate must undertake at least 30% of the 1824 hours of supervised practice required for initial registration to be eligible to undertake NFECE, the Pharmacy Law (Victoria) Examination and APCAT;*
2. *A pass in NFECE, the Pharmacy Law (Victoria) Examination and APCAT remain valid for a period of 12 months (or until a date determined and notified by the Board), after which a candidate is required to re-sit the examination(s) to meet the criteria for eligibility for entry into the oral component of the registration examination;*
3. *A candidate must lodge an application form with payment of the fee for each examination no later than the closing date for the examinations).*

b) by the date of commencement of the oral examination, undertaken
   (i) a minimum of 85% of the 1824 hours of supervised practice required for initial registration (unless specifically approved by the Board to take the examination earlier);
   (ii) at least 912 supervised practice hours in a pharmacy and / or a pharmacy department;

c) lodged an application form with payment of the examination fee no later than the closing date for the oral examination, declaring that he/she is eligible to undertake the oral examination;

d) been evaluated by a Board Education Pharmacist in regard to their progress in on-site practical training; and

e) been evaluated by their preceptor as having progressed satisfactorily in the form of periodic written evaluations sought by the Board during the training period.

Note*:*

1. *Candidates should refer to the Board's 'Registration Examination Candidate Guide' for further information regarding the examinations and examination rules.*
2. *As outlined in the information under 'The role of APC', in the case of overseas qualified pharmacists undertaking the APC process for registration, details regarding the APC examinations must be obtained from APC.*
3. *Unsuccessful candidates seeking to undertake a subsequent oral examination conducted by the Board should note that the Board expects such candidates to seek further supervised practice experience to remedy any deficiencies noted in their previous examination attempt. The Board mutually recognises the outcomes of registration examinations conducted by other examining bodies where the candidate has been unsuccessful in those examinations. In the case of interns who were unsuccessful in registration examinations conducted by other examining bodies, the Board will not admit an intern into the oral component of its registration examination:*
   - *within the three month period between an unsuccessful examination attempt and the date of commencement of the Board's oral examination, and*
   - *if the intern, at the time of the Board's oral examination, does not hold a current pass in NFECE, the Pharmacy Law (Victoria) Examination and APCAT or met any other eligibility criteria for entry into the oral examination.*

3.2 SUPERVISED PRACTICE (SECTION 5(b))

3.2.1 Conduct of supervised practice

Policy

In regard to the conduct of any proportion of the supervised practice hours for initial registration required under section 5(b) of the Act, both the preceptor and intern must comply with the following requirements,:

(i) Intern requirements

a. the intern is a provisionally registered person in accordance with section 9 of the Act;

b. the intern's provisional registration is valid for the entire period of practical training; and

c. the intern has informed the preceptor regarding

any condition imposed on his / her provisional registration by the Board which will impact on training.

(ii) Preceptor requirements

a. the pharmacist has been registered and has practised as a pharmacist for the previous 12 months or longer (unless the pharmacist has been registered for a shorter period and is approved by the Board to act as preceptor);

b. the pharmacist has sighted evidence of provisional registration (in the form of a provisional registration certificate, issued by this Board) which is valid at the time training commences (provisional registration must remain valid throughout the proposed period of training);

c. the pharmacist has taken into consideration any condition which applies to the provisional registration and planned the training accordingly;

d. the pharmacist has general registration to practise and no conditions placed on his/her registration which would otherwise impact on training;

Note*:*

1. *The Board conducts training sessions each year for preceptors of interns. Preceptors who have not undertaken this period of training for three years, or who are new preceptors are advised to attend this training. In addition, the Board's Education Pharmacist is available to provide advice to preceptors regarding the training they provide interns.*
2. *Refer to the Pharmacy Intern Practical Training Guide (Preceptor Manual) on the Board's website.*

(iii) Premises requirements

a. the premises in which the training will be conducted is an approved pharmacy business or pharmacy department under section 103 of the Act, an accredited school of pharmacy or a pharmaceutical manufacturing premises;

b. in the case of a pharmacy business or pharmacy department, practice is conducted in accordance with the Act and the Board's guidelines, policies and procedures including maintaining current editions of all required reference books listed in ???

(iv) Approval requirements

the provisionally registered person or the pharmacist

seeking approval as preceptor has submitted to the office of the Board and prior to commencement of training, an "Application for approval of supervised practice" form (completed in full) for the Board to approve the premises and preceptor for that proposed period of training to be undertaken by the intern.

Note*:*

1. *An application must be submitted on every occasion, prior to commencement of practical training for each occasion that a period of training is conducted by a preceptor.*
2. *More than one site may be included for training purposes if all sites are part of a rotation program under the direction of one approved preceptor.*
3. *For short rotations (totalling 180 hours or less during the internship period) additional approval from the Board is not required.*
4. *In the case of rotations totalling more than 180 hours during the training period, each additional site must be nominated for each intern and the number of hours to be undertaken at each site specified.*
5. *An intern may commence supervised training after the training approval application has been received at the office of the Board.*
6. *A certificate of approval is issued to both the preceptor and the intern subsequent to the meeting of the Board at which the training approval application was considered (usually within four weeks).*
7. *Approval granted by the Board for the nominated preceptor to conduct practical training hours for the intern at the nominated site remains valid for 12 months from the date of approval.*

(v) On-site training requirements

a. in the case where as preceptor, the pharmacist cannot directly supervise an intern, the responsibility for supervision is devolved to a suitably experienced pharmacist;

b. the intern must receive a level of supervision which ensures that an individual registered pharmacist is present on the premises at all times for each intern who is present (the number of interns must not exceed the number of pharmacists);

c. where additional premises are involved in the conduct of supervised training, the approved preceptor is in consultation and agreement with the supervising

pharmacist at each additional premises, regarding that parts of the training program to be conducted at respective sites during the rotation;

d. a training program has been implemented at the approved training site and conducted by the approved preceptor and has been designed to instruct the intern in the following topics:

- **dispensing procedures and practice;**
- **clinical pharmacy;**
- **treatment of commonly occurring minor ailments;**
- **communication to patients, health professionals and the community;**
- **law applying to pharmacy practice;**
- **pharmacy and pharmacy department practice management;**
- **good manufacturing practice;**
- **drug information procedures**

Note*:*

1. *This program should include the opportunity for the intern to attend seminars provided through an approved pharmacy pre-registration training program (refer 3.3.1(iii)).*
2. *Offsite training events/programs cannot replace the onsite training program which is to be conducted by the preceptor.*
3. *The performance and progress of interns in the on-site training program will be evaluated three times each year. Evaluation forms will be provided to preceptors who will be required to complete them carefully and discuss them with the intern(s). Interns are to be given the opportunity to comment in writing about those evaluations, either on the form itself or directly to the Board).*
4. *Further information regarding on-site training requirements is provided in the Preceptor Manual on the Board's website.*

3.2.2 Record of training

A true record of supervised training undertaken as an intern must be submitted with an application for initial registration as evidence of meeting the requirements outlined in section 5(b) of the Act.

Policy

The preceptor is responsible for entering into the 'Training Record Book' provided by the Board, an accurate record of supervised training hours, which have been:

(i) undertaken by an intern after successful completion of the final year of an accredited course where the board of examiners of the course have passed that candidate at those examinations and all undergraduate requirements have been satisfactorily completed rendering the student eligible to be admitted to the degree of Bachelor of Pharmacy;

(ii) undertaken under the direction and / or supervision of the one pharmacist for a minimum period of 114 hours and accumulated at a rate such that during any three consecutive weeks of a training period, a minimum of 90 hours have been undertaken;

Note: *During a three consecutive week period, a maximum of 135 hours may be counted as training hours.*

(iii) undertaken at premises approved by the Board and under the supervision of the pharmacist nominated in the "Application to Conduct Practical Training" form submitted to the office of the Board prior to commencement of training,

Note: *The approved preceptor must sign the record of training, even when the responsibility of supervision has been devolved to other suitably experienced pharmacists);*

(iv) undertaken at approved premises or other premises during rotations or by means of attending seminars of an approved pharmacy pre-registration training program;

Note*: Absences from work for public holidays, accrued days off, sick leave or for other purposes (unless by prior approval of the Board) are not to be counted towards the period of supervised training to be completed before initial registration.*

3.3 ELIGIBILITY & APPLICATION FOR INITIAL GENERAL REGISTRATION

3.3.1 Additional requirements to be satisfactorily completed for initial general registration

Policy

In addition to achieving the qualifications for general registration outlined in section 5 of the Act (and further

detailed in 3.2.1 of this document), interns seeking initial (general) registration are required to have satisfactorily completed the following additional requirements:

(i) A Level 2 / Senior first aid course or equivalent

Note*:*

1. *Equivalent first aid courses completed prior to the pre-registration training period may be acceptable if the certificate received is valid at the time that application is made for initial registration.*
2. *Enquiries regarding the equivalence of courses should be directed to course providers.*

(ii) An approved management course which may be one of either:

a. the management course for pharmacy interns offered by the Small Business Training Centre of the South Australian Institute of TAFE's Trainee Management Course ("Pharmacy Management – Victoria"); or

b. the management course for pharmacy interns offered by the Australian College of Pharmacy Practice and Management ("Introduction to Pharmacy Management Program"); or

c. "Diploma in Frontline Management" course delivered by the Pharmaceutical Society of Australia – Victoria; or

d. the management components of the undergraduate pharmacy courses conducted by Monash University and La Trobe University; or

e. evidence of satisfactory training and management experience accepted by the Board (applications for recognition of prior learning must be made in writing to the Board early during the pre-registration training period).

Note*: An application for recognition of prior learning may be made to the Board, in writing, prior to lodging an application for initial registration.*

(iii) An approved Victorian pharmacy pre-registration training program which may be one of either:

a. the Monash University Pre-registration Program; or

b. the Pharmaceutical Society of Australia Pre-registration Program; or

c. a pharmacy pre registration training program approved by the Board.

(iv) An on-site assessment on the preparation of extemporaneously prepared products conducted under the direction of the preceptor.

Note*:*

1. *The relevant assessment material is provided by the Board to all preceptors and may also be accessed on the Board's website).*
2. *This assessment is not a set requirement for APC interns however, it may be undertaken as a training exercise.*
3. *Interns are required to submit this assessment by due dates published by the Board.*

3.3.2 Application for general registration in the State of Victoria as initial registration (Section 6)

A person who has met the requirements of section 5 of the Act may apply for general registration in accordance with section 6 of the Act by lodging an application for registration (available from the Board's office or on the Board's website) in accordance with the procedures outlined on the application form and include any additional information or documentation specified on the application form.

Note*: An applicant for initial general registration must lodge an application in person at the Board's office.*

PART 4
PRACTISE AS A PHARMACIST

4.1 ROLE OF THE PHARMACIST IN CHARGE

4.1.1 Appointments and duties

In accordance with the Act, the owner of a pharmacy business or the board of management of a hospital or other institution that operates a pharmacy department must appoint a pharmacist to be regularly and usually in charge of the pharmacy or pharmacy department.

Guidelines

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department is either:

1. the owner or in the case of a partnership, one (or more) of the owners of that pharmacy;
2. a pharmacist who has been appointed by the owner(s) of the pharmacy or in the case of a pharmacy department, the board of management (however titled);
3. a pharmacist who is appointed to be in charge of a pharmacy business for the executors, administrator or trustee of the estate of a deceased pharmacist; or
4. a pharmacist who is appointed to administer the property of a pharmacist who is bankrupt, or under the terms of a mortgage, bill of sale or security interest.

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department is responsible for:

1. ensuring compliance with statutory obligations and ethical standards;
2. the general security of the premises, including control of the keys or other entry devices and intrusion alarm systems;
3. ensuring the correct supervision of students, pre-registrants and dispensary assistants;
4. ensuring that in his or her absence, another pharmacist is in charge for the time being;
5. the preparation and maintenance of an operations manual for use in the pharmacy; and
6. the maintenance at the premises of the required references and equipment.

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department:

1. may not practise as such in more than one pharmacy or pharmacy department at a time; and
2. must notify the Board as soon as practicable when appointed to the position at a hospital or at a pharmacy business.

The owner of a pharmacy business who is not regularly and usually in charge of the pharmacy must notify the Board as soon as practicable of the name of the pharmacist so appointed. The notification may be supplied electronically or other means.

A pharmacist who has been appointed to be the pharmacist regularly and usually in charge of a pharmacy department of a hospital or institution or a friendly society pharmacy must notify the Board as soon as practicable of that appointment. The notification may be supplied electronically or other means.

If the pharmacist regularly and usually in charge is absent for more than 28 days, another pharmacist is to be appointed as the pharmacist regularly and usually in charge.

Extra pressures can affect the performance of locums who are working in new surroundings. Locums should be given a full briefing before commencing, with particular attention being paid to computer software, opening and closing procedures, and dispensary layout. Contact telephone numbers should be made available.

4.1.2 Death or bankruptcy of a pharmacist – duty of manager

The pharmacist who is appointed to manage a pharmacy business of a deceased or bankrupt pharmacist or of a pharmacist whose property is subject to a mortgage, bill of sale or security interest under the terms of section 101 of the *Health Professions Registration Act 2005* must inform the Registrar as soon as practicable of the circumstances of the appointment.

4.1.3 Responsibilities of proprietors

The Act permits non-practising pharmacists to have a proprietary interest in a pharmacy. Other pharmacists may hold practising registration but not attend or work in a pharmacy business in which they have a proprietary interest.

Every owner or partner of a pharmacy, if that pharmacist is not the pharmacist who is regularly and usually in charge of that pharmacy, must on a regular basis make himself or herself sufficiently aware of the manner in which the pharmacy is being conducted to determine that it is being carried on in accordance with the law and good pharmaceutical practice. If the proprietor finds that it is not, he or she must intervene to ensure that the pharmacy is properly conducted.

For the purposes of this section, being aware of how the pharmacy business is being conducted includes maintaining a direction over the kinds of goods being sold – particularly those known to be subject to abuse or misuse – and that the owner's procedures and policies are being followed. The procedures and policies should be documented and available within the pharmacy.

In a partnership or other business structure, a member cannot abdicate his or her professional obligations even if that partner is essentially silent or absent. (See: *David Loewy and Sandra Lowey* v *The Pharmacy Board of Victoria*, [1991] VSC 11301).

4.2 DISPENSING

4.2.1 Labelling of dispensed medicines

Dispensed medicines are to be labelled in accordance with any statutory provisions and in accordance with these guidelines with a view to maximising the benefits of the therapy, improving the patient's understanding of the treatment, enhancing compliance and minimising adverse effects.

Guidelines

4.2.1.1 Labels

The label is to be firmly attached to the immediate container (including each component of multiple therapy packs) unless the immediate container is so small or is so constructed that the label would compromise the patient's ability to use the medicine; metered aerosols and some eye drops are examples. In such instances, the label should be attached to the primary pack or alternatively, purpose-designed labelling tags may be used.

The label should be clearly and legibly printed in unambiguous and understandable English; other languages that are accurate translations of the English may be used additionally.

The special needs of patients with disabilities, such those with poor eyesight, should be accommodated and the patient adequately informed.

The label should be placed to leave visible any of the manufacturer's statements that may be important to the patient, including the expiry date, storage conditions and where possible, the name and strength of the drug.

4.2.1.2 Label content

The label is to include:

1. the brand and generic names of the medicine, the strength, the dose form and the quantity supplied. For extemporaneously prepared medicines and medicines not dispensed by count, the name and strength of each active ingredient and the name and strength of any added preservatives or the name of the formula as described in a standard reference book;

2. directions for use;

3. the patient's name or, in the case of an animal, the owner's name and the kind of animal;
4. the date of dispensing or supply;
5. the dispenser's initials;
6. a unique identifying code;
7. the name, address and telephone number of the pharmacy or pharmacy department at which the prescription was dispensed;
8. storage directions (where important) and expiry date (where applicable); and
9. the words "Keep out of reach of children".

4.2.1.3 Ancillary labels

Some ancillary labels are mandatory; these are listed in the *Standard for the Uniform Scheduling of Drugs and Poisons*. The routine use of other ancillary labels in the *Australian Pharmaceutical Formulary and Handbook* is recommended having regard to each patient's circumstances.

4.2.2 Extemporaneous dispensing

In the absence of any formulation published in a standard reference, there should be good clinical and pharmaceutical evidence to support the quality, safety, efficacy and rationality of any extemporaneous formulation. Evidence is best obtained from peer-reviewed journals rather than being solely based on testimonials and impressions.

Particular care should be exercised in the case of medicines for which there are no precedents in standard references. Examples are oral and topical hormone preparations, those containing substances whose use has not been approved in Australia for therapeutic use, and preparations that contain well-established drugs for oral use but for which there are inadequate safety and efficacy data when the same drug is used topically.

An extemporaneous preparation should be used only in circumstances where a commercial product is unavailable or unsuitable.

The Board has regard to the *Australian Pharmaceutical Formulary and Handbook's* statement, "Extemporaneous Dispensing".

Guidelines

Starting materials are to comply with pharmacopoeial standards, have validated expiry dates and be obtained from a reputable licensed supplier. If the material is not the subject of a pharmacopoeial monograph, the supplier should be asked to supply a standard.

The composition of the medicine is to be based on sound pharmacological, clinical and pharmaceutical principles. Ingredients and processing conditions that would result in potentially toxic or ineffective preparations must be avoided.

Expiry dates are determined from the date the medicine is prepared. Because the medicine is intended for immediate use or following short-term storage, the expiry dates are based on criteria different from those applied in commercial manufacture.

Pharmacists should consult and apply drug-specific and general stability documentation and literature when available, taking into account the properties of the drug, its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

Equipment should be appropriate to the quantities to be made up having regard to possible complications arising from scaling up the quantity prepared for one patient.

In the case of specialised or novel formulations that are frequently prepared, such as those that include high potency substances, samples should be submitted from time to time to a competent analytical laboratory for assay.

Modified-release formulations should only be made up if there is credible *in vivo* and *in vitro* data that support the quality, safety, efficacy, rationality and relevance of the precise formulation.

Adding substances to commercially manufactured medicines is discouraged because the full formulation details of the latter are not generally available.

Protective clothing and equipment are required when handling drugs of high milligram potency, such as hormones. These include non-shedding disposable laboratory coats or overalls with elasticised cuffs and closures up to the neck; particulate respirators (N95 rated) or HEPA filtered (P100) respirator masks; nitrile gloves; hair and beard coverings and shoe covering. A powder containment cabinet that meets Australian Standard *AS 2252.1 – 2002: Biological safety cabinets (Class I) for personnel and environment protection* is required for operator protection. Australian Standard *AS 2252.1 – 2002* must be read in conjunction with *AS/NZS 2647 – 2000: Biological safety cabinets – Installation and use,* which describes recommended practices for the installation and use of the cabinets. Base line and periodic pathology monitoring is also required.

Sterile medicines should be made up only if:

1. the premises meet the Australian Standard for clean rooms;
2. sterilisation equipment operates in accordance with the manufacturer's specification and the performance is validated;
3. procedures are fully documented and implemented; and
4. staff are suitably trained in the preparation of sterile products.

Notes

Extemporaneous dispensing in community pharmacies

The regulatory regime in Victoria results from the relationship between the Therapeutic Goods (Victoria) Act 1994*, the* Therapeutic Goods Act 1989 *(Cwth) and the* Therapeutic

Goods Regulations 1990 *(Cwth). The general rules relating to the manufacture and supply of therapeutic goods are:*

1. *the goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied, unless they are "exempt goods"; and*
2. *the premises where the medicines are manufactured must be licensed, unless the person carrying out the manufacturing is an "exempt person".*

"Exempt goods" include "medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person".

"Exempt persons" include "pharmacists in relation to the manufacture of therapeutic goods produced by the pharmacist" in a pharmacy where the pharmacist practises and is open to the public; or on the premises of a dispensary conducted by a Friendly Society; or on the premises of a private hospital for supply (other than by wholesale) on or from those premises.

The following table summarises the requirements.

CIRCUMSTANCES	**Are the goods required to be entered on the ARTG?**	**Are premises required to be licensed?**	**References**
Medicine made up for a named patient. Patient-specific label and records of supply kept. [1]	No	No	TG Reg Sch 5, Item 6 TG Reg Sch 8, Item 2
Medicine made up and supplied for general sale only from the pharmacy where it was made up.[2]	Yes	No	TG Reg Sch 8, Item 2 TG(V) Act s.14
Medicine made up and supplied to another person for on-supply.[3]	Yes	Yes	TG(V) Act s.14 TG(V) Act s.38

1. *The first situation presents no difficulties and applies to medicines dispensed on prescription and to medicines that the pharmacist prescribes on his or her own motion. The usual recording and labelling requirements apply.*
2. *The second situation applies when a pharmacist decants from a bulk pack (of either a commercial product or something that he or she makes) into smaller containers with the pharmacy's own label for supply other than as in the previous paragraph.*
3. *In the third situation, the pharmacist is no different from any other manufacturer in that the premises would require licensing*

from the Therapeutic Goods Administration. The Code of Good Manufacturing Practice would have to be implemented.

Therapeutic goods that are prepared by pharmacists employed by a public hospital or public institution for supply in hospitals or public institutions within the State are exempt from having to be entered on the ARTG and the hospital or institution is not required to hold a manufacturing licence.

4.2.3 Counselling patients about prescribed medicines

A patient has the right to expect that the pharmacist will counsel him or her privately about his or her medicine but the patient reserves the right not to be counselled. Every effort should be made to counsel, or to offer to counsel the patient whenever a medicine is supplied.

Guidelines

More detailed advice is especially important when certain drugs are supplied and in certain circumstances. Examples are:

- the taking of drugs that can sedate;
- the taking of drugs that have a narrow therapeutic index;
- unusual dose forms (e.g. fentanyl patches);
- unusual frequency of use (e.g. alendronate, methotrexate);
- when a new drug is prescribed;
- when there is a change in the dose or frequency of administration;
- if the patient is taking many drugs; or
- an acute illness.

In the case of patients taking repeat prescriptions, counselling provides the opportunity to inquire if the patient is taking the medicine correctly, if the medicine is having the desired outcome or if there are unwanted effects. It offers a further opportunity to detect any errors.

The supply of Consumer Medicine Information (CMI) leaflets or other counselling aids is recommended. The contents of a CMI, such as mention of certain diseases or side-effects may cause confusion or even alarm among some patients; therefore the pharmacist may need to work through the CMI with the patient in order to relate its contents to the individual circumstances.

Face to face counselling is the best way of communicating information about medicines but where that is not possible or practicable, written information and/or a telephone call are recommended while making sure that the information is provided directly to the patient.

4.2.4 Return of unwanted medicines

The Board encourages pharmacists to accept for safe disposal unwanted medicines from the public.

Guidelines

Any unwanted medicines are preferably placed immediately and without examination in a suitable disposal bin that is stored to prevent unauthorised access. It is not necessary to empty any medicine containers or remove tablets from their immediate wrappers.

The bins are collected by an approved waste disposal contractor, details of which may be obtained from the Drugs and Poisons Regulation Group of the Department of Health.

4.2.5 Patient records

The maintenance of accurately and sufficiently detailed patient medication records is essential for the benefit of patients and for pharmaceutico-legal reasons. Clinical notes must not be capable of deletion but notes of a temporary or occasional nature may be deleted.

Guidelines

As well as statutory recording requirements, the use of additional notes on the computer file is recommended to detect matters of clinical importance, such as unusual dosage or usage or significant drug interactions.

The notes should also make mention of any discussions with the patient's doctor in relation to therapeutic matters, significant warnings conveyed verbally to patients or information that is passed on to other parties, such as a referral under section 36 of the *Drugs, Poisons and Controlled Substances Act 1981* or a report of a suspected forgery.

The supply of non-prescription medicines may also be added to the computer file for completeness of the records if it is relevant to the patient's drug regime or illness.

4.2.6 Privacy and confidentiality

Schedule 1 of the *Health Records Act 2001* sets out the Privacy Principles applicable to health providers in Victoria; see: www.legislation.vic.gov.au and follow the prompts.

Information about a person that a pharmacist obtains in the course of professional practice is confidential and may be disclosed only:

1. with that person's permission; or
2. to other persons authorised to the extent of the latter person's lawful jurisdiction or;
3. on a court order; or

4. if, in the pharmacist's opinion, it is in the patient's best interest to divulge pertinent information to another health practitioner who is treating the patient.

Authorised persons include:

1. a Pharmacy Board officer;
2. a person authorised under the *Drugs, Poisons and Controlled Substances Act 1981* (including a member of the Victoria Police in accordance with section 42 of that Act);
3. a member of the Victoria Police or other enforcement agency in accordance with the *Privacy Act 1988* (Cwth), the *Information Privacy Act 2000* or the *Health Records Act 2001*;
4. an authorised officer of Medicare Australia for the purposes of examining prescriptions supplied as pharmaceutical benefits under the *National Health Act 1953* (Cwth); and
5. an authorised officer of the WorkCover Authority or the Traffic Accident Commission.

Guidelines

Particular care should be exercised if other official bodies seek information. The Office of the Victorian Privacy Commissioner (Privacy Victoria) should be contacted in cases of uncertainty. (tel: 1300 666 444; email: enquiries@privacy.vic.gov.au)

Members of staff at pharmacies and pharmacy departments are to be trained about the need to observe confidentiality in all their dealings with the public.

The name or details of a therapeutic product (medicines and devices) should not be identified in information given to other than the person for whom it was intended, unless the person waives that right. Examples of persons to whom information may be inadvertently disclosed could include a person paying a family account or to third party organisations (including service companies) that process accounts, and organisations collecting statistical data.

The inadvertent disclosure of the identities of patients' medicines (and therefore the patients' medical conditions) to third parties is to be avoided. Ensuring that dispensed medicines are not transferred to checkouts in open baskets for other people to look at or comment on, is essential. Similarly, dispensed medicines that are waiting collection should be stored in a manner that prevents third parties from relating them to the person for whom the medicines are intended. Schedule 3 of the *Health Professions Registration Act 2005* makes specific mention of these matters; see www.legislation.vic.gov.au and follow the prompts.

Dispensary counters should be designed so that privacy is not compromised and in such a way that members of the public cannot view private information.

4.2.7 Dispensing errors and near misses

All reasonable steps need to be taken to minimise the occurrence of errors.

Guidelines

Good practice dictates that there should be a systematic approach in dealing with errors and near misses so that lessons can be learned from them and corrective action taken.

Routine checking throughout the dispensing process is necessary with particular emphasis being attached to the final check at the time of actual supply when the patient is counselled about his or her medicines.

Bar code scanners are mandatory at dispensing stations in pharmacies and pharmacy departments and are to be used for the intended purpose. They are an aid to, but not a substitute for, minimising selection errors.

Adequate time must be allowed to dispense properly every prescription (see also Workloads).

Distractions, such as clients talking to the pharmacist while prescriptions are being dispensed, are to be avoided by suitable design of premises.

4.2.8 Incident records

The Board recommends that a diary (electronic or paper) be kept for the purpose of contemporaneously recording incidents that may give rise to queries from the authorities or are complaints of a non-commercial nature.

Guidelines

The record will show when the incident was recorded, when it occurred, who was involved (both actual and alleged), the nature of the incident or complaint, what actions were taken and any conclusions. If contact was made with third parties, such as government departments, prescribers, lawyers or professional indemnity insurance companies, details of the conversation should be recorded.

The more serious the incident, the more the detail that should be recorded.

The diary should be kept for three years because of the delayed nature of some forms of litigation.

4.2.9 Workloads

Workloads must be kept at reasonable and manageable levels to ensure the safety of the patient and to ensure that the work environment is conducive to good pharmaceutical practice. Proprietors or managers must ensure that conditions are in place to meet the public's right to receive an appropriate pharmaceutical service in an accurate, professional and timely manner.

Consumers' expectations have reached a stage when many people expect immediate attention irrespective of the amount of work required to dispense that person's medicines, contact with prescribers, or that other prescriptions

have been lodged before theirs. Consumers should be encouraged to return or invited to use a waiting area rather than standing at the serving counter.

Guidelines

This guideline has been prepared following consultation and is based on experience and current work practices. The Board will continue to undertake research to inform itself on safe dispensing levels. The guideline will be reviewed when this research is completed.

In-pharmacy practices of imposing on staff maximum prescription waiting times and any associated bullying or threats are unacceptable to the Board. The Act prohibits inciting unprofessional conduct.

A pharmacy should be staffed to meet the expected workload. As a benchmark, not less than one full-time equivalent pharmacist dispensing an average of 150 prescriptions over a typical 9.00am to 6.00pm day should be regarded as the minimum staffing level. Attention should be paid to predictable spikes in activity during specific times, days or months. Sustainable workload may also be affected by other factors such as dispensing technologies, staff familiarity with systems and other non-dispensing responsibilities.

The preparation of each take-away dose of methadone and each administration of an opioid substitution medicine is counted as being the equivalent of one prescription.

If dispensing levels are in the range of 150 to 200 prescriptions daily, a trained dispensary assistant may assist but if the workload exceeds 200 daily, an additional pharmacist may be required for at least part of the day.

The Board acknowledges that a pharmacist may be required to dispense above this rate in unforseen circumstances. The Board recognises that in such circumstances, it is appropriate for the pharmacist to take effective short term measures to allow him or her to deal with the workload and meet his or her professional obligations.

4.2.10 Internet and mail order dispensing

The Board views Internet and mail order dispensing as less than the optimal way of delivering a pharmaceutical service because communication may be compromised. The Board recognises, however, that there are circumstances where these forms of communication are necessary in, or appropriate to, the patient's circumstances.

With the rise in electronic commerce and communication, it is essential to remember that:

1. prescriptions for Schedule 4 poisons must be written by medical and certain other health practitioners who are registered in an Australian jurisdiction;
2. prescriptions for Schedule 8 poisons must be written by medical and certain other health practitioners who are registered in Victoria; and
3. the supply of Schedule 3 poisons, except on prescription, by the Internet or by mail order is not permitted because of the regulatory requirement that the supply must be personal on the part of the pharmacist.

Guidelines

The patient and the pharmacist are to have one another's contact details.

The pharmacist is to obtain from the patient sufficient clinical information, including the patient's current medication, to ensure safe dispensing recognising that in some cases, the patient may also attend a local pharmacy in person for other medication. An offer of verbal counselling must be made on each occasion.

The supply of a Consumer Medicines Information (CMI) leaflet is recommended whenever a new medicine is supplied.

Standard operating procedures that set out the steps in the receipt and dispatch of medicines are required to ensure that the correct medicines reach the patient for whom they were prescribed. The procedures are to include mention of any special packaging or storage requirements while the parcel is in transit and the exclusion of any reference to the identity of the contents.

4.2.11 Facsimile prescriptions

A pharmacist may dispense a prescription transmitted by facsimile, subject to the following Guidelines.

Guidelines

Except in accordance with the next paragraph, the medicine should not be supplied until the pharmacist has possession of the original prescription (or valid PBS repeat authorisation) and is satisfied that the dispensed medicine agrees with it.

Where the facsimile prescription:

1. has been transmitted from a pharmacy depot, hospital or aged care facility; and
2. where clear standing instructions have been provided to responsible staff at these places that:
   (a) the medicines so supplied are not consumed by the patient until the pharmacist has checked the original prescription: and
   (b) the pharmacist has specifically authorised the supply or administration of the medicine,

the medicine may be supplied from the facsimile.

Visible fax "noise" has been identified as a source of error such as introducing or omitting decimal points.

If a facsimile of the prescription has been transmitted by the prescriber confirming verbal instructions, the medicine may be supplied before the actual prescription is in the hands of the pharmacist.

4.2.12 Dispensing multiple repeat prescriptions at one time

The Board endorses the position statement by the Australian Pharmacy Council on multiple dispensing of repeat prescriptions. The Australian Pharmacy Council represents all Australian pharmacy registering authorities.

The Australian Pharmacy Council (APC) believes that the simultaneous supply of multiple quantities e.g. supply of multiple repeats at once may not be in accordance with the prescriber's intention and is contrary to good pharmaceutical practice.

The APC further believes that this practice is contrary to the National Medicines Policy and may deprive the consumer of regular review and provision of medicine information which assist in minimising medicine misadventure. The APC, however, recognises that extenuating circumstances may exist such as those under regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960.

4.3 SPECIALISED SUPPLY ARRANGEMENTS

4.3.1 Dose administration aids

Dose Administration Aids (DAAs) may be used for selected patients where the benefits of compliance with a medication regime outweigh the disadvantages inherent in the use of the DAA.

Guidelines

An inherent disadvantage with DAAs is that each solid dose form is not individually identified and there is the risk that a filling error may persist for the duration of a DAA's use.

The filling of DAAs is repetitive yet it requires close and systematic concentration to minimise the risk of error. The role may be delegated to suitably trained pharmacy students and interns and dispensary assistants, and the work subjected to checking by a pharmacist. Sufficient space and time, freedom from interruption and good lighting are necessary for safe performance of the task. The area where the work is carried out must be tidy and orderly. Adequate breaks are necessary owing to the mechanistic nature of the task. The ability to review the patient's medication history is essential.

Tablets and capsules may be distributed into the compartments, preferably using forceps, or transferring them with the aid of a spatula and tablet counting tray or pressing them from their foil wrappers.

It is sufficient to wash the hands with soap and water regularly and thoroughly and to dry them with a paper towel or an air dryer before, during and at the end of the session. In hospitals and other establishments where microbiological control is more critical, the establishment's policies should be observed; this will typically require the use of a skin disinfectant. Latex surgical gloves

may be used but they may give rise to allergy. Skin disinfectants, such as chlorhexidine, pose the risk of skin sensitivity developing.

All reusable components of DAAs will require cleaning and thorough drying.

The label on the DAA is to identify clearly the name of the patient, the name and address of the pharmacy, the name, strength and dose form of the medicines, the directions for use and the date of filling. In appropriate circumstances, a photograph of the patient may be attached to the DAA. Where cautionary and advisory labels are needed, these can be attached directly to the DAA or provided on a separate sheet. A product identification option to assist nurses and carers is recommended.

A record of each filling should be generated under the patient's name showing the date of filling, the initials of the person who filled it and the medicine's name and dose. The filling record should be retained for at least 6 months.

Procedures should be established to indicate how changes of medication, dose or frequency are recorded.

4.3.2 Automated dose packaging systems

Automated dose packaging systems may be used to prepare and pack medicines into unit dose packaging for use by patients.

Guidelines

Pharmacists who use dose packaging machines must ensure:

1. there is a cleaning and maintenance protocol that is adhered to;
2. testing is undertaken at the start of each day and at any other time as may be operationally required;
3. any person using the machine is an intern, a trained dispensary assistant or dispensary technician and has received initial and on-going training in its use;
4. the machine is operated in a clean environment away from the dispensing bench and the dispensing computer, and where the temperature is controlled by an air conditioner to ensure the temperature is below 25°C;
5. the patient's right to privacy is understood and that if a third party is involved in the packing of the dose administration container, the patient or agent must so consent;
6. the labelling of the container in which any strip packs are placed meets any statutory requirements and the Board's guidelines;
7. the records maintained at the pharmacy include the batch number, the expiry date, the packing date and the initials of the pharmacist or dispensary assistant who is responsible. [Note: If a dispensary assistant packs the container, the pharmacist must also initial the packing]; and

8. there is a written procedure describing the use of the machine; and
9. a written quality assurance program to include the refilling of bulk canisters..

A pharmacist who uses automated dose packaging systems to pack sachets or similar packs on behalf of another pharmacist may require licensing by the Therapeutic Goods Administration.

4.3.3 Periodic administration of medicines

Where the patient or the prescriber so requests, a pharmacist should be prepared to retain the patient's medicines for periodic administration to the patient.

Guidelines

The medicine is to be dispensed in accordance with the prescription and any legal requirements, and retained in the dispensary.

One or more doses are supplied or administered in accordance with the patient's or the prescriber's request.

The patient's consent should be obtained where possible but there are circumstances where this is not possible or practicable.

The patient should sign for the dose or doses of the medicine so supplied or administered in cases where there is concern about potential or actual substance abuse or misuse, safety or false representation. This record is also signed or initialled and dated by the pharmacist who supplies or administers the periodic quantity.

The medicine is to be administered discreetly so that the patient's privacy is not compromised.

Specific requirements apply to opioid substitution and antagonist therapy.

4.3.4 Opioid substitution and antagonist therapy

Where a pharmacist elects to provide opioid substitution or antagonist therapy, the pharmacist must communicate to the patient the rules of providing the service. Specific records are required, adequate equipment and facilities made available, and privacy and confidentiality observed.

Guidelines

1. The patient is to be given a copy of the Pharmaceutical Society of Australia (Victorian Branch) charter of rights.
2. The patient is to be informed about the complaint resolution mechanism with unresolved matters being referred to the Office of the Health Services Commissioner (tel: 8601 5222).
3. Where dosing is provided at the pharmacy, the consumption of the medicine must not be in the dispensary.

4. References specific to the policy are:
   - *Policy for Maintenance Pharmacotherapy Dependence (2006)*
   - *National Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence (2003)*
   - *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Opioid Dependence (2003)*
   - *Pharmacotherapy Newsletter* (Department of Health, Victoria)

All of the above publications are available on www.health.vic.gov.au/dpu/pharm

The area where the therapy is administered should be so designed as to respect the patient's privacy.

4.4 PHARMACY PRACTICE

4.4.1 Pharmacies that do not supply pharmaceutical benefits

The public is entitled to know if a pharmacy is not approved to supply pharmaceutical benefits.

Guidelines

There should be a prominent sign stating that:

- Pharmaceutical Benefits (of all kinds) are not available from the pharmacy; and
- Patient Record Forms cannot be completed; and
- Repeat Authorisation forms for Pharmaceutical Benefits are not issued.

Persons presenting prescriptions at the pharmacy are to be directed to the sign (above) and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them.

4.4.2 Complementary and alternative therapy when practised by pharmacists

A pharmacist who is acting in the capacity of an alternative therapies consultant is to carry out that function separately and distinctly from the practice of pharmacy in approved pharmacy premises.

Guidelines

A pharmacist in an approved pharmacy practising complementary and alternative therapies such as naturopathy, homoeopathy or herbalism that involve a private consultation with a client is to do so in a room that is:

1. separate from the dispensary, general trading area or professional service area; and
2. approved by the Board.

Another pharmacist is to be in charge of the pharmacy when the first pharmacist is acting as a complementary therapist.

The supply of complementary medicines and any accompanying advice in the ordinary course of pharmacy practice does not imply that the pharmacist is practising complementary medicine.

4.4.3 Complementary and alternative therapy when practised by other persons in the pharmacy

The dispensing of medicines and any advice by the employees of a pharmacy business are responsibilities of the proprietors and individual pharmacists.

Guidelines

Naturopaths and other therapists who are employees of a pharmacy business are not permitted to compound or otherwise dispense any medicines at the pharmacy, use any dispensing labels relating to the pharmacy or to maintain exclusive records.

Subject to Board approval, a pharmacist may rent or lease consulting rooms in a pharmacy to a naturopath or other person provided the person is not an employee of the pharmacy business.

4.4.4 Pathology testing

Pharmacists who conduct pathology or other screening tests are expected to follow the guidelines issued by the Pharmaceutical Society of Australia.

4.4.5 Substances not approved for human use in medicines

The supply or use of chemicals and other substances for therapeutic purposes that have not been approved by Australian health authorities for use in humans should only be used after careful consideration.

Guidelines

Manufacturers of Analytical Reagents (AR) do not usually sanction the use of their products for therapeutic use, despite the implicitly high level of purity.

When such substances are used in a medicine, it is prudent to keep records of the supply to and from the pharmacy.

4.4.6 Drugs of abuse

As part of their continuing professional knowledge, pharmacists are expected to have a contemporary knowledge of the drugs that are subject to abuse or misuse, both generally and in their own localities.

Guidelines

Keeping abreast of the Australian professional literature and the public media and engagement with colleagues is recommended.

Requests for drugs to which this policy relates are to be treated circumspectly because of manipulative behaviour on the part of drug seekers. A genuine therapeutic need is to be established by careful questioning.

Evidence of any developing trend should be communicated to the authorities, such as the Department of Health, and to colleagues and professional bodies.

4.4.7 Pseudoephedrine

Pseudoephedrine is used as a precursor in the illicit manufacture of amphetamines. It is extracted from products in which pseudoephedrine is the sole active ingredient or is one of several active ingredients. Extra obligations devolve on pharmacists in managing requests to supply products containing it.

Guidelines

Only one package is to be supplied at a time unless there are exceptional circumstances, documentation of which should be kept. The sale of multiple packs of pseudoephedrine-containing products (other than in exceptional circumstances) and failure to comply with the regulations applying to Schedule 3 poisons and these guidelines may be considered as unprofessional conduct that invites disciplinary action.

Only one shelf facing per product type is to be displayed. There are to be no window displays, in-store merchandising or similar promotions.

Stock levels are to be kept to no more than one week's supply and any reserve stock is to be kept out of public view.

Suspicious requests for pseudoephedrine products should be communicated to the Major Drug Investigation Division of the Victoria Police (tel: 9865 2618 or by email to chemical.diversion@police.vic.gov.au).

4.4.8 Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines)

The Board adopts the *Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy,* produced by the Pharmaceutical Society of Australia and any substance-specific protocol. Statutory requirements also apply.

Guidelines

Staff need to be trained to ask specific questions of intending purchasers of Schedule 2 poisons and any queries that arise from the person's response should be referred to a pharmacist. Any request by a member of the public for a particular Schedule 3 poison must be referred directly to the pharmacist.

For Schedule 3 poisons (Pharmacist Only Medicines), regulation 61 of the Drugs, Poisons and Controlled Substances Regulations 2006 requires that the pharmacist is satisfied that there is a therapeutic need. This means more than agreeing to supply the medicine on request or merely asking the patient if he or she has used the medicine previously and knows how to use it.

4.4.9 Supply of tobacco products

The sale or supply of tobacco products from a pharmacy is inconsistent with the practice of pharmacy and is considered as unprofessional conduct within the meaning of the Act.

4.5 DISPENSARY ASSISTANTS/DISPENSARY TECHNICIANS OR HOSPITAL PHARMACY TECHNICIANS

Suitably trained persons may assist a pharmacist in the dispensing of medicines in the dispensing area of a pharmacy business or pharmacy department, in accordance with the guidelines. The descriptions, "dispensary assistant", "dispensary technician" or "hospital pharmacy technician" do not apply to a pharmacist or a registered pharmacy student.

For the purposes of these guidelines, "dispensary assistant" and "dispensary technician" have the same meaning. In different industrial relations circumstances, both terms are used.

4.5.1 Responsibilities of the pharmacist in charge

The pharmacy regularly and usually in charge of the pharmacy business or pharmacy department is responsible for ensuring the guidelines are complied with.

Guidelines

1. A pharmacist must supervise a dispensary assistant or dispensary technician.
2. A pharmacist must not supervise more than one dispensary assistant or dispensary technician actually engaged in dispensing prescriptions at a time. The number of dispensary assistants or dispensary technicians employed in a pharmacy business or a pharmacy department must not exceed at any one time, the number of pharmacists present in the dispensary of that pharmacy business or pharmacy department.
3. Dispensary assistants' or dispensary technicians' functions are limited to those that do not require them to exercise professional judgement or discretion.
4. Written records of a dispensary assistant's or dispensary technician's duties are to be maintained [see: 4.5.3].
5. Documentation verifying that a dispensary assistant and dispensary technician has completed an approved course must be available at all times when a person is working in that capacity.
6. A dispensary assistant or dispensary technician must possess a valid certificate of competency from a registered training organisation and on-going validation of the employer for each of the following areas where he or she assists a pharmacist in dispensary operations:
   - non-sterile preparation;

- sterile preparation;
- cytotoxic preparation; or
- clerical and administrative components of clinical pharmacy services.

7. Notwithstanding the dispensary assistants' or dispensary technicians' duties, a pharmacist must review the patient's history; check the dispensed medicine for accuracy and that it complies with the prescriber's intentions, ensure that it is safe for the patient and counsel the patient.

4.5.2 Training of dispensary assistants/dispensary technicians

Pharmacists may employ persons as dispensary assistants/technicians provided those persons have completed a course in their chosen area of practice that is recognised by the Board and have satisfactorily completed the course of forensic instruction approved by the Board.

Guidelines

1. The person may be employed if he or she is actually enrolled in the next available course relevant to their area of employment and scheduled to take place within the next six months, or is currently undertaking such a course.
2. If the person is to undertake non-sterile, sterile or cytotoxic preparative work, the person must have completed the relevant course of instruction that is recognised by the Board and have current validation in the area of practice. The validation is current for 12 months and initially will be issued by the course provider and thereafter by the pharmacist regularly and usually in charge following an assessment of competence in the specific area of practice.
3. The Board will consider for recognition course of suitable duration for dispensary assistants conducted by providers who can demonstrate they have the resources, background and support to provide a suitable course and submit appropriate course information, consistent with the Australian National Training Authority (ANTA) framework of the relevant national competency standards for dispensary assistants, for approval by the Board.
4. The Board will approve a course of forensic instruction for dispensary assistants provided the content is suitable, and the instruction is provided by a person with expertise and is delivered by face-to-face teaching with provision for questions by participants. [Note: The approved forensic course may be included in recognised Victorian courses].
5. Courses recognised and/or approved by the Board will receive documentation setting out the conditions of such recognition and/approval and the period of validity.

Participants in courses conducted outside Victoria or by correspondence should determine from the course provider if a Board approved forensic component is included in the course. If it is not included, the participant

will be required to complete an approved forensic component separately with another approved course provider.

The Board's website may be visited or the Board's Assistant Registrar (Education) contacted to ascertain up to date information on the status of the courses.

4.5.3 Duties of dispensary assistants/dispensary technicians

Dispensary assistants/dispensary technicians are subject to personal supervision by a pharmacist in carrying out their duties.

Guidelines

The duties are:

1. performing routine maintenance procedures on computers;
2. assisting in dispensary stock control, including stocktaking, ordering, unpacking, checking and putting stock away;
3. checking expiry dates and rotating stock;
4. pre-packing stock;
5. assisting in dispensary administration;
6. assisting in the dispensing process, including selecting stock; preparing dispensing labels; attaching cautionary and advisory labels (provided important patient information on the manufacturer's pack is not obscured and that the pharmacist can check the manufacturer's label); arrange all documentation and medicines in such a way that permits the pharmacist to check the prescription;
7. setting out dispensed medicines into dose administration containers, provided the setting out is checked by a pharmacist;
8. preparing extemporaneous, cytotoxic and non-sterile medicines, provided the assistant has completed a course recognised by the Board and has current validation so to do; and
9. carrying out clerical and administrative functions in a clinical setting.

The duties are not:

1. receiving prescriptions over the telephone;
2. discussing with or counselling patients about any aspect of the content of a prescription (other than Medicare and similar details);
3. deciding the brand to be used in dispensing generic prescriptions;
4. issuing a dispensed medicine unless the pharmacist has reviewed the patient's medication history, checked the dispensed medicine for accuracy and compliance with the prescriber's intentions and ensured that the supply is consistent with the patient's safety; and

5. selecting or altering the storage conditions of medicines;
6. making entries in the Controlled Drugs (Schedule 8 poisons) register; and
7. placing Controlled Drugs in, or removing them from the locked storage facility.

4.5.4 Summary of requirements of training and duties

DESCRIPTION	DUTIES	TRAINING	REMARKS
Dispensary assistant	As per text (above).	Certificate of Level 3 National Competency Standards for Pharmacy Assistants – Assist in Dispensary Operations from a course provider approved by the Board.	Valid from date of issue.
Approved to assist in non-sterile preparation	As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile preparation, including the reconstitution of oral liquids.	As for dispensary assistant plus completion of an approved course in non-sterile preparation.	Certificate to assist in non-sterile preparation initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge.
Approved to assist in sterile preparation	As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile or sterile preparations.	As for dispensary assistant plus completion of an approved course in sterile preparation.	Certificate to assist in non-sterile and sterile preparation initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge.

Approved to assist in cytotoxic preparation	As per text (above) plus assist in preparation of medicines prescribed for a patient requiring extemporaneous non-sterile or sterile preparations including cytotoxic products.	As for dispensary assistant plus completion of an approved course in non-sterile preparation, sterile preparation and in cytotoxic preparation.	Certificate to assist in non-sterile, sterile and cytotoxic preparation initially provided by a course provider valid .for 12 months then annual validation by the pharmacist in charge.
Approved to assist in clerical and administrative components of clinical pharmacy services	As per text (above) plus assist in the delivery of clinical pharmacy services not involving professional pharmaceutical judgement.	As for dispensary assistant plus completion of an approved course in clerical and administrative components of clinical pharmacy services.	Certificate to assist in clerical and administrative components of clinical pharmacy services initially provided by a course provider valid for 12 months then annual validation by the pharmacist in charge.

4.5.5 Written records

The pharmacist regularly and usually in charge of a pharmacy or pharmacy department who employs any dispensary assistants must keep written records about their work.

Guidelines

The records are to include:

1. the names of each dispensary assistant employed;
2. the details of each assistant's training;
3. the details of each certificate of competency where applicable;
4. a job description for the assistant employed at the premises that includes those tasks that the assistant is *not* to undertake; those tasks the assistant may undertake; and instruction as to the supervision and conduct of assistants; and
5. a copy of the job description must be readily available or displayed at all times in the premises in a place where the assistant is able to refer to it during his or her normal work in the dispensary or pharmacy department; and be provided personally to each dispensary assistant employed at the premises.

PART 5
PHARMACIES, PHARMACY DEPARTMENTS AND DEPOTS

5.1 APPROVAL TO CARRY ON A PHARMACY BUSINESS OR PHARMACY DEPARTMENT

5.1.1 Application process

The proprietor or governing body must be approved before commencing to carry on a pharmacy business or pharmacy department.

Guidelines

The proprietor or governing body is required to:
1. complete the appropriate application form obtained from the Board's office or website; and
2. forward the completed application to the Board by the last working day of the month for it to be considered by the Board at its meeting during the following month.

For a pharmacy business, go to www.pharmacybd.vic.gov.au/cmsdocs/112bus_cont.pdf

For a pharmacy department, go to www.pharmacybd.vic.gov.au/cmsdocs/112dept_form.pdf

If the Board determines it is appropriate and that the applicant is eligible, the Board will issue:
1. an interim Approval letter; and
2. a "Notice of Commencement" form.

When the applicant commences to carry on the pharmacy business or pharmacy department, the applicant must complete and sign the "Notice of Commencement" form and send it to the Board.

The Board will then write to the applicant setting out the next steps.

5.1.2 Other persons carrying on a business in the pharmacy

A business carried on within the pharmacy business (by a person other than the owner of the pharmacy business), must be compatible with the pharmacy business.

Guidelines

For the purposes of section 103(6) of the Act, the Board may approve a business other than a pharmacy business to be carried on in a pharmacy by

a person other than the owner of the pharmacy business. The Board will not approve any such business that appears to be incompatible with a pharmacy business.

If the Board approves another business to be carried on, it may impose conditions on that business.

A pharmacist who wishes to have the Board approve the carrying on of another business in the pharmacy premises should apply to the Board in writing and provide:

1. details of the proposed business including a description of the goods and services to be offered by that business;
2. a plan of the approved premises showing where the business is to be located within the premises; and
3. details of signs to identify the business and its proprietor.

5.2 APPROVAL OF PREMISES

5.2.1 Application process

The practice of pharmacy must be carried out in premises that are approved by the Board.

Guidelines

For new premises to be approved as a pharmacy business or pharmacy department, or for existing premises to be altered, the proprietor or governing body is required to:

1. complete the appropriate application form obtained from the Board's office or website; and
2. forward the completed application to the Board by the last working day of the month for it to be considered by the Board at its meeting during the following month.

For a pharmacy business, go to www.pharmacybd.vic.gov.au/cmsdocs/apprprem_form.pdf

For a pharmacy department, go to www.pharmacybd.vic.gov.au/cmsdocs/apprdept_form.pdf

When the Board has considered the application and agrees to the plan "in principle", the Board will issue:

1. an "Agreement in Principle" letter; and
2. a "Notice of Completed Premises" form.

When the work has been completed in accordance with the approved application, the applicant must complete and sign the "Notice of Completed Premises" form, as supplied, and send it to the Board.

The Board will then write to the applicant setting out the next steps.

5.3 PREMISES

5.3.1 Access to the premises

The public is entitled to have reasonable access to approved pharmacy premises.

Guidelines

To be approved, pharmacy premises must have:
1. in the case of a pharmacy business, at least one doorway opening from the premises to allow members of the public access to the premises from a street, public walkway, mall or public foyer; or
2. in the case of a pharmacy department, access from a public place within the institution.

For the purposes of section 103(5) of the Act, the Board will refuse to approve the use of any premises as a pharmacy or pharmacy department if it is freely accessible to persons from other premises where the business carried on in the other premises appears to be incompatible with a pharmacy business.

An approval issued under section 103(5) is conditional on the business in the other premises remaining of the same or similar character. If the business changes in character or to another form of business, the owner of the pharmacy business must advise the Board immediately.

A proprietor of a pharmacy business who wishes to have the Board approve access to pharmacy premises from other premises should apply to the Board in writing and provide:
1. a description of the business from which access is proposed; and
2. a completed application for approval of the pharmacy premises. Application forms are available from the Board's office or website.

5.3.2 Solaria

The Board will not approve any premises as a pharmacy for the purposes of the Act if the premises contain a solarium.

5.3.3 Parts of the premises

The design and equipping of pharmacies and pharmacy departments are to ensure that the premises:
1. are secure and sanitary;
2. are suitable for the safe dispensing and supply of therapeutic products;
3. provide an environment that ensures confidentiality in dealings with the public; and
4. are directly accessible from a public place.

Guidelines

5.3.3.1 Security

Pharmacies and pharmacy departments are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows,

walls and ceilings. They are to be fitted with a security intrusion detector alarm which is control room monitored to a central agency on a 24 hour basis. The monitoring company facilities should be graded in accordance with Australian Standard 2201.2 – 2004 (Intruder Alarm Systems – Monitoring Centres) to grade 1, 2 or 3 and should hold a security firm licence.

Deterrence is enhanced by a secure perimeter that includes security lighting (particularly of rear entrances) and signs, such as "this property has security alarms", "all narcotics and cash stored in substantial safe".

Front doors are to be fitted with a substantial lock for the type of door; a locksmith's advice is recommended as some doors require several locking systems.

Where the building code permits, each perimeter door must be fitted with a locking system that prevents the doors from being opened by hand from the inside when the premises are *not lawfully occupied.* Otherwise, measures are needed to prevent entry through ceilings or roofs e.g. floor to roof walls or ceiling space alarm sensors.

Other perimeter doors are to be constructed of solid core with heavy gauge metal sheeting fitted with a four way locking system with deadlocks. A substantial metal security grille door may be installed in addition to the solid core door as an alternative to sheeting it. Bolts and bars are to be fitted into the building structure.

Doors to rooms in the public area of the pharmacy e.g. beauty rooms should be fitted with locks to prevent unauthorised entry to the room.

Display windows should not be capable of being moved and should include a glass break detector.

Other windows and skylights should have substantial locks if capable of being opened. Bars or grilles should be erected internally if possible and grouted into the brickwork or bolted through wall thickness. Bolts are to be welded to bars.

Roller shutters are recommended for large or recessed entry areas.

Patrols are supplementary to physical security and are not a substitute for it.

The intrusion detector must at least cover any area where drugs are kept, including the dispensary, drug safe, professional service area and storerooms.

Silent "hold up" alarms (panic buttons) are strongly recommended.

Schedule 4 poisons must be stored in a manner that they can be supervised; particular attention therefore, needs to be paid to the contents of, and accessibility to, storerooms and refrigerators.

5.3.3.2 Professional service area in a pharmacy

To reflect the professional nature of a pharmacist's dealings with the public, a professional service area is required. It is a distinct area, distinguished by

décor and sign(s) stating "Professional Service Area". The area is solely for the purposes of displaying and storing products for therapeutic use and information about them.

5.3.3.3 Counselling area

A distinct area (which may be part of the professional service 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 privacy screens at least 800 mm apart and rising not less than 600 mm above the bench 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 in the Professional Service Area for the more routine patient interactions.

5.3.3.4 Dispensary

5.3.3.4.1 General dispensary requirements

The dispensary is a private area dedicated to the dispensing of medicines. 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.

The public is not permitted access to the dispensary.

The dispensary should be designed to prevent persons from entering the dispensary or any part of it, without being noticed by the pharmacist on duty.

The pharmacy should be designed so that the dispensary is not used as a thoroughfare to access "back of house" areas.

Therapeutic products are not to be removed from the dispensary without the express permission of a pharmacist unless by a student, intern or trained dispensary assistant under the supervision of a pharmacist.

Pharmacy departments that:

1. provide both in-patient and out-patient services; and
2. are within a hospital that has more than 100 beds

should be not less than 140 m^2.

Pharmacy departments in hospitals that do not meet the above description will be considered on their merits.

A dispensary in a pharmacy is to include:

1. provision for the storage of S4 poisons that facilitates the accurate selection of medicines and restricts access to dispensary staff only;
2. a safe or drug cabinet for the storage of S8 poisons that facilitates the accurate selection of medicines;
3. a bench or bench area of at least 0.6 m^2 for the unpacking and sorting of dispensary orders received;
4. one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9 am and 6 pm;
5. a hot and cold water sink with drainer;
6. a bench or bench area of at least 0.6 m^2 located near to the sink for the compounding or preparation of medicines that provides storage for compounding equipment; and
7. a bench or bench area of at least 0.6 m^2 for dispensary or clerical and research use;

AND
if the pharmacy provides pharmacotherapy to 20 or more persons per day:

8. a bench or bench area dedicated to the pharmacotherapy program of at least 0.6m^2 that is not accessible to the public and provides for the secure storage of "in use" S8 medicines.

The pharmacotherapy area may be located away from the dispensary provided:

9. it is air-conditioned;
10. it is alarmed;
11. it is fitted with a hot and cold water sink with drainer;
12. it is fitted with a safe or drug cabinet to store S8 poisons;
13. it is fitted with lockable storage for client records; and
14. suitable arrangements are in place in the pharmacy to protect the privacy of pharmacotherapy clients;

AND
if the pharmacy regularly fills dose administration aids (DAAs) for 15 or more persons per week;

15. a bench or bench area of at least 1 m^2 dedicated to the filling of DAAs; and

16. secure storage for dispensed medicines.

The area for the filling of DAAs may be located away from the dispensary provided:

17. it is air-conditioned;

18. it is alarmed;

19. it has access to hand washing facilities;

20. it has a 'patient history look up' computer terminal and DAA printing equipment; and

21. it provides lockable storage for dispensed medicines.

A dispensing station is to include a dispensing bench of at least 0.6 m^2 (e.g. 1000 mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, a dedicated printer for labels, a dedicated printer for repeat forms and adequate stationery. 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.

If a dispensary assistant is involved with dispensing at a dispensing station, then an additional bench area of at least 0.6 m^2, equipped with a keyboard and screen without label and printing capability, is recommended for the dispensing station. The bench area may be separate from, or an extension of the dispensing bench.

The requirements for dispensaries set out in this section apply to all existing and new pharmacies. Pharmacists should regularly assess their dispensary to ensure compliance in the face of changed business circumstances including business growth. Compliance with dispensary guidelines will be a priority of Board officers during all inspections.

In special circumstances demonstrated by the applicant, the Board may approve variations to the requirements of this section.

5.3.3.4.2 Dispensary size

Applications for approval of new pharmacy premises or alterations to existing pharmacy premises should provide a dispensary to be of an area not less than 10 per cent of the total trading area to a maximum required area of 30 m^2 but not less than 20 m^2.

Examples: A pharmacy up to 200 m^2, the dispensary area will be not less than 20 m^2.

A pharmacy of 300 m^2 or more, the dispensary area will be not less than 30 m^2.

In special circumstances demonstrated by the applicant, the Board may approve variations to the requirements of this section.

In calculating the size of the dispensary;

1. the total trading area is the sum of the areas of the professional trading area and the general trading area;
2. a pharmacotherapy area that is located away from the dispensary may not be included in the calculation of the dispensary size; and
3. a dose administration aid filling area that is located away from the dispensary may not be included in the calculation of the dispensary size.

5.3.3.5 Client waiting area

A pharmacy or pharmacy department should include at least one client waiting area. Its use should be encouraged to minimise congestion at the serving counter where privacy may be compromised, and to reduce pressure on the dispensing staff. In the interests of safe dispensing, chairs in the waiting area should be positioned in such a way that dispensing staff are not subject to staring or body language that indicates impatience. Provision of reading matter is suggested.

5.3.4 Point of sale (POS) data entry station

POS data entry stations, non-dispensary clerical work areas and staff areas are to be located outside of the dispensary.

5.3.5 Display of names

The public is entitled to know the names of the pharmacists with whom they are dealing in a professional capacity.

Guidelines

The name or names of the proprietor of a pharmacy, natural or corporate, must be displayed on a sign at eye height placed at all the entrances to the pharmacy where the public has access so as to be clearly visible from the street or public thoroughfare. The font size should be at least 72 points.

The name of the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department and the name or names of other pharmacists on duty are to be displayed in the professional service area or the place where medicines are usually collected by the public.

There is neither a requirement for, nor objection to, the wearing of name badges.

5.3.6 Removal of signs

The public is entitled to know that a pharmacy or pharmacy department has ceased to operate.

Guidelines

When a pharmacy or pharmacy department ceases to operate, the owner or the pharmacist who is regularly and usually in charge of the pharmacy

or pharmacy department, or the administrators, trustees or executors must remove all signs that indicate that the premises were a pharmacy or a pharmacy department.

5.3.7 Controlled temperature storage

Pharmacies and pharmacy departments are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range.

Guidelines

Temperatures in a pharmacy or pharmacy department should not exceed 25°C; 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 25°C 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 connected to the computer (or functionally similar arrangements) to alert staff to a malfunction when the premises are unoccupied.

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.

5.4 EQUIPMENT

5.4.1 References

The pharmacist regularly and usually in charge of a pharmacy or pharmacy department must keep at that pharmacy or pharmacy department the current edition, together with any supplements, addenda or amendments to the references listed below. These may be in the form of a published document (hard copy) or via electronic means such as a computer provided the information is immediately available to the pharmacist during the dispensing process. Substitution of the references listed below with unlisted texts is not acceptable.

Guidelines

a. the Australian Pharmaceutical Formulary and Handbook (APF)

b. the Australian Medicines Handbook (AMH)

c. a reference work on prescription products:

- MIMS Annual with bimonthly addenda (e-MIMS)

d. copies of the legislation controlling the practice of pharmacy:

- Health Professions Registration Act 2005*
- Drugs, Poisons and Controlled Substances Act 1981*
- Drugs, Poisons and Controlled Substances Regulations 2006*
- Guide to the Drugs, Poisons and Controlled Substances Regulations 2006**

* These are contained in the Office Consolidation or accessed on the Internet on www.legislation.vic.gov.au

** The Guide is accessed on www.health.vic.gov.au

e. the Pharmacy Board of Victoria's Guidelines

f. Drug interaction references – two of either of the following (at least one must be an electronic version):

(i) Drug Interaction Facts – Facts and Comparisons
- Loose-leaf with quarterly amendments
- CD (with quarterly or monthly amendments)
- Online

(ii) Drug Interactions Analysis and Management, Hansten and Horn Loose–leaf quarterly amendments

(iii) eMIMS DrugAlert Interactions
- Updated quarterly (CD)

(Note: monthly amendments are available online)

(iv) Micromedex
- CD
- Online

(v) Stockley's Drug Interactions
- Online only

(vi) Lexi-Interact Online

g. the Merck Manual of Diagnosis and Therapy (Merck, Sharp and Dohme), or Murtagh J, General Practice (McGraw Hill, Sydney)

h. the Therapeutic Guidelines Series, including:

Analgesic
Antibiotic
Cardiovascular
Dermatology
Endocrinology
Gastrointestinal
Neurology
Oral and Dental
Palliative Care
Psychotropic
Respiratory
Rheumatology

i. the Royal Children's Hospital Paediatric Pharmacopoeia

Note 1: *If participating in the methadone treatment programme, a copy of the Department of Health's "Methadone Guidelines Prescribers and Pharmacists" is required; see: paragraph 4.3.4.*

Note 2: *If participating in the buprenorphine programme, a copy of the National Drug Strategy, "National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence" is required; see: paragraph 4.3.4.*

Note 3: The Standard for the Uniform Scheduling of Drugs and Poisons *(SUSDP) is no longer required. Changes to scheduling will be advised on the Board's website (www.pharmacybd.vic.gov.au). Specific queries about scheduling should be directed to the Drugs and Poisons Regulation Group of the Department of Health (Tel: 1300 364 545). The SUSDP may be accessed on the Internet by typing: Comlaw poisons standard, in the search engine.*

5.4.2 Dispensing equipment

All community pharmacies are to be equipped with Class 1 or Class 2 certified and approved scales and a range of accurately calibrated metric measures; blending equipment for powders, liquids and pastes; and suitable storage containers.

All pharmacy departments are to have access to certified and approved scales commensurate with the services provided within an institution.

Guidelines

Operating instructions, including the minimum weighable mass, are to be prominently displayed.

The scales should be stored in such a way that their accuracy is not compromised.

Pharmacists are responsible for the accuracy of the weighing equipment they use. Good practice suggests that weighing equipment should be tested at least every five years by a person licensed by the Director of Consumer Affairs, Victoria.

In the case of institutions, "access to certified and approved scales" means the scales will be within and controlled by the institution.

Note 1: *"Certified" means that the make and model of the scales has been certified by a person licensed by Consumer Affairs Victoria as a servicing licensee.*

Note 2: *"Approved" means that the make and model of the scales has been approved by the National Measurement Institute.*

Note 3: *Further information may be obtained from:*

Trade Measurement
Consumer Affairs Victoria
PO Box 123A
MELBOURNE VIC 3000.
(tel: (03) 8684 6200 or 1300 558 181)
(tel: 1300 365 500 for local trade measurement inspector)
(fax: (03) 8684 6222)

5.4.3 Schedule 8 poisons – storage

Schedule 8 poisons (Controlled Drugs) are to be stored in accordance with the Drugs, Poisons and Controlled Substances Regulations 2006.

Guidelines

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. Products should be arranged to minimise selection errors.

Specifications about drug safes and 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 2006 and be 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.

5.5 SATELLITES OF PHARMACY DEPARTMENTS

A hospital pharmacy department may include one or more satellites that are approved by the Board. Each satellite is to be within the hospital and is part of the department but remote from it. The satellite and its staff are to be personally supervised by a pharmacist and may perform any function of the department, subject to it being suitable, sanitary and adequately equipped.

Guidelines

The satellite's area is to be not less than 20 m^2 (including the shelving and working areas), unless the Board approves a smaller area in a particular case.

The satellite pharmacy is to be equipped with:

1. a sink made of stainless steel or similar with an impervious surrounding area and supplied with hot and cold running water;
2. an impervious dispensing bench of not less than 400 mm width and of

sufficient length as to provide not less than 3 m^2 of free working space, in addition to the space occupied by computers and other equipment;

3. adequate lighting and ventilation;
4. a security intrusion detector alarm that is monitored in a control room to a central agency throughout the 24 hours;
5. a password-protected computer networked to the department computer;
6. direct access to a complete set of texts mandated by the Board;
7. dispensing equipment appropriate to the intended function; and
8. a telephone.

The satellite is to be constructed to:

1. provide an area for patients to be counselled privately about their medicines;
2. maintain suitable conditions of temperature and humidity for the storage of all the drugs stored within; and
3. prevent unauthorised access by persons other than the staff of the pharmacy department.

5.6 WARD DISPENSING STATIONS

A hospital pharmacy department may, with specific Board approval, establish, separate from the department, a ward dispensing station within the hospital to enable ward pharmacists to dispense prescriptions for patients of up to two wards. A satellite that is approved by the Board is required if the ward dispensing station is to service more than two wards.

Guidelines

The ward dispensing station is to be equipped with:

1. a password-protected computer networked to the department computer;
2. direct access to a complete set of texts mandated by the Board;
3. dispensing equipment appropriate to the activities of the ward, including labels, ancillary cautionary and advisory labels, tablet counters;
4. a telephone; and
5. a lockable drug storage facility, if required.

The ward dispensing station is to:

1. be located in or adjacent to the ward drug storage area, preferably a lockable room;
2. be in a position that minimises distraction to the dispensing pharmacist; and have adequate lighting;

3. have ready access to handwashing facilities;
4. provide an impervious bench of sufficient size to accommodate dispensing equipment and provide 0.6 m^2 of clear working space; and
5. be dedicated to pharmacy use.

5.7 PHARMACY DEPOTS

5.7.1 Establishing a pharmacy depot

The Board may approve a pharmacist who carries on a pharmacy business or a pharmacy department to establish and operate a pharmacy depot in accordance with section 104 of the Act.

Guidelines

The depot is to be situated at least 15 km by the normal access route from the nearest pharmacy. If Schedule 2 poisons are to be stored at, or supplied from the depot, the depot must be connected to the pharmacy by an audio-visual link. A Schedule 2 poison may only be sold from the depot by a pharmacist following a consultation he or she has had with the client using the audiovisual equipment on every occasion of a sale.

In making application to the Board for approval of the depot, the pharmacist is to describe the depot and how it is to be conducted. The description is to include:

1. the means by which orders for medicines and prescriptions are to be received at the depot and their transmission to the pharmacy;
2. how prescriptions are to be collected from the depot and conveyed to the pharmacy;
3. the operation of a confidential audio-visual link between the depot and its clients with the pharmacy;
4. how the pharmacist intends to counsel the patient who obtains medicine from the depot;
5. how medicines supplied to the depot are to be packaged and transported to the depot;
6. how the medicines are to be stored at the depot, with reference to security, confidentiality and maintaining the integrity of the medicine;
7. the name of the person in charge of the depot and certification that the person has attained 18 years;
8. the kinds of medicines to be stocked at the depot and the maximum quantities of Schedule 2 poisons;
9. a copy of procedures that the person in charge is to follow with particular reference to confidentiality of any information about clients of the

pharmacy and the need to refer all queries about the medicine to the pharmacist;

10. the business name of the depot (note: the words "pharmacy" or "chemist" must not be used to imply that the depot is, or operates as, a pharmacy); and
11. a statement that a pharmacist agrees to visit the depot at intervals of not less than two months to ensure that the procedures are adhered to.

5.7.2 Continuity of services after a change of ownership

When a person assumes ownership of a pharmacy business that operates a depot, that person is deemed to be approved to operate the depot for a period of three months after commencing ownership. This is intended to allow the depot to continue to operate while the new owner applies for approval.

5.8 SUPPLYING ETC MEDICINES IN SPECIAL CIRCUMSTANCES

The Board may approve in a particular case a pharmacist to supply, compound or dispense medicines in special circumstances under section 107(1)(b) of the Act.

5.8.1 Application process

Guidelines

The pharmacist seeking to practise under special circumstances is required to:

1. complete the appropriate application form obtained from the Board's office or website (www.pharmacybd.vic.gov.aucmsdocs/1071b_form.pdf); and
2. forward the completed application to the Board by the last working day of the month for it to be considered by the Board at its meeting during the following month.

If the Board approves the application, it will issue an approval letter valid for a maximum of three years. The Board will also arrange for an inspection by a Board officer.

5.8.2 Continuity of services in special circumstances

Guidelines

Where a person commences to carry on a pharmacy business or pharmacy department that provides a service the special circumstances of which are approved under section 107(1)(b) of the Act, then the special circumstances are deemed to be approved for a period of three months after commencing to carry on the pharmacy business or department. This is intended to allow the service to continue to operate while the new owner applies for approval.

PART 6
MISCELLANEOUS

6.1 SERVICE COMPANIES

Pharmacists who engage companies to provide services to a pharmacy business may do so provided:

1. the company does not enjoy any proprietary interest in the pharmacy business; and
2. there is a written agreement, contract, memorandum of understanding or other document between the parties setting out the details of the services and how they are paid for; and
3. any documentation is made available for inspection by the Board at any reasonable time.

Notes:

1. A "proprietary interest" means a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as the trustee or beneficiary of a trust.

2. Section 116 of the Act makes void a provision in any bill of sale, mortgage, lease or in any other commercial arrangement that gives a right to anyone (other than a person approved under the Act) the right to receive any consideration that varies according to the profits or takings of the business.

Guidelines

The documentation and practice must not give any suggestion that the service company has any ownership rights in connection with the pharmacy business.

If the service company maintains customer accounts on behalf of the pharmacy or provides computer services, the pharmacist must not supply the company with any information about a person's medication.

The purchase of any stock (especially scheduled poisons) for or on behalf of the pharmacy business is indicative of ownership in the assets of the pharmacy business. Subject to any licensing requirements imposed by law, a service company may carry on a *bona fide* business as a wholesaler but in such circumstances, it is a separate and distinct entity having its own premises and books of account.

APPENDIX 1
SECURITY

ELECTRONIC ALARM SYSTEMS

Any alarm system installed should conform to Australian Standard 2201: Intruder alarm systems. Some of the key items of this requirement are:

1. standby backup battery with a minimum capacity of 4 hours for a monitored alarm;
2. automatic rechargeable batteries;
3. concealed or protected wiring;
4. routine maintenance;
5. operating procedure instructions; and
6. weekly testing of the alarm system by the user.

The alarm system should be monitored offsite by a monitoring company. The monitoring company should be required to verify the alarm by multi-sector alarms (more than one sensor) / multi-breaks on one sensor or duress alarm or communication failure when the alarm fails to report to the monitoring station. The method of monitoring should provide for tamper proof monitoring ensuring an alarm response is received by the monitoring company if the alarm system is tampered with. Options to achieve this include but are not limited to:

1. direct line – dedicated line from premises to the security company;
2. mobile data – utilise a digital radio network;
3. Securitel – a Telstra product which recognises tampering with the telephone line immediately;
4. cellular back up – cellular telephone technology providing a back-up facility should the telephone line be cut;
5. radio – wireless monitoring by the security company.

Some of these options are not available in all areas. Any reputable and licensed security firm registered with the Private Agents Register and which is a member of an organisation such as the Australian Security Industry Association Limited (ASIAL) should be consulted for further advice and assistance.

Responding to confirmed alarm activations should involve attendance by security personnel and police. Staff should not attend alarm responses until

security and police have first attended and assessed the situation. Serious occupational health and safety issues could occur should staff attend before security or police. Staff attendance would be required to provide key assess for further investigation by security or police.

In addition to offsite monitoring, the installation of satellite sirens (battery back-up audible alarms both internally and externally) assist in discouraging offenders from remaining on premises for extended periods. External sirens should be located to avoid tampering; likewise, internal sirens can be mounted in roof space out of view.

General advice on alarm systems include:

1. ensure adequate alarm detector coverage within the dispensing area and drug safe to ensure multi-break alarms and detect tampering with detectors;
2. alarm detectors should be positioned high to avoid tampering (consider tamper resistant alarms). PIR (passive infra red) detectors to have movement indicating LED lights deactivated or covered to prevent walk-testing what areas are or are not covered by the alarm;
3. ensure any changes to the layout of premises do not obscure the view of alarm detectors. Examples include displays, blinds, posters etc;
4. consider incorporating or utilising existing duress capabilities within the alarm control keypad panel. This could involve a specific additional number utilised when staff are operating the alarm system under threat;
5. consider protecting a building's perimeter with early warning detectors such as reed switches (on doors), break glass or vibration sensors on or near windows; and
6. duress facilities (panic or hold-up buttons) should be considered at counters.

Alarm systems are an integral element of a number of security measures which when combined provide greater deterrence and protection.

Ram raids and smash grabs

Pharmacies are at risk to vehicle ram raids and smash grabs. Consideration should be given to reducing these risks. Options include, but are not limited to:

1. installing purpose designed removable or fixed bollards internally or externally fitted, subject to municipal council approval. Dual purpose bollards include fixed bicycle racks and fixed seating;
2. reinforcing windows with security film or security grilles or shutters or trellises; and
3. ensuring that displays of targeted expensive items such as some perfumes and sunglasses are securely stored with a suitable locking system; and
4. cash is stored in a locked safe or drawer.

Bulk stocks of drugs that are subject to abuse

Consideration should be given to storing *bulk* stocks of drugs that are subject to abuse in a locked facility.

'Closed' dispensary storage systems such as 'Rhombic Units' should be locked after hours in a similar manner to a filing cabinet if drugs that are prone to abuse are stored in them.

The advice of the Victoria Police in the preparation of this appendix is acknowledged.

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CONTACT NUMBERS

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Approval of premises, alterations, plans	t: 9356 8408	e: planning@pharmacybd.vic.gov.au
Pharmacists	t: 9356 8409	e: inspection@pharmacybd.vic.gov.au
Registration	t: 9356 8401	e: registration@pharmacybd.vic.gov.au
Accounts	t: 9356 8402	e: finance@pharmacybd.vic.gov.au
Education, interns	t: 9356 8406	e: education@pharmacybd.vic.gov.au

Facsimile	f: 9348 0608
Website	www.pharmacybd.vic.gov.au

Department of Health
(Drugs and Poisons Regulation Group)

All enquiries	t: 1300 364 545
Facsimile	f: 1300 360 830

Medicare Australia

Senior pharmacist	t: 9605 7510
PBS approvals, change of address	t: 9605 7558
PBS authority information	t: 1800 888 333
PBS general enquiries, stationery	t: 13 22 90

Victoria Police Drug Task Force

Crimestoppers	t: 1800 333 000
Pseudoephedrine line	t: 9865 2618

Health Services Commissioner t: 8601 5200

Poisons Information Centre t: 13 11 26

Stolen prescription pads see Board's website, pharmacists login

PHARMACY BOARD OF VICTORIA

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