Pharmacy Regulation Act 2010
No. 39 of 2010

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The Parliament of Victoria enacts:

PART 1—PRELIMINARY

1 Purposes
The main purposes of this Act are—

(a) to provide for the regulation of pharmacy businesses, pharmacy departments and pharmacy depots; and

(b) to establish the Victorian Pharmacy Authority.
2 Commencement

(1) Subject to subsection (2), this Act comes into operation on a day or days to be proclaimed.

(2) If a provision of this Act does not come into operation before 1 July 2011 it comes into operation on that day.

3 Definitions

(1) In this Act—

*Australian lawyer* means an Australian lawyer within the meaning of the *Legal Profession Act 2004*;

*authorised person* means a person authorised under section 65 to carry out functions and exercise powers under Part 4;

*Authority* means the Victorian Pharmacy Authority established under this Act;

*Authority standard* means a standard published by the Authority under section 86;

*commencement day* means the date of commencement of Part 3;

*condition* includes limitation or restriction;

*Fund* means the Victorian Pharmacy Authority Fund established under this Act;

*licence* means a licence granted or taken to be granted under Part 3 by the Authority to an eligible person to carry on a pharmacy business or pharmacy department;

*licensee* means a person who holds a licence to carry on a pharmacy business or pharmacy department;
operator means a person who is responsible for the operation and security of the premises of a pharmacy depot;

pharmacy means premises in or from which a registered pharmacist supplies, compounds or dispenses medicines to the public and includes the part of the premises where the registered pharmacist sells or offers to sell goods of any kind, but does not include a pharmacy department or pharmacy depot;

Pharmacy Board of Australia means the Pharmacy Board of Australia established by the Health Practitioner Regulation National Law;

pharmacy business means a business carried on at a pharmacy and includes the business of providing pharmacy services and that part of the business where goods of any kind are sold or offered to be sold but does not include a pharmacy department or pharmacy depot;

pharmacy department means the part of the premises of a registered funded agency, registered community health centre, private hospital or privately operated hospital within the meaning of the Health Services Act 1988 set aside for supplying, compounding or dispensing medicines on order or prescription to patients and staff of the agency, registered community health centre or hospital;

pharmacy depot means premises at which—

(a) written prescriptions for the supply, compounding or dispensing of medicines may be left for a pharmacist;
(b) medicines supplied, compounded or dispensed by a registered pharmacist may be left for collection by or on behalf of the person to whom they are addressed;

**pharmacy services** includes—

(a) the supply, compounding or dispensing of medicines; and

(b) advice and counselling on the effective and safe use of medicines;

**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;

**registered pharmacist** means a person registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession (other than as a student);

**registrar** means a person responsible for maintaining the register to be kept by the Authority;

**registration** means a registration granted or taken to be granted under Part 3 to a licensee to register the premises of a pharmacy business, pharmacy department or pharmacy depot;

**Secretary** means the Department Head of the Department of Health within the meaning of the **Public Administration Act 2004** and includes a person acting as the Secretary to the Department of Health under that Act.

(2) For the purposes of this Act, a person is to be treated as carrying on a business (including a pharmacy business) or pharmacy department or pharmacy depot if the person owns, manages,
controls, conducts or operates the business or the pharmacy department or pharmacy depot.

4 Act to bind the Crown

This Act binds the Crown in right of the State of Victoria and, to the extent that the legislative power of the Parliament permits, the Crown in all its other capacities.
PART 2—OWNERSHIP AND OPERATION

Division 1—Requirements of ownership

5 Ownership of pharmacy businesses

(1) A person must not own or have a proprietary interest in a pharmacy business unless the person is—

(a) a registered pharmacist; or

(b) a company registered under the Corporations Act—

(i) whose directors are all registered pharmacists; and

(ii) in which all the shares and the beneficial and legal interest in those shares are held by registered pharmacists; or

(c) a company registered under the Corporations Act—

(i) that immediately before 1 July 1999 was registered or incorporated as a friendly society under a Friendly Societies Code of a State or Territory that was in force at that time; and

(ii) that is a company limited by guarantee or shares or by guarantee and shares; and

(iii) that has at least 100 members; and

(iv) whose members have equal voting rights on a poll or at a meeting or equal voting rights to elect a representative to vote on their behalf; and
Part 2—Ownership and Operation

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(v) whose objects include the provision of health or welfare facilities or services for its members or their dependants; and

(vi) whose undistributed surplus if the company were wound up is to be distributed among its members at the time of winding up or transferred to another person or body with a similar structure and objects; and

(vii) that satisfies the Authority as to the matters set out in subsection (4); or

(d) a company registered under the Corporations Act that is a wholly owned subsidiary of a company referred to in paragraph (c); or

(e) a company registered under the Corporations Act that—

(i) satisfies the requirements of paragraph (c)(ii) to (vii); and

(ii) is an amalgamation of 2 or more companies that comply with paragraph (c) or, at the time of amalgamation, complied with paragraph (c); or

(f) a person approved by the Authority to carry on a pharmacy business in an area that the Authority determines needs a pharmacy business but in which there is no person referred to in paragraphs (a) to (e) who is able to own and carry on the pharmacy business.

Penalty: 240 penalty units in the case of a natural person;
1200 penalty units in the case of a body corporate.
(2) A registered pharmacist and a company referred to in subsection (1)(b) must not own or have a proprietary interest in more than 5 separate pharmacy businesses.

(3) A person is not to be treated as having a proprietary interest in a company referred to in subsection (1)(c), (d) or (e) in respect of an interest as a director, member or shareholder of that company.

(4) For the purposes of subsection (1)(c)(vii), the Authority must be satisfied that—

(a) the company is not carrying on business for the dominant purpose of securing a profit or pecuniary gain for its members; and

(b) any object or intention of the company to provide a dividend to its shareholders or members is a limited and not dominant purpose of the company; and

(c) the property and income of the company is applied towards the objects of the company.

(5) In this section registered pharmacist does not include a registered pharmacist who holds provisional registration under the Health Practitioner Regulation National Law.

6 Exception for executors and administrators

(1) Nothing in section 5 prevents a person who—

(a) is the executor, administrator or trustee of the estate of a pharmacist who has died and who carried on a pharmacy business at the time of his or her death; or
(b) is appointed or authorised under the laws of bankruptcy to administer the property of a pharmacist who carried on a pharmacy business and is bankrupt; or

(c) assumes the administration of the property of a person under a mortgage, bill of sale or security interest of that person's pharmacy business—

from continuing to carry on the pharmacy business for a period of 6 months or for any further period permitted by the Authority if the pharmacy services of the business are provided by a registered pharmacist in accordance with this Part.

(2) Nothing in section 5(1) or (2) applies to an interest created when a person referred to in section 5(1)(a) to (f) gives a mortgage, bill of sale or security interest in respect of the person's pharmacy business if the mortgage, bill of sale or document creating the security interest does not contravene section 11.

7 Notice to Authority about change to company with mutual structure

A company referred to in section 5(1)(c), (d) or (e) must inform the Authority within 30 days after a notice is lodged with, or an application is made to, the Australian Securities and Investments Commission under Part 5 of Schedule 4 to the Corporations Act about—

(a) the company; or

(b) a company referred to in section 5(1)(d) of which it is a wholly owned subsidiary.
8 Provision of information to Authority

The Authority may require a person referred to in section 5(1) to give the Authority any information or produce any documents relating to the person's ownership or proprietary interest in a pharmacy business.

9 Offence not to comply with section 7 or 8

A person must not fail or refuse to give the Authority any information required under section 7 or 8 or fail or refuse to produce any documents required under section 8 or wilfully mislead the Authority when giving the information.

Penalty: 60 penalty units in the case of a natural person;
300 penalty units in the case of a body corporate.

10 Pharmacy businesses at separate premises

Each pharmacy business carried on at separate premises including a pharmacy business carried on by the same person or under the same name as another pharmacy business is to be treated as a separate pharmacy business for the purposes of this Act.

11 Undue influence

A provision in a bill of sale, mortgage, lease or in any other commercial arrangement in respect of a pharmacy or pharmacy business that gives to any person other than the person licensed under section 38 to carry on the pharmacy business—

(a) the right to control the manner in which the pharmacy business is carried on; or
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(b) the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or

(c) the right to receive any consideration that varies according to the profits or takings in respect of the business—is void.

Division 2—Caps on growth of pharmacy ownership

12 Definition

In this Division, a reference to—

own, in relation to a pharmacy business, includes a reference to having a proprietary interest in the pharmacy business.

13 Application

This Division only applies to a pharmacy business—

(a) if the business is carried on at premises approved or taken to be approved by the Pharmacy Board of Victoria under the Pharmacy Practice Act 2004 before 1 July 2007 or under the Health Professions Registration Act 2005 before the commencement day;

(b) if the business is carried on at premises registered or taken to be registered by the Authority under this Act on or after the commencement day.
14 Cap on growth of pharmacy ownership for friendly society type companies

A company referred to in section 5(1)(c), (d) or (e) must not acquire ownership of any pharmacy business except in accordance with this Division.

Penalty: 1200 penalty units.

15 Exception for existing ownership

Section 14 does not apply to a company that—

(a) immediately before 16 November 2004, did not own a pharmacy business or owned less than 6 pharmacy businesses and, after that date, acquired ownership of any pharmacy business so that the total number of pharmacy businesses owned by the company at any one time does not exceed 6; or

(b) immediately before 16 November 2004, owned 6 or more pharmacy businesses and on or after 17 November 2008, acquired ownership of any additional pharmacy business so that the total number of pharmacy businesses owned by the company at any one time does not exceed 30% more than the number of pharmacy businesses that the company owned immediately before 17 November 2008.

16 Exception for amalgamations on or after 16 November 2004 and before 17 November 2008

Section 14 does not apply to a company referred to in section 5(1)(e) that was formed by amalgamation on or after 16 November 2004 and before 17 November 2008 if the number of pharmacy businesses the company owns at any one time does not exceed the total of the number of pharmacy businesses referred to in paragraphs (a) and (b) that were owned individually by each
of the companies that were amalgamated to form the company—

(a) in the case of a company that formed part of the amalgamation and, immediately before 16 November 2004, did not own a pharmacy business or owned less than 6 pharmacy businesses—6 pharmacy businesses; and

(b) in the case of any other company that formed part of the amalgamation—30% more than the number of pharmacy businesses that the company owned immediately before 16 November 2004.

17 Exception for amalgamation on or after 17 November 2008

(1) Section 14 does not apply to a company referred to in section 5(1)(e) that was formed by amalgamation on or after 17 November 2008 if the number of pharmacy businesses the amalgamated company owns at any one time does not exceed—

(a) in the case of the amalgamated company being formed only by companies that, immediately before 16 November 2004, did not own a pharmacy business or owned less than 6 pharmacy businesses—6 pharmacy businesses; or

(b) in the case of the amalgamated company being formed by at least one company that, immediately before 16 November 2004, owned 6 or more pharmacy businesses—30% more than the number of pharmacy businesses that the largest amalgamating company owned immediately before 17 November 2008.
(2) In this section *largest amalgamating company* means a company that—

(a) was amalgamated with other companies to form a company; and

(b) owned more pharmacy businesses than any other company that was amalgamated to form the company.

18 **Pharmacy businesses owned by a subsidiary of a company**

For the purposes of this Division, the number of pharmacy businesses owned by a company referred to in section 5(1)(c) includes any pharmacy business owned by a wholly owned subsidiary of that company if the subsidiary was acquired or incorporated on or after 16 November 2004.

19 **Calculating number of pharmacy businesses**

For the purposes of calculating the total number of pharmacy businesses owned by a company under section 15(b), 16 or 17, the total number of pharmacy businesses may be rounded up to the next whole number.

**Division 3—Requirements of establishment and operation**

20 **Notice of intention to establish a pharmacy business**

If a person intends to establish or carry on a pharmacy business, the person must notify the Authority as soon as is practicable.

21 **Establishment of pharmacy businesses**

(1) A person must not establish or carry on a pharmacy business unless—

(a) the requirements of section 5(1) and (2) are satisfied; and
(b) the Authority has registered the premises of the pharmacy business; and

(c) the Authority has granted a licence to the person to carry on a pharmacy business at the registered premises.

Penalty: 240 penalty units in the case of a natural person;
1200 penalty units in the case of a body corporate.

(2) Nothing in this section applies to a person referred to in section 6 who is carrying on a pharmacy business in accordance with that section.

22 Where establishment of a pharmacy department not permitted

A person must not establish or carry on a pharmacy department unless—

(a) the person is a registered funded agency, registered community health centre, private hospital or privately-operated hospital within the meaning of the Health Services Act 1988 that is acting in accordance with the provisions of the Health Services Act 1988; and

(b) the Authority has registered the premises of the pharmacy department; and

(c) the Authority has granted a licence to the person to carry on a pharmacy department at the registered premises.

Penalty: 240 penalty units in the case of a natural person;
1200 penalty units in the case of a body corporate.
23 Establishment of pharmacy depot

A person must not establish or carry on a pharmacy depot unless—

(a) the person is a licensee; and

(b) the Authority has registered the premises of the pharmacy depot.

Penalty: 60 penalty units.

24 Controls on business activity at registered premises

A licensee must not authorise, cause or permit any other person to carry on in the registered premises of the licensee any business or activity unless the business or activity is permitted by the licence or approved by the Authority.

Penalty: 60 penalty units.

25 Notifications about pharmacy businesses

A licensee of a pharmacy business must notify the Authority as soon as practicable, and in any event at least 14 days, before the licensee ceases carrying on the pharmacy business.

Penalty: 10 penalty units.

26 Notifications for a pharmacy department that ceases operation

If a pharmacy department is to cease operation, the licensee carrying on the pharmacy department must notify the Authority at least 14 days before the pharmacy department is closed.

Penalty: 10 penalty units.
27 Notifications for a company licensee

If a licensee is a company it must notify the Authority within 14 days of a change to—

(a) the shareholding of the company; and
(b) the directorship of the company; and
(c) the office bearers of the licensee.

Penalty: 10 penalty units.

28 Notification by pharmacists

(1) A registered pharmacist must, within 14 days after the pharmacist commences to supply, compound or dispense medicines from a pharmacy or pharmacy department, notify the Authority of the address of the pharmacy or pharmacy department.

Penalty: 10 penalty units.

(2) Subsection (1) does not apply to a person who has agreed in writing with the Authority to notify the Authority in the circumstances agreed with the Authority.

29 Controls over the supply, compounding or dispensing of medicines

(1) A registered pharmacist must not supply, compound or dispense medicines except—

(a) from the premises of a pharmacy business or pharmacy department registered by the Authority; or

(b) in any other special circumstances that are approved by the Authority in a particular case.

(2) A registered pharmacist providing pharmacy services from the premises of a pharmacy business or a pharmacy department registered by the Authority must not permit any person to supply, compound or dispense medicines except when the
person is doing so under the supervision of a registered pharmacist.

30 Personal supervision of pharmacy or pharmacy department

(1) A pharmacy or a pharmacy department must be personally supervised by a registered pharmacist at all times it is open for business.

(2) Any of the following persons is guilty of an offence and liable to a penalty not exceeding 60 penalty units if the person knowingly or negligently allows a pharmacy service to be provided at a pharmacy or a pharmacy department unsupervised by a registered pharmacist—

(a) in the case of a pharmacy, the person licensed to carry on the pharmacy business of that pharmacy;

(b) in the case of a pharmacy department, the person licensed to carry on the pharmacy department;

(c) the registered pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department;

(d) the registered pharmacist (if he or she is not the pharmacist referred to in paragraph (c)) who had in respect of that period of time been placed in charge of and had undertaken to personally supervise the pharmacy or pharmacy department.

(3) In this section personally supervised by a registered pharmacist means personally supervised by a registered pharmacist who is present at the pharmacy or the pharmacy department.
31 Access to closed pharmacies and pharmacy departments

(1) The registered pharmacist who is regularly and usually in charge of a pharmacy and the person licensed to carry on the pharmacy business must not allow a person to have access to that pharmacy when it is not open for business unless a registered pharmacist is present.

Penalty: 60 penalty units.

(2) The registered pharmacist who is regularly and usually in charge of a pharmacy department and the person licensed to carry on the pharmacy department must not allow a person to have access to that pharmacy department when it is not open for providing pharmacy services unless a registered pharmacist is present.

Penalty: 60 penalty units.

32 Dispensing and recording of prescriptions

(1) A registered pharmacist must take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription or order is consistent with the safety of the person named in that prescription or order.

(2) A registered pharmacist must keep a record of every prescription supplied, compounded or dispensed by the pharmacist in accordance with subsection (3).

(3) The record of a prescription must be in English and include—

   (a) the name and address of the person to whom the medicine is dispensed;
   (b) the date the medicine is dispensed;
   (c) the name and dose form of the medicine dispensed;
(d) the strength or identifying formula;
(e) the quantity or number of doses ordered;
(f) the directions for the use of the medicine;
(g) any other ancillary written instructions supplied on the label;
(h) the name, address and telephone number of the prescriber;
(i) any alteration to the original prescription;
(j) any other information concerning the medicine and its use.

(4) The record of the prescription must—

(a) be retained in a secure place at the pharmacy or pharmacy department for at least 3 years;
(b) be made at the time of dispensing or, in the case of an emergency, within 24 hours after the dispensing;
(c) be certified by the registered pharmacist who dispensed the prescription with his or her handwritten signature within 24 hours after the dispensing—

(i) in the prescription record; or
(ii) if the prescription record is made in a manner which precludes handwritten endorsement, in a separate record kept for that purpose, that he or she dispensed the prescription and the certified record must be kept as part of the prescription record;
(d) be readily retrievable by reference to the name and address of the person to whom the medicine was dispensed, the date of dispensing and from information on the label on the container.
33 Security at pharmacy depots

The operator of a pharmacy depot must keep secure—

(a) medicines left for collection at the depot until they are collected by or on behalf of the persons to whom they are addressed; and

(b) prescription and client records kept at the depot.

Penalty: 60 penalty units.

34 Claims by persons as to licence to operate

(1) A person must not intentionally or recklessly use the title "pharmacy", "pharmacy practice" or "pharmacy business" except in relation to a pharmacy or pharmacy business to which a licence applies.

Penalty: 60 penalty units in the case of a natural person;

300 penalty units in the case of a body corporate.

(2) This section does not apply to the use of a name or a title by or in relation to—

(a) a museum if—

(i) the words are used to identify premises where items relating to the history of pharmacy are exhibited; and

(ii) pharmacy services are not provided from those premises; or

(b) a teaching institution providing a course of study in pharmacy practice; or

(c) professional associations representing registered pharmacists; or
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(d) any other person or body in circumstances approved by the Authority and notified in the Government Gazette and any publication circulating generally among registered pharmacists.

35 Use of title

(1) Despite anything to the contrary under the Health Practitioner Regulation National Law, it is not an offence under that law for a person to use the name or title "pharmacist" in respect of a pharmacy business, where a person is licensed to carry on a pharmacy business, if the pharmacy services are provided by or under the supervision of a registered pharmacist.

(2) A registered pharmacist who—

(a) carries on a pharmacy business; and

(b) does not personally provide pharmacy services from the pharmacy—

is not to be treated for the purpose of the Health Practitioner Regulation National Law as practising as a pharmacist in respect of that pharmacy business.
PART 3—LICENSING AND REGISTRATION

Division 1—Licensing

36 Application for a licence

(1) An eligible person may apply to the Authority for a licence to carry on a pharmacy business or pharmacy department.

(2) The application must—

(a) be in writing; and

(b) contain the information required by the Authority to determine the application; and

(c) specify the premises at which the pharmacy business or pharmacy department is to be established; and

(d) be accompanied by the fee fixed by the Authority.

(3) If the period of the licence applied for under subsection (1) is less than 12 months, the proportion of the fixed fee that applies may be determined on a pro rata basis.

37 Eligibility to apply for a licence

(1) A person is eligible to apply for a licence to carry on a pharmacy business if the person—

(a) satisfies the requirements under section 5; and

(b) is not prohibited from carrying on the pharmacy business under Division 2 of Part 2.
(2) A person is eligible to apply for a licence to carry on a pharmacy department if the person is—
   (a) a registered funded agency; or
   (b) a registered community health centre; or
   (c) a private hospital or privately-operated hospital—
   within the meaning of the Health Services Act 1988 that is acting in accordance with the provisions of the Health Services Act 1988.

38 Decision to grant licence

(1) The Authority may grant a licence to carry on the pharmacy business or pharmacy department if the Authority is satisfied that—
   (a) the applicant is eligible to be granted a licence; and
   (b) the facilities, equipment, security, management and operation of the pharmacy business or pharmacy department at the premises at which it is to be carried on comply with—
      (i) good pharmacy practice; and
      (ii) without limiting subparagraph (i), the relevant requirements in the Schedule and any other requirements that are prescribed.

(2) The Authority may also have regard to the following matters in determining whether or not to grant a licence to a person to carry on a pharmacy business or pharmacy department—
   (a) the applicant's compliance with this Act, the regulations and any standards issued by the Authority;
(b) the commitment of the applicant to utilising quality improvement programs that promote quality and safety in the dispensing and use of medicines;

(c) the applicant's participation in public health programs relevant to the provision of pharmacy services;

(d) the applicant's provision of affordable pharmacy services to disadvantaged groups.

(3) The Authority must not grant a licence to a registered funded agency to carry on a pharmacy department unless the Authority has first consulted with the Secretary.

39 Grounds for refusal of a licence

(1) If the Authority is not satisfied of any matters set out in section 38, the Authority may refuse to grant the licence sought.

(2) The Authority may refuse to grant a licence if the Authority is satisfied that the applicant—

(a) has failed to carry on a pharmacy business or pharmacy department in accordance with this Act or the regulations or the conditions on any other licence or registration granted by the Authority; or

(b) has been convicted of an offence against this Act or the regulations; or

(c) has contravened an Authority standard on one or more occasions and the Authority believes that it is against the public interest for the person to be licensed to carry on the pharmacy business or pharmacy department; or
(d) is found guilty of an offence that affects the suitability of the person to carry on a pharmacy business and the Authority believes it is not in the public interest that the person be licensed to carry on the pharmacy business or pharmacy department; or

(e) is of a character such that it would not be in the public interest to allow the applicant to hold a licence to carry on a pharmacy business.

40 Conditions on licence

(1) The Authority may impose any condition it thinks appropriate on a licence.

(2) The licence must set out any condition to which it is subject.

(3) The Authority may impose a condition on a licence during the period of a licence—

   (a) with the consent of the licensee; or

   (b) without the consent of the licensee if 28 days prior to imposing the condition the Authority provides to the licensee—

      (i) written notice of the proposed condition; and

      (ii) the grounds for imposing the condition.

(4) The Authority may impose a condition on the renewal of a licence.

41 Notice of decision on application

(1) The Authority must give written notice to the applicant of its decision on an application for a licence.

(2) If the decision is to refuse the application, the Authority must set out in the notice the reasons for its decision.
42 Period of licence
A licence ends on 30 June next following the date on which it is granted.

43 Licence renewal—application and fee
(1) An application to renew an existing licence to carry on a pharmacy business or pharmacy department must be made before 1 July each year.

(2) The Authority may fix the annual fee for any given year.

(3) An application under subsection (1) must be made to the Authority.

(4) An application must—
(a) be in writing; and
(b) be accompanied by the fee fixed by the Authority; and
(c) contain the information required by the Authority to determine the application.

(5) An application to renew a licence may be for a period of up to 12 months.

(6) If the period of a licence applied for under subsection (1) is less than 12 months the proportion of the fixed fee that applies may be determined on a pro rata basis.

Division 2—Registration of premises

44 Application for registration of premises of pharmacy business or pharmacy department
(1) A person who is eligible to be granted a licence to carry on a pharmacy business or pharmacy department may apply to the Authority to register the premises for the pharmacy business or pharmacy department.
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(2) The application must—

(a) be in writing; and

(b) contain the information required by the Authority to determine the application; and

(c) be accompanied by the relevant fee fixed by the Authority.

(3) An application for the registration of premises may be made at the same time as the application for a licence to carry on a pharmacy business or pharmacy department at those premises.

(4) If the period of registration applied for under subsection (1) is less than 12 months, the proportion of the fixed fee that applies may be determined on a pro rata basis.

45 Registration of premises of pharmacy businesses or pharmacy departments

(1) The Authority may register the premises of a pharmacy business or pharmacy department if the Authority is satisfied that—

(a) the applicant is eligible to be granted a licence to carry on the pharmacy business or pharmacy department; and

(b) the premises are suitable for the provision of pharmacy services; and

(c) without limiting paragraph (b), the premises comply with—

   (i) the requirements in the Schedule that relate to premises; and

   (ii) any other requirements that are prescribed.
(2) The Authority must not register part of the premises of a registered funded agency as a pharmacy department, unless the Authority has first consulted with the Secretary.

46 Grounds for refusal of registration of premises

(1) Without limiting section 45, the Authority may refuse an application for registration of premises if satisfied that the applicant—

(a) has failed to carry on a pharmacy business or pharmacy department in accordance with this Act or the regulations or the conditions on any licence or registration granted by the Authority; or

(b) has been convicted of an offence against this Act or the regulations; or

(c) has contravened an Authority standard on one or more occasions and the Authority believes that it is against the public interest for the premises to be registered; or

(d) is found guilty of an offence that affects the suitability of the person to carry on a pharmacy business and the Authority believes it is not in the public interest for the premises to be registered; or

(e) is of a character such that it would not be in the public interest to register the premises.

(2) Without limiting section 45, the Authority may refuse to register premises if the premises are freely accessible to persons from other premises where a business or activity other than that of providing pharmacy services is carried out.

(3) The Authority must not refuse to register the premises of a pharmacy business on the ground that the Authority disapproves of the geographical location of those premises.
47 Application for registration of a pharmacy depot

(1) A person who is licensed to carry on a pharmacy business or pharmacy department may apply to the Authority to register a pharmacy depot.

(2) The application must—

(a) be in writing; and

(b) contain the information required by the Authority to determine the application; and

(c) be accompanied by the fee fixed by the Authority.

(3) If the period of registration applied for under subsection (1) is less than 12 months, the proportion of the fixed fee that applies may be determined on a pro rata basis.

48 Registration of pharmacy depot

The Authority may register a pharmacy depot if it is satisfied that—

(a) the applicant is a licensee who will provide pharmacy services in respect of those premises; and

(b) the premises of the pharmacy depot provide secure storage for prescriptions and medicines; and

(c) the applicant will have suitable arrangements at the pharmacy depot to ensure that—

(i) client records are kept confidential and secure; and

(ii) conversations at the pharmacy depot can be conducted between a registered pharmacist and the person to whom the medicines are dispensed; and

(iii) the conversations are able to be conducted in confidence; and
(d) the person who will operate the pharmacy depot will be at least 18 years of age.

49 Conditions on registration

(1) The Authority may impose any condition it thinks appropriate on the registration of premises of a pharmacy business, pharmacy department or pharmacy depot.

(2) The registration must set out any conditions to which it is subject.

(3) The Authority may impose a condition on the registration of premises of a pharmacy business, pharmacy department or pharmacy depot during the period of a registration—

   (a) with the consent of the registration holder; or

   (b) without the consent of the registration holder if 28 days prior to imposing the condition, the Authority provides to the registration holder—

       (i) written notice of the proposed condition; and

       (ii) the grounds for imposing the condition.

(4) The Authority may impose a condition on the renewal of the registration of premises of a pharmacy business, pharmacy department or pharmacy depot.

50 Notice of decision on application

(1) The Authority must give written notice to the applicant of its decision on an application for registration.

(2) If the decision is to refuse the application, the Authority must set out in the notice the reasons for its decision.
51 **Period of registration**

A registration ends on 30 June next following the date on which it is granted.

52 **Registration renewal: application and fee**

(1) An application to renew an existing registration of a pharmacy business, pharmacy department or pharmacy depot must be made before 1 July each year.

(2) The Authority may fix the annual fee for any given year.

(3) An application under subsection (1) must be made to the Authority.

(4) An application must—

   (a) be in writing; and

   (b) be accompanied by the fee fixed by the Authority; and

   (c) contain the information required by the Authority to determine the application.

(5) An application to renew a registration may be for a period of up to 12 months.

(6) If the period of registration applied for under subsection (1) is less than 12 months, the proportion of the fixed fee that applies may be determined on a pro rata basis.

**Division 3—Investigations**

53 **Notifications about a licensee or holder of a registration**

(1) A person may notify the Authority about any matter relating to a licensee if the person believes it indicates that—

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(a) the licensee's ability to carry on a pharmacy business may be affected because—

(i) of the physical or mental health of the licensee; or

(ii) the licensee has an incapacity; or

(iii) the licensee is an alcoholic or drug-dependent person; or

(b) the licensee is not of good character; or

(c) the licensee has contravened the requirements regarding ownership of pharmacies; or

(d) the licensee is no longer eligible to hold a licence; or

(e) the licensee has contravened an Authority standard; or

(f) the licensee has contravened this Act; or

(g) the licence was or may have been improperly obtained because the Authority was provided with false or misleading information.

(2) A person may notify the Authority about any matter relating to a holder of a registration if the person believes it indicates that—

(a) the registered premises do not meet the requirements of this Act or of an Authority standard; or

(b) the registration holder has or may have contravened a condition of a licence or a condition of the registration of the premises; or

(c) the registration was or may have been improperly obtained because the Authority was provided with false or misleading information.
54 Investigations without notification

(1) The Authority may investigate a matter relating to a licence or a registration without notification if the Authority believes that there is evidence of any of the matters referred to in section 53.

(2) The Authority may investigate a matter relating to a licence or registration even if a notification about the matter is withdrawn.

Division 4—Revocation of a licence or registration

55 Grounds on which licence may be revoked

Subject to this Division, the Authority may revoke a licence granted in respect of a pharmacy business or pharmacy department—

(a) if the person carrying on the pharmacy business or pharmacy department—

(i) is no longer eligible to hold a licence; or

(ii) has been convicted of an offence against this Act or the regulations; or

(iii) has contravened an Authority standard on one or more occasions and the Authority believes that it is against the public interest for the person to continue to carry on the pharmacy business or pharmacy department; or

(iv) is found guilty of an offence that affects the suitability of the person to carry on a pharmacy business or pharmacy department and the Authority believes it is not in the public interest that the person continue to carry on a pharmacy business or pharmacy department; or
(v) is of a character such that it would not be in the public interest to allow the applicant to continue to hold a licence to carry on a pharmacy business; or

(b) there has been a failure of security at the pharmacy business or pharmacy department that presents a serious risk to public health or safety; or

(c) the premises of the pharmacy business or pharmacy department are unhygienic or no longer suitable for use for this purpose; or

(d) there has been a failure of good pharmaceutical practice at the premises of the pharmacy business or pharmacy department that presents a serious risk to public health and safety.

56 Grounds for revocation of registration

Subject to this Division, the Authority may revoke a registration of premises of a pharmacy business, pharmacy department or pharmacy depot carried on by a person—

(a) if the person carrying on the pharmacy business, pharmacy department or pharmacy depot is no longer eligible to hold a licence; or

(b) if the person carrying on a pharmacy business, pharmacy department or pharmacy depot has failed to carry on the pharmacy business, pharmacy department or pharmacy depot in accordance with this Act or the regulations or any conditions on the registration; or

(c) on any other ground on which the person's licence could be revoked; or
(d) there has been a failure of security at the pharmacy business, pharmacy department or pharmacy depot that presents a serious risk to public health and safety; or

(e) if the premises of the pharmacy business, pharmacy department or pharmacy depot are unhygienic or no longer suitable for use for this purpose; or

(f) there has been a failure of good pharmaceutical practice at the premises of the pharmacy business, pharmacy department or pharmacy depot that presents a serious risk to public health and safety.

57 Convening of a panel

(1) The Authority may convene a panel to hear a matter which has been the subject of an investigation under Division 3 of Part 3.

(2) A panel convened under subsection (1) may be comprised of 3 members of whom—

(a) at least 2 are members of the Authority; and

(b) one may be a person co-opted by the Authority for the purpose of the hearing of the matter; and

(c) at least 2 are registered pharmacists.

(3) A person co-opted by the Authority under subsection (2) is entitled to the fees and allowances that are fixed from time to time by the Governor in Council.

58 Procedure of a panel

At a panel hearing—

(a) the proceedings must be conducted with as little formality and technicality as the requirements of this Act and the proper consideration of the matter permit;
(b) there is no right to legal representation at the panel hearing;
(c) the licensee or registration holder is entitled to be present and to make submissions and to be accompanied by another person who may be a lawyer;
(d) the panel is not bound by rules of evidence but may inform itself in any way it thinks fit;
(e) the panel is bound by the rules of natural justice;
(f) the proceeding must not be open to the public;
(g) the procedure of the panel is otherwise in its discretion.

59 Decisions of a panel

(1) At the end of a hearing, the panel may decide that—
   (a) a condition be placed on a licence; or
   (b) a condition be placed on a registration; or
   (c) a licence be revoked; or
   (d) a registration be revoked; or
   (e) the licensee or registration holder be cautioned or reprimanded; or
   (f) the licence or registration continue.

(2) The decision of the panel under this section is the decision of the Authority.

60 Notice of revocation of licence or registration

(1) If the Authority decides to revoke a licence or registration without referring the matter to a panel, the Authority may give written notice to the person who holds the licence or registration.
(2) The notice may—

(a) revoke the licence or registration at the end of 28 days after the day on which the notice is given; or

(b) state an intention to revoke the licence or registration unless within a period (not being less than 28 days) specified in the notice satisfactory arrangements are made to remedy any specified failure or circumstance.

(3) In determining whether to give a notice under subsection (2), the Authority must consider—

(a) the conduct of the person carrying on the pharmacy business, pharmacy department or pharmacy depot; and

(b) the seriousness of any breach of this Act, the regulations or any condition of the licence or registration; and

(c) whether the breaches could have been avoided by the exercise of reasonable care; and

(d) any circumstances that may prevent the person from being able to continue to carry on the pharmacy business, pharmacy department or pharmacy depot in accordance with this Act, the regulations or any condition of the licence or registration.

(4) The Authority may revoke a licence or registration without giving the notice if it believes it is necessary to immediately revoke the licence or registration to reduce or prevent a serious risk to public health and safety.
61 Other sanctions by Authority

If it considers it appropriate to do so, the Authority may caution or reprimand a licensee or holder of registration instead of revoking the licence or registration.

Division 5—VCAT review

62 Application to VCAT for review

(1) A person affected by a decision of the Authority—
(a) to refuse to grant a licence; or
(b) to refuse to grant a registration; or
(c) to impose conditions on a licence or registration; or
(d) to revoke a licence or registration—
may apply to VCAT for a review of that decision.

(2) An application under subsection (1) must be made within 28 days after the date on which the person concerned received notice of the decision and the reasons for it.

(3) The Authority must publish a notice of the determination of VCAT on a review under this section on the Authority's Internet site.

(4) If a decision has been reviewed by VCAT, the Authority must notify any person who was notified of the original decision by the Authority, of the determination of VCAT.
Part 3—Licensing and Registration

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Division 6—Public register

63 Public register

(1) The Authority must keep a public register of all—
   (a) licensees; and
   (b) registered premises of a pharmacy business, pharmacy department or pharmacy depot.

(2) The following particulars must be included on the public register—
   (a) the name of each licensee of a pharmacy business or pharmacy department; and
   (b) the number of pharmacies owned by a person; and
   (c) the registration status of the premises of a pharmacy business, pharmacy department or pharmacy depot; and
   (d) any conditions on a licence or registration.

(3) The Authority may publish on the Authority's Internet site a list of persons who have had a licence or registration revoked.

(4) The Authority may also publish on the Authority's Internet site the public register as set out in subsections (1) and (2).
PART 4—ENFORCEMENT

64 Proceedings for offences

(1) The Authority may authorise the registrar or another person employed by the Authority under section 99 to take proceedings under this Act in the name of the Victorian Pharmacy Authority.

(2) Any prosecution instituted in the name of the Authority must, in the absence of evidence to the contrary, be taken to have been instituted by the Authority.

65 Authorisation of persons to assist in enforcement

(1) The Authority may authorise any of the following persons to carry out functions and exercise powers under this Part—

(a) the registrar or another person employed by the Authority under section 99; or

(b) a person engaged by the Authority to provide services to the Authority.

(2) The registrar or any other person employed by the Authority under section 99 who is authorised by the Authority under subsection (1) may exercise powers under section 68.

66 Identification

(1) The Authority must issue an identity card to each authorised person.

(2) An authorised person must produce his or her identity card for inspection—

(a) before exercising a power under this Part other than a requirement made by post; and

(b) at any time during the exercise of a power under this Part, if asked to do so.
67 Victorian Pharmacy Authority may examine documents

(1) The Authority may—

(a) require a registered pharmacist or a person licensed under this Act to submit for examination at its offices any documents kept by the pharmacist or person in connection with the carrying on of a pharmacy business; and

(b) direct that—

(i) copies of or extracts from the documents be made and certified by the registrar as true and correct copies or extracts for the purpose of any hearing under this Act or any review of any decision of the Authority; or

(ii) the documents or any part of them be held by the registrar in accordance with this Part for the purpose of any hearing under this Act or any review of any decision of the Authority.

(2) Before requiring a registered pharmacist or person under subsection (1) to submit a document the Authority must—

(a) warn the registered pharmacist or person that a refusal or failure to comply with the requirement, without reasonable excuse, is an offence; and

(b) in the case of a natural person inform the registered pharmacist or person of the effect of section 78.
68 Special powers of entry to pharmacies

(1) In order to ascertain whether provisions of this Act and the regulations are being complied with a person referred to in section 65(2)—

(a) may enter into the premises of any pharmacy business, pharmacy department or pharmacy depot or other place where medicines are supplied, compounded or dispensed; and

(b) may examine any room or part of the premises so entered for the purpose of inspecting stocks of medicines and other goods in the premises or any equipment, prescriptions, or other documents in the premises; and

(c) may make or cause to be made copies of or extracts from documents in the premises.

(2) An authorised person may only enter the premises of a pharmacy business, pharmacy department or pharmacy depot when the pharmacy business, pharmacy department or pharmacy depot is open for business or providing pharmacy services.

(3) A person must not—

(a) refuse or fail to admit an authorised person requiring entry into premises under this section; or

(b) cause or permit the refusal or failure referred to in paragraph (a).

(4) Before requiring a person to permit the activities provided for under subsection (1), the authorised person must—

(a) warn the person that a refusal or failure to comply with the requirement, without reasonable excuse, is an offence; and
(b) in the case of a natural person inform the person of the effect of section 78.

69 Certified copy of examined document

A copy of, or extract from, a document certified as correct by an authorised person is taken to be a true and correct copy or extract for the purposes of any hearing under this Act or any review of any decision of the Authority.

70 General powers of entry with warrant

(1) A person appointed for that purpose by the Authority may apply to a magistrate for the issue of a search warrant in relation to particular premises if that person believes, on reasonable grounds—

(a) that there is or has been a contravention of this Act or the regulations on the premises; or

(b) that entry into or onto the premises is necessary for the purpose of investigating a matter in a notification made under this Act which, if substantiated, may provide grounds for the revocation by the Authority of a licence or registration.

(2) If a magistrate is satisfied by evidence on oath, whether oral or by affidavit, that there are reasonable grounds for suspecting that there is on the premises a particular thing that may be evidence of the commission of an offence against this Act or the regulations or of grounds for the revocation by the Authority of a licence or registration, the magistrate may issue a search warrant authorising any person named in the warrant—

(a) to enter the premises or the part of the premises named or described in the warrant; and
(b) to search for and seize a thing named or described in the warrant; and

(c) to bring the thing before the Magistrates' Court so that the matter may be dealt with according to law.

(3) A search warrant must be issued in accordance with the Magistrates' Court Act 1989 and in a form prescribed under that Act.

(4) In addition to any other requirement, a search warrant issued for the purposes of this section must state—

(a) the offence or grounds of revocation of a licence or registration suspected; and

(b) the premises to be searched; and

(c) the name or a description of the thing to be searched for; and

(d) any conditions to which the warrant is subject; and

(e) whether entry is authorised to be made at any time or during stated hours; and

(f) a day, not later than 7 days after the issue of the warrant, on which the warrant ceases to have effect.

(5) The rules to be observed with respect to search warrants mentioned in the Magistrates' Court Act 1989 extend and apply to warrants under this section.

71 Announcement before entry

(1) Immediately before executing a search warrant, a person named in the warrant must announce that he or she is authorised by the warrant to enter the premises.
(2) The person need not comply with subsection (1) if he or she believes on reasonable grounds that immediate entry to the premises is required to ensure the safety of any person or that the effective execution of the search warrant is not frustrated.

72 Copy of warrant to be given

If the occupier or another person who apparently represents the occupier is present at premises when a search warrant is being executed, the person or persons named in the warrant must—

(a) identify themselves to that person by producing their identity card for inspection by that person; and

(b) give to that person a copy of the execution copy of the warrant.

73 Copies or receipts to be given

(1) If a person seizes—

(a) a document, disk or tape or other thing that can be readily copied; or

(b) a storage device the information in which can be readily copied—

under this Part the person, on request by the occupier or the person from whom it was seized, must give a copy of the thing or information to the occupier or person as soon as practicable after the seizure.

(2) If a person seizes a thing under this Part and has not provided a copy of the thing or information under subsection (1) the person must provide a receipt for that thing as soon as practicable after the seizure.
74 Copies of seized documents

(1) If an authorised person retains possession of a document taken or seized from a person under this Part, the authorised person must give the person, within 21 days of the seizure, a copy of the document certified as correct by the authorised person.

(2) A copy of a document certified under subsection (1) shall be received in all courts and tribunals to be evidence of equal validity to the original.

75 Retention and return of seized documents or things

(1) If an authorised person seizes a document or other thing under this Part, the authorised person must take reasonable steps to return the document or thing to the person from whom it was seized if the reason for its seizure no longer exists.

(2) If the document or thing seized has not been returned within 3 months after it was seized, the authorised person must take reasonable steps to return it unless—

(a) proceedings for the purpose for which the document or thing was retained have commenced within that 3-month period and those proceedings (including any appeal) have not been completed; or

(b) the Magistrates' Court makes an order under section 76 extending the period during which the document or thing may be retained.

76 Magistrates' Court may extend 3-month period

(1) An authorised person may apply to the Magistrates' Court—

(a) within 3 months after seizing a document or other thing under this Part; or
(b) if an extension has been granted under this section, before the end of the period of the extension—

for an extension (not exceeding 3 months) of the period for which the authorised person may retain the document or thing but so that the total period of retention does not exceed 12 months.

(2) The Magistrates' Court may order such an extension if it is satisfied that—

(a) it is in the interests of justice; and

(b) the total period of retention does not exceed 12 months; and

(c) retention of the document or other thing is necessary—

(i) for the purposes of an investigation into whether a contravention of this Act or the regulations has occurred; or

(ii) to enable evidence of a contravention of this Act or the regulations to be obtained for the purposes of a proceeding under this Act; or

(iii) for the purpose of investigating a matter in a notification made under this Act which, if substantiated, may provide grounds for the revocation of a licence or registration.

(3) At least 7 days before the hearing of an application under this section, notice of the application must be sent to the owner of the document or thing described in the application.
77 **Refusal or failure to comply with requirement**

A person must not, without reasonable excuse, refuse or fail to comply with a requirement of the Authority or an authorised person under this Part.

Penalty: 60 penalty units.

78 **Protection against self-incrimination**

(1) It is a reasonable excuse for a natural person to refuse or fail to give information or do any other thing that the person is required to do by or under this Act, if the giving of the information or the doing of that other thing would tend to incriminate the person.

(2) Despite subsection (1), it is not a reasonable excuse for a natural person to refuse or fail to produce a document that the person is required to produce by or under this Act, if the production of the document would tend to incriminate the person.

(3) If the person claims, before producing the document, that production of the document would tend to incriminate them, the document, is not admissible in evidence against the person in criminal proceedings.

79 **Offence to give false or misleading information**

A person must not—

(a) give information to an authorised person under this Act that the person believes to be false or misleading in any material particular; or

(b) produce a document to an authorised person under this Act that the person knows to be false or misleading in a material particular without indicating the respect in which it is
false or misleading and, if practicable, providing correct information.

Penalty: 60 penalty units.

80 Offence to hinder or obstruct authorised person

A person must not, without reasonable excuse, hinder or obstruct an authorised person who is exercising a power under this Part.

Penalty: 60 penalty units.
PART 5—VICTORIAN PHARMACY AUTHORITY

Division 1—Establishment

81 Establishment of Victorian Pharmacy Authority

(1) The Victorian Pharmacy Authority is established.

(2) The Authority—

(a) is a body corporate with perpetual succession;

(b) has a common seal;

(c) may sue and be sued in its corporate name;

(d) may acquire, hold and dispose of real and personal property;

(e) may do and suffer all acts and things that a body corporate may, by law, do and suffer.

(3) The common seal must be kept as directed by the Authority and must not be used except as authorised by the Authority.

(4) All courts must take judicial notice of the common seal on a document and, until the contrary is proved, must presume that the document was properly sealed.

Division 2—General powers and functions

82 Functions of Authority

The Authority has the following functions—

(a) to license a person to carry on a pharmacy business or a pharmacy department;

(b) to register the premises of a pharmacy business, pharmacy department or pharmacy depot;
(c) to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots;

(d) to advise the Minister on any matters relating to its functions;

(e) when so requested by the Minister, to give to the Minister any information reasonably required by the Minister;

(f) to keep a public register;

(g) any other function conferred on the Authority by or under this or any other Act.

83 Powers of Authority

The Authority has all the powers necessary to enable it to perform its functions.

84 Consultation requirements

In carrying out its functions and exercising its powers, the Authority must consult with the Minister and have regard to the Minister's advice.

85 Objectives

In carrying out its functions and exercising its powers, the Authority is to have regard to the following objectives—

(a) the need to control who may own and operate pharmacy businesses in Victoria;

(b) the need to maintain standards relating to the licensing of persons to carry on pharmacy businesses and pharmacy departments and the registration of pharmacy premises, pharmacy departments, pharmacy depots.

86 Standards

(1) The Authority may issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots.
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(2) Before issuing a standard, the Authority must consult with licensees affected by the standard.

(3) The Authority must not issue any standard unless the Minister has approved the standard.

(4) The Authority must publish any standard approved by the Minister in the Government Gazette.

(5) A standard takes effect on the day on which it is published in the Government Gazette or any later date specified in the standard.

(6) The Authority must publish a standard on the Authority's Internet site as soon as practicable after the Minister approves the standard.

(7) The Authority is not required to consult in accordance with subsection (2) before issuing a standard if, in the opinion of the Authority, there is an immediate need to issue the standard to address a matter of public health or safety.

(8) If there is any inconsistency between any practices recommended under a standard published by the Authority and a provision of this Act or the regulations or any other Act or regulations, the provision of the Act or the regulations prevails.

Division 3—Membership and procedure

87 Membership of the Authority

(1) The Authority consists of members appointed by the Governor in Council on the nomination of the Minister.

(2) Of the persons appointed to the Authority—

(a) 3 must be persons who are registered pharmacists; and

(b) one must be an Australian lawyer; and
(c) one must be a person who is not a registered pharmacist.

88 Terms of office

(1) A member of the Authority holds office for the period, not exceeding 3 years, that is specified in the instrument of appointment of the member.

(2) A member of the Authority is eligible for reappointment.

(3) The Public Administration Act 2004 (other than Part 3 of that Act) applies to a member in respect of the office of a member.

(4) Despite subsection (1) and anything to the contrary in the member's instrument of appointment, a member may, with the consent of the Minister, continue to hold office at the end of his or her appointment for a period not exceeding 3 months to enable the vacancy in the member's office to be filled.

89 Resignation and removal

(1) A member of the Authority ceases to be a member if he or she is absent, without leave first being granted by the Authority, from 3 consecutive meetings of which reasonable notice has been given to that member, either personally or by post.

(2) A member of the Authority may resign the office of member by writing signed by the member and delivered to the Minister.

(3) The Governor in Council may at any time remove a member of the Authority from office.

(4) If a member of the Authority dies, resigns or is removed from office, the Minister may fill the vacant position by appointing a person who is qualified to be appointed as an acting member.
(5) A member appointed under subsection (4) holds office for the rest of the term of appointment of the member whose place he or she fills.

90 Chairperson and deputy chairperson

(1) The Governor in Council may, on the recommendation of the Minister, appoint members of the Authority to be Chairperson and Deputy Chairperson.

(2) The Minister may only recommend a member who is a registered pharmacist for appointment to the office of Chairperson or Deputy Chairperson, unless the Minister considers that it is necessary for the good operation of the Authority to recommend a member who is not a registered pharmacist.

(3) A person appointed to an office under subsection (1) holds office for the term specified in his or her instrument of appointment and is eligible for reappointment.

(4) A person appointed to an office under subsection (1) may resign that office by writing signed by the person and delivered to the Minister.

(5) The Governor in Council may at any time remove a person appointed under subsection (1) from office.

(6) A person appointed to an office under subsection (1) ceases to hold that office on ceasing to be a member of the Authority.

91 Acting members

(1) If a member of the Authority is unable to perform the duties or functions of the office, the Minister may appoint a person who is qualified to be appointed as a member to act as the member during the period of inability.
(2) The terms and conditions of appointment for an acting member are the same as for the member for whom they act.

(3) The Minister may at any time terminate the appointment.

(4) While the appointment of an acting member remains in force, the acting member has and may exercise all the powers and perform all the duties and functions of the member.

92 Payment of members

(1) A member or acting member of the Authority, other than a member who is an employee of the public service within the meaning of the Public Administration Act 2004, is entitled to receive the fees that are fixed from time to time by the Governor in Council for that member.

(2) Each member or acting member of the Authority is entitled to receive the allowances that are fixed from time to time by the Governor in Council.

93 Procedures of the Authority

(1) The Chairperson or, in the absence of the Chairperson, the Deputy Chairperson, must preside at a meeting of the Authority at which he or she is present.

(2) If neither the Chairperson nor the Deputy Chairperson are present at a meeting, the members present may elect a member to preside at the meeting.

(3) The person presiding at a meeting has a deliberative vote and a second or casting vote.

(4) A majority of the members of the Authority currently holding office constitutes a quorum.

(5) Subject to this Act, the Authority may regulate its own proceedings.
94 Effect of vacancy or defect

An act or decision of the Authority is not invalid only because—

(a) of a vacancy in its membership; or

(b) of a defect or irregularity in the appointment of any of its members; or

(c) in the case of an acting member, the occasion for that member so acting had not arisen or had ceased.

95 Resolutions without meetings

(1) If—

(a) the Authority has taken reasonable steps to give notice to each member setting out the terms of a proposed resolution; and

(b) a majority of the members for the time being sign a document containing a statement that they are in favour of the resolution in the terms set out in the document—

a resolution in those terms is taken to have been passed at a meeting of the Authority held on the day on which the document is signed or, if the members referred to in paragraph (b) do not sign it on the same day, on the day on which the last of those members signs the document.

(2) If a resolution is, under subsection (1), taken to have been passed at a meeting of the Authority, each member must as soon as practicable be advised of the matter and given a copy of the resolution.

(3) For the purposes of subsection (1), 2 or more separate documents containing a statement in identical terms, each of which is signed by one or more members, are deemed to constitute one document.
(4) The majority of members referred to in subsection (1)(b) must not include a member who, because of Part 5 of the Public Administration Act 2004, is not entitled to vote on the resolution.

Note
Part 5 of the Public Administration Act 2004 sets out the requirements of operation of a public entity including requirements relating to conflicts of interest.

(5) This section does not apply to any resolution of the Authority relating to a matter being considered under Division 3 or 4 of Part 3.

96 Approved methods of communication for Authority

(1) If not less than a majority of the members of the Authority for the time being holding office so agree, a meeting of the Authority may be held by means of a method of communication, or by means of a combination of methods of communication, approved by the Chairperson of the Authority for the purposes of that meeting.

(2) For the purposes of this Part, a member of the Authority who participates in a meeting held as permitted by subsection (1) is present at the meeting even if he or she is not physically present at the same place as another member participating in the meeting.

(3) This section—
(a) applies to a meeting or a part of a meeting;
(b) does not apply to a meeting conducted for the purposes of Division 3 or 4 of Part 3.

97 Limited immunity of member of a panel

(1) A member of the Authority or a member of a panel co-opted by the Authority under section 57 is not personally liable for anything done or omitted to be done in good faith—
(a) in the exercise of a power or the discharge of a duty under Part 3 of this Act; or
(b) in the reasonable belief that the act or omission was in the exercise of a power or the discharge of a duty under Part 3 of this Act.

(2) Any liability resulting from an act or omission that would, but for subsection (1), attach to a member of the Authority or a member of a panel co-opted by the Authority under section 57, attaches instead to the Authority.

98 Delegation

(1) The Authority may, in writing, delegate to—
(a) a member of the Authority; or
(b) the registrar or another person employed by the Authority under section 99; or
(c) a person engaged by the Authority to provide services to the Authority—
any of its functions and powers under this Act, other than—
(d) the power to refuse or to revoke a licence to carry on a pharmacy business or pharmacy department; or
(e) the power to refuse or to revoke the registration of premises of a pharmacy business, pharmacy department or pharmacy depot; or
(f) a power under Part 4; or
(g) this power of delegation.
Division 4—Staff

99 Staff

The Authority may employ a registrar and any other persons that are necessary for the purposes of administering this Act.

Division 5—Committees

100 Establishment of committees

(1) The Authority may establish a committee for the purposes of providing advice to the Authority on any matter relating to—

(a) the licensing of persons to carry on a pharmacy business or pharmacy department under this Act; and

(b) the registration of pharmacy premises; and

(c) the operation of pharmacy businesses, pharmacy departments and pharmacy depots.

(2) The Authority may determine the matters to be considered by a committee.

101 Membership of a committee

The members of a committee are to be appointed by the Authority and—

(a) at least one member of a committee is to be a member of the Authority; and

(b) each member of the committee is to have expertise in the matters to be considered by the committee.
Division 6—Authority funds, assets and fees

102 Victorian Pharmacy Authority Fund

(1) The Authority must establish and keep a fund to be called the Victorian Pharmacy Authority Fund.

(2) All fees, fines and penalties paid or recovered by the Authority under this Act must be paid into the Fund.

(3) The Authority must pay any other money received by it into the Fund, including income from the investments of the Fund.

(4) The Authority must pay out of the Fund—
   
   (a) the expenses incurred by it in carrying out its functions and powers; and
   
   (b) any other expenses incurred in the administration of this Act; and
   
   (c) any payments to be made to members of the Authority under this Act and any payments to be made to other persons under this Act; and
   
   (d) any other payments recommended by the Authority and approved by the Minister.

(5) The Authority must pay out of the Fund each financial year an amount determined by the Authority to meet the expenses of VCAT in performing functions under this Act during that year.

(6) The amount in any financial year must not be less than the amount (if any) specified in relation to that year by the Attorney-General by written notice given to the Authority.
103 Investment powers

The Authority may invest money credited to the Fund that it does not immediately require—

(a) in any manner in which money may be invested under the Trustee Act 1958; or

(b) in any other manner that the Minister approves.

104 Powers of the Authority in relation to fees

(1) In the case of any fee which the Authority is empowered to fix under this Act—

(a) the Authority must fix the fee for a period of 12 months and may amend or vary the fee at the end of that period; and

(b) the Authority may fix a different fee for a different case or classes of cases and may allow for the reduction, waiver or refund, in whole or in part, of any fee; and

(c) the Authority must publish any fee it has fixed in the Government Gazette and on the Authority's Internet site.

(2) In fixing fees under this Act, the Authority is entitled to ensure that the amount of money collected in fees under this Act is sufficient to cover the cost to the Authority of administering this Act and the regulations.

105 Repayment of advances

(1) The Authority must pay into the Public Account any amounts that the Minister administering section 14 of the Financial Management Act 1994, in consultation with the Treasurer, determines are required to repay advances from the Public Account for the operation of the Authority.
(2) Payments under subsection (1) must be made in accordance with any other terms and conditions from time to time determined by the Minister administering section 14 of the Financial Management Act 1994 in consultation with the Treasurer.

(3) The Authority must, as and when directed to do so by the Minister administering section 14 of the Financial Management Act 1994, provide a plan for the repayment of advances referred to in subsection (1).

(4) The Authority must at any time that the Minister administering section 14 of the Financial Management Act 1994 directs it to do so, report to that Minister in writing on its progress in making payments under subsection (1).
PART 6—GENERAL

106 Provision of information to Minister

(1) The Victorian Pharmacy Authority must collect and keep information that the Authority receives in carrying out its functions under this Act.

(2) The Authority must provide to the Minister any of the information kept under subsection (1) that is reasonably required by the Minister for matters related to—

(a) the licensing of pharmacy businesses and pharmacy departments; and

(b) the registration of premises of pharmacy businesses, pharmacy departments and pharmacy depots.

107 Disclosure of information to other agencies

(1) The Authority may disclose information relating to registered pharmacists, applicants under this Act for licences and registration of premises, licensees and registration holders that it collects or is given under this Act or the regulations to—

(a) the Pharmacy Board of Australia;

(b) a committee of the Pharmacy Board of Australia;

(c) the Secretary, in relation to the administration of the Drugs, Poisons and Controlled Substances Act 1981 and the regulations made under that Act;

(d) a person or body established under a law of another jurisdiction that has functions or powers that correspond to the functions or powers of the Authority under this Act.
(2) The Authority may only disclose information in accordance with this section for the purpose of—

(a) fulfilling its functions under this Act;

(b) assisting a person or body referred to in subsection (1) to fulfil their functions;

(c) if the Authority is of the opinion that the information is relevant to the registration of the pharmacist under the Health Practitioner Regulation National Law.

108 Regulations

(1) The Governor in Council may make regulations for or with respect to—

(a) licences to carry on a pharmacy business or a pharmacy department; and

(b) registration of premises of a pharmacy business, pharmacy department or pharmacy depot; and

(c) any other matter or thing required or permitted by this Act to be prescribed or necessary to be prescribed to give effect to this Act.

(2) Regulations made under this section—

(a) may be of limited or general application; and

(b) may differ according to differences in time, place or circumstance; and

(c) may apply, adopt or incorporate any matter contained in any document, code, standard, rule, specification, or method, formulated, issued, prescribed or published by any person whether—

(i) wholly or partially or as amended by the regulations; or
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(ii) as formulated, issued, prescribed or published at the time the regulations are made or at any time before then; or

(iii) as formulated, issued, prescribed or published from time to time; and

(d) may leave anything for the approval or satisfaction of a specified person.
PART 7—TRANSITIONAL PROVISIONS

109 Definitions

In this Part—

*HPRA* means the *Health Professions Registration Act 2005*;

*old Board* means the Pharmacy Board of Victoria continued under the HPRA;

*pharmacy-related* means related to the regulation of a pharmacy business, pharmacy premises, a pharmacy department or any other pharmacy-related entity that is not an individual.

Note

*Commencement day* is defined in section 3 as the date on which Part 3 of this Act commences.

110 Interpretation of Legislation Act 1984 not limited

Nothing in this Part limits the operation of the *Interpretation of Legislation Act 1984*.

Example

A number of provisions of this Act re-enact, with modifications, provisions of the HPRA. Section 16 of the *Interpretation of Legislation Act 1984* would apply in relation to the re-enacted provisions.

111 Victorian Pharmacy Authority to be successor in law of old Board

On the commencement day—

(a) the old Board is abolished; and

(b) its members go out of office; and

(c) the Victorian Pharmacy Authority becomes the successor in law of the old Board.
112 Assets and liabilities

(1) From the commencement day, any pharmacy-related assets, and liabilities of the old Board are taken to be assets and liabilities of the Victorian Pharmacy Authority and are to be paid into or out of the Fund.

(2) From the commencement day, any pharmacy-related contract entered into by or on behalf of the old Board is taken to have been entered into by the Victorian Pharmacy Authority.

(3) From the commencement day, any pharmacy-related property that, immediately before the commencement day was held on trust, or subject to a condition, by the old Board, continues to be held by the Victorian Pharmacy Authority on the same trust, or subject to the same condition and is to be paid into the Fund.

113 Pharmacy-related records

From the commencement day, any pharmacy-related records of the old Board are taken to be records of the Victorian Pharmacy Authority.

114 Existing applications for approval

(1) An application for approval of a pharmacy business or pharmacy department that was made under the HPRA but not determined before the commencement day is taken to be an application under this Act for a licence to carry on that pharmacy business or pharmacy department.

(2) An application for approval of premises of a pharmacy business, pharmacy department or pharmacy depot that was made under the HPRA but not determined before the commencement day is taken to be an application under this Act for registration of those premises.
115 Existing approvals to carry on pharmacy businesses and pharmacy departments

(1) Subject to subsection (2), a person who immediately before the commencement day was approved under Part 6 of the HPRA to carry on a pharmacy business or pharmacy department is taken until 30 September 2010 to hold a licence under this Act to carry on that pharmacy business or pharmacy department and that licence may be renewed under this Act.

(2) A person who immediately before the commencement day was approved under Part 6 of the HPRA to carry on a pharmacy business or pharmacy department and had applied for that approval on or after 31 March 2010 is, until 30 June 2011, taken to hold a licence under this Act to carry on that pharmacy business or pharmacy department and that licence may be renewed under this Act.

116 Existing approvals of premises

(1) Subject to subsection (2), premises that immediately before the commencement day were approved under Part 6 of the HPRA for a pharmacy, pharmacy department or pharmacy depot are taken until 30 September 2010 to be registered premises under this Act and that registration may be renewed under this Act.

(2) Premises that immediately before the commencement day were approved under Part 6 of the HPRA for a pharmacy, pharmacy department or pharmacy depot and the application for that approval was made after 31 March 2010 are taken until 30 June 2011 to be registered premises under this Act and that registration may be renewed under this Act.
117 Authority to complete reports of old Board

The Authority must prepare, or continue and complete, under the Financial Management Act 1994 the report of operations and financial statements of the old Board for a period of time prior to the financial year ending 30 June 2010, if this has not been completed by the old Board before the commencement day.

118 Regulations dealing with transitional matters

(1) The Governor in Council may make regulations containing provisions of a transitional nature, including matters of an application or savings nature, arising as a result of the enactment of this Act, including any repeals and amendments made as a result of the enactment of this Act.

(2) Regulations made under this section may—

(a) have a retrospective effect to a day on or from a date not earlier than the commencement day; and

(b) be of limited or general application; and

(c) leave any matter or thing to be decided by a specified person or class of person.

(3) Regulations under this section have effect despite anything to the contrary in any Act (other than this Act or the Charter of Human Rights and Responsibilities Act 2006) or in any subordinate instrument.

(4) For the avoidance of doubt, the Subordinate Legislation Act 1994 applies to any regulations made under this section.

(5) This section is repealed on 1 July 2012.
PART 8—REPEALS AND CONSEQUENTIAL AMENDMENTS

Division 1—Amendments to the Drugs, Poisons and Controlled Substances Act 1981

119 Definitions

In the Drugs, Poisons and Controlled Substances Act 1981—

(a) in section 4(2)(a) for "approved under Part 6 of the Health Professions Registration Act 2005" substitute "registered under Part 3 of the Pharmacy Regulation Act 2010";

(b) in section 4(2)(b) for "Part 6 of the Health Professions Registration Act 2005" substitute "Part 3 of the Pharmacy Regulation Act 2010";

(c) in section 4(2)(c) for "Part 6 of that Act" substitute "Part 3 of that Act".

120 Persons authorized to have possession etc. of poisons or controlled substances

(1) In section 13(6) of the Drugs, Poisons and Controlled Substances Act 1981 for "Part 6 of the Health Professions Registration Act 2005" substitute "Part 3 of the Pharmacy Regulation Act 2010".

(2) In section 13(6) of the Drugs, Poisons and Controlled Substances Act 1981 for "approved" substitute "licensed".
Division 2—Amendments to the Education and Training Reform Act 2006

121 Definitions

(1) In section 2.6.35A of the Education and Training Reform Act 2006, for the definitions of registered health practitioner and registered medical practitioner substitute—

"registered health practitioner means—

(a) a registered health practitioner within the meaning of the Health Professions Registration Act 2005;

(b) a person registered under the Health Practitioner Regulation National Law to practise a health profession other than as a student;

registered medical practitioner means a person registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);

"(d) persons registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);"

(2) For section 2.6.35F(3)(d) and (e) of the Education and Training Reform Act 2006 substitute—

"(d) persons registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);

(e) persons registered under the Health Practitioner Regulation National Law to practise in the psychology profession (other than as a student);".

(3) For section 2.6.41B(1)(b) of the Education and Training Reform Act 2006 substitute—

"(b) one must be a person registered under the Health Practitioner Regulation National Law—

(i) to practise in the medical profession (other than as a student); or

(ii) to practise in the psychology profession (other than as a student); and".

(4) In section 2.6.41E(3)(d) of the Education and Training Reform Act 2006, after "Act 2005" insert "or a person registered under the Health Practitioner Regulation National Law to practise a health profession".

Division 3—Amendments to the Health Professions Registration Act 2005

122 Definitions

(1) In section 3(1) of the Health Professions Registration Act 2005—

(a) the definition of pharmacy is repealed;

(b) the definition of pharmacy business is repealed;

(c) the definition of pharmacy department is repealed;

(d) the definition of pharmacy depot is repealed;

(e) the definition of pharmacy services is repealed;

(f) for the definition of unprofessional conduct paragraph (j) is repealed.

(2) Section 3(4) of the Health Professions Registration Act 2005 is repealed.
123 Part 6 repealed

Part 6 of the Health Professions Registration Act 2005 is repealed.

124 Repeal of section 186

Section 186 of the Health Professions Registration Act 2005 is repealed.

125 Schedule 3 repealed

Schedule 3 to the Health Professions Registration Act 2005 is repealed.

Division 4—Amendments to the Mental Health Act 1986

126 Amendments to the Mental Health Act 1986

In sections 73(2), 74(3), 84(2), 124(1), 124(2) and 126(1) of the Mental Health Act 1986 for "Medical Practitioners Board of Victoria" substitute "Medical Board of Australia".

Division 5—Amendments to the Severe Substance Dependence Treatment Act 2010

127 Definitions

(1) In section 4 of the Severe Substance Dependence Treatment Act 2010 for the definition of registered medical practitioner substitute—

"registered medical practitioner means a person registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student);".

(2) In section 4 of the Severe Substance Dependence Treatment Act 2010 the definition of registered nurse is repealed.
Pharmacy Regulation Act 2010
No. 39 of 2010
Part 8—Repeals and Consequential Amendments

(3) In section 4 of the Severe Substance Dependence Treatment Act 2010 insert the following definition—

"nurse means a person registered under the Health Practitioner Regulation National Law to practise in the nursing and midwifery profession as a nurse (other than as a midwife or as a student);".

(4) In section 4 of the Severe Substance Dependence Treatment Act 2010 for the definition of nurse practitioner substitute—

"nurse practitioner means a nurse whose registration is endorsed by the Nursing and Midwifery Board of Australia under section 95 of the Health Practitioner Regulation National Law;".

128 Power to restrain or sedate a person

(1) In section 38(3) of the Severe Substance Dependence Treatment Act 2010 omit "registered".

(2) In section 38(8) of the Severe Substance Dependence Treatment Act 2010, in paragraph (a) of the definition of suitably qualified person, omit "registered".

Division 6—Amendments to the Statute Law Amendment (National Health Practitioner Regulation) Act 2010

129 Repeal of sections 22 and 23

Sections 22 and 23 of the Statute Law Amendment (National Health Practitioner Regulation) Act 2010 are repealed.
130 Amendment of Division 5 of Part 11

In section 29 of the Statute Law Amendment (National Health Practitioner Regulation) Act 2010 proposed section 186 is repealed.

Division 7—Amendments to the Victorian Civil and Administrative Tribunal Act 1998

131 Amendment of Schedule 1

After Part 15AB of Schedule 1 to the Victorian Civil and Administrative Tribunal Act 1998 insert—

"PART 15AC—PHARMACY REGULATION ACT 2010

51AE Constitution of Tribunal for hearings

The Tribunal is to be constituted for the purposes of a proceeding under Division 5 of Part 3 of the Pharmacy Regulation Act 2010 by at least 3 members of whom at least 2 must be registered pharmacists that are regulated under the Health Practitioner Regulation National Law."

Division 8—Repeal of amending Part

132 Repeal of amending Part

This Part is repealed on 1 July 2012.

Note

The repeal of this Part does not affect the continuing operation of the amendments made by it (see section 15(1) of the Interpretation of Legislation Act 1984).
SCHEDULE

MATTERS REQUIRED FOR APPLICATIONS UNDER DIVISIONS 1 AND 2 OF PART 3

1 The premises are to be—
   (a) laid out in a manner consistent with safe pharmacy practice;
   (b) maintained in a clean and hygienic manner;
   (c) maintained at a suitable temperature and humidity;
   (d) equipped with the necessary equipment and reference material.

2 The different parts of the premises are properly situated and are secure and suitable for the purposes for which they are to be used.

3 The general physical security of the premises is assured and the control of keys or other entry devices is restricted to registered pharmacists authorised by the person carrying on the pharmacy business or pharmacy department.

4 There is no access to the dispensary of the pharmacy or pharmacy department except under the direct supervision of a registered pharmacist.

5 A registered pharmacist must be appointed to act as the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department when the pharmacy or pharmacy department is open for business.

6 When the pharmacist who is appointed as the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department is absent or not available, another registered pharmacist must be appointed to act as the pharmacist in charge of the pharmacy or pharmacy department when the pharmacy or pharmacy department is open for business.
A registered pharmacist must oversee the area of the pharmacy or pharmacy department where pharmacy services are provided.

A registered pharmacist appointed to act as the pharmacist in charge must oversee, supervise and monitor all registered pharmacists providing pharmacy services in the pharmacy or pharmacy department and any other staff who assist in the provision of pharmacy services.

Adequate arrangements are in place to ensure that—

(a) medicines are dispensed in accordance with an order or prescription as far as the dispensing is consistent with the safety of the person who is to use the medicines;

(b) medicines are not re-used after dispensing and after they have left the pharmacy or pharmacy department;

(c) written or electronic records are kept of all medicines supplied, compounded or dispensed and the records are kept confidential and secure;

(d) the sale of medicines particularly those known to be abused or misused are supervised and monitored;

(e) therapeutic goods are not removed from the premises except with the express permission of the registered pharmacist in charge of the pharmacy or pharmacy department;

(f) distance dispensing is carried out according to good pharmaceutical practice;

(g) confidential discussions can occur between pharmacists and their clients in privacy;

(h) the identity of a medicine being supplied or dispensed to a client of the pharmacy or pharmacy department cannot be known by another person present in the pharmacy or pharmacy department who is not a person carrying on the pharmacy
business or pharmacy department or a member of the staff of the business or department.

10 Adequate arrangements are in place to ensure that records of prescriptions are in English and include—

(a) the name and address of the person to whom the medicine is dispensed;
(b) the date the medicine is dispensed;
(c) the name and dose form of the medicine dispensed;
(d) the strength or identifying formula;
(e) the quantity or number of doses ordered;
(f) the directions for the use of the medicine;
(g) any other ancillary written instructions supplied on the label;
(h) the name, address and telephone number of the prescriber;
(i) any alteration to the original prescription;
(j) any other information concerning the medicine and its use.

11 Adequate arrangements are in place to ensure that records of prescriptions are—

(a) retained in a secure place at the pharmacy or pharmacy department for at least 3 years;
(b) made at the time of dispensing or, in the case of an emergency, within 24 hours after the dispensing;
(c) certified by the registered pharmacist who dispensed the prescription with his or her handwritten signature within 24 hours after the dispensing—
    (i) in the prescription record; or
    (ii) if the prescription record is made in a manner which precludes handwritten endorsement, in a separate record kept for that purpose, that he
or she dispensed the prescription and the certified record must be kept as part of the prescription record;

(d) readily retrievable by reference to the name and address of the person to whom the medicine was dispensed, the date of dispensing and from information on the label on the container.
ENDNOTES

† Minister's second reading speech—
Legislative Assembly: 6 May 2010
Legislative Council: 10 June 2010

The long title for the Bill for this Act was "A Bill for an Act to regulate the ownership and operation of pharmacy businesses, pharmacy departments and pharmacy depots, to establish the Victorian Pharmacy Authority, and to make consequential amendments to other Acts and for other purposes."
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