

National Competition Policy Review of Pharmacy

PART B

REPORTS ON STATE AND TERRITORY ACTS

NEW SOUTH WALES *PHARMACY ACT 1964*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1964* (the Act) has six Parts and two Schedules, plus two sets of Regulations, one of which has three Schedules. The principal objectives of the Act are to regulate the carrying on of business of a pharmacist and to authorise friendly societies to carry on pharmacy businesses.

The functions of the Pharmacy Board of New South Wales (the Board) are set out in Part 2 of the Act. These include “to generally carry out all matters relating to the practice of pharmacy authorised or required by [the Act]”.

The *Pharmacy (General) Regulation 1998* (the General Regulation) contains details relating to a relatively small number of clauses in the Act. These include requirements for work as an assistant in a pharmacy in order to qualify for registration, the prescribed form for a certificate of registration and details of the physical requirements of pharmacies. The *Pharmacy (Elections) Regulation 1998* (the Elections Regulation) set out the requirements for elections for the Board.

2. OWNERSHIP OF PHARMACIES

Ownership is dealt with in Part 5 – Control of Pharmacies. It is concerned with the registration of pharmacies and their owners, including details of business arrangements such as sale and purchase contracts and pecuniary interest. In practice the Board takes a particular interest in banner (or marketing) group agreements, all other financial arrangements and service agreements.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The relevant sections are 24C, 25 and 27A. These establish a Register of Pharmacies and prohibit the carrying on of the business of a pharmacist in any premises that are not approved by the Board and included in the Register.

In addition, the owner of the business must be included in the Register of Pharmacies. Section 25 specifies that only pharmacists or partnerships consisting solely of pharmacists may have an interest in pharmacists' businesses. No-one else is able to have any interest in a pharmacy, including a pecuniary interest, except where permitted in accordance with savings provisions set out in the Regulation 21 of the General Regulation.

The approach taken in the Act is quite clear, in that both pharmacists and pharmacy businesses are registered by the Board. Only registered pharmacists can have an interest in pharmacy businesses and these businesses must also be registered.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. "Pharmacist", as used in the section 25 ownership provisions, is defined by section 3 as a person registered under the Act.

ASSESSMENT

These provisions are consistent with the Review's recommendations

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Provisions relating to ownership structures are in Part 5 of the Act. Sub-section 25(1) specifically excludes a person who is not registered pharmacist and a corporation or an unincorporated body of persons to carry on as "owner or otherwise" the business of a pharmacist. Sub-section 25(1A) also excludes such persons and bodies from having a direct or indirect pecuniary interest in the business of a pharmacist.

A partnership consisting only of pharmacists and formed specifically to carry on, as owner or otherwise, the business of a pharmacist in a pharmacy, or for the purpose of having a direct or indirect pecuniary interest in such a business, is permitted under sub-section 25(2) .

ASSESSMENT

The Act's limitation of permitted ownership structures to sole traderships and pharmacist partnerships, and its express exclusion of bodies corporate, is very restrictive compared to a number of other jurisdictions.

While the provisions are consistent with the Review's recommendation, there may be some scope for **amending** them to include coverage of bodies corporate as outlined in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 26(1) of the Act limits ownership and "direct or indirect pecuniary interest" to no more than three pharmacies. This provision applies to pharmacists either alone or in partnership. Sub-section 26(2) limits the number of partnerships of which a pharmacist may be a member to one, and this applies to carrying on the business of a pharmacist or a direct or indirect pecuniary interest.

There is a savings provision for ownership or pecuniary interest that exceeded this number on 27 November 1949. Friendly societies are also exempted from the restriction, as are interests in after-hours pharmacies.

Section 27 of the Act provides that a pharmacist is to be in charge, and personally superintend, every pharmacy and dispensary. Owners who allow this requirement to be breached, as well as the pharmacist in charge if he or she is an employee, are guilty of an offence under the Act.

ASSESSMENT

The provisions relating to the number of pharmacies a person or partnership may own or in which they may have a pecuniary interest are not consistent with the Review's recommendation and should be **removed**.

The pharmacist supervision provisions are consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Section 27A of the Act exempts the conduct of a pharmacy business operated by a friendly society from certain other sections relating to the control of pharmacies. There is no actual ceiling on the number of pharmacies that can be owned by Friendly Societies.

Approval to open new pharmacies is subject to ministerial discretion under Section 27A of the Act. The approval is conditional upon the Minister being satisfied that the profits from the operation of the pharmacy are applied solely to the provision of benefits to members of the friendly society and that the operation of the pharmacy is justified in the interests of members of the friendly society or the public, or both. The approval can be subject to conditions and approval can be varied or revoked at any time. There are also restrictions on existing friendly society pharmacies relocating more than 1.6 kilometres from their present site.

In addition to the friendly societies, sub-section 26(3) provides that limitations on ownership and pecuniary interests in pharmacies do not apply to non-pharmacist owned pharmacies owned as at 27 November 1940. These provisions also permit businesses to be carried on in another pharmacy provided it is within 16 kilometres of the original pharmacy, or in the counties of Cumberland (Sydney), Northumberland (Newcastle), or the City of Greater Wollongong.

ASSESSMENT

There are 11 friendly society pharmacies currently operating in New South Wales¹. The Review understands that there has only been one new friendly society pharmacy approved in the last 50 years.

¹ Australian Friendly Societies Pharmacies Association, *Friendly Societies Pharmacies Directory*, February 2000.

The restrictions in relation to grandparented owners other than friendly societies are consistent with the Review's recommendation, although the restrictions on their relocation are somewhat excessive, and should be **removed** in the interests of consistency.

In relation to friendly societies, however, the Act's restrictions are discriminatory insofar as they impose far greater restrictions on one class of lawful pharmacy operator compared to another. Private pharmacist-owned pharmacies do not have to undergo a ministerial approval process in the same way that friendly societies are scrutinised. Similarly, private pharmacies are not constrained by State law as to where they may relocate, nor do they require ministerial approval to make what is essentially a matter of commercial and professional judgment.

These provisions should be **amended** to be consistent with the Review's recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The relevant sections are 25, 25A and 25B. These prohibit persons other than pharmacists from having an interest in pharmacies, including a pecuniary interest. Section 25B authorises the Board to direct pharmacists to provide information relating to pecuniary interest in a business. There is no definition of pecuniary interest as such, although certain provisions in bills of sale are specifically prohibited in Section 25A. These include provisions relating to:

- The requirement to purchase or otherwise obtain goods or services;
- Giving power to others to control the manner in which the business is conducted;
- Giving access to books of account; and
- Providing any consideration that varies according to the profits or takings of the business.

What constitutes a direct or indirect pecuniary interest is not defined anywhere in the Act.

ASSESSMENT

Insofar as they go beyond restricting the proprietary interests in a pharmacy (that is, who may own, hold shares in or be a director of a pharmacy-operating entity), these provisions are inconsistent with the Review's recommendation.

Section 25A and other relevant provisions should be **replaced** by:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making the pharmacist's acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Registration of pharmacy businesses and owners and the approval of premises is a central feature the regulation of community pharmacy in NSW, together with requiring the provision to the Board of details of the financial arrangements of pharmacy businesses.

The Act does not specifically require the registration of businesses, but details of bills of sale and pecuniary interests as set out in Sections 25A and 25B are integral to the control of pharmacies. Section 25C of the Act requires the registration of owners of pharmacy businesses and the approval of pharmacies.

Section 12 of the General Regulation lists the standards that are to be complied with for approved pharmacy premises. These include provisions relating to:

- Direct public access;
- Secure doors, windows and roof;
- The minimum size of the dispensing area; and
- A refrigerator for the storage of biological and pharmaceutical products at appropriate temperatures.

There are other requirements relating to the provision of equipment and reference material. Section 32 allows for inspectors and other authorised persons to enter premises for the purpose of ascertaining whether the provisions of the Act are or have been complied with.

ASSESSMENT

These registration premises provisions are not consistent with the Review's recommendation and should be **removed**. Provisions relating to premises standards and powers of inspection are not affected by the recommendation.

2. REGISTRATION OF PHARMACISTS

Provisions relating to the registration of pharmacists are contained in Part 3 of the Act. The provisions describe the qualifications required for registration, including overseas qualifications. The use of qualifications and titles is included in Part 6, whilst Part 5 governs the control of pharmacies by registered pharmacists.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Constitution of the Board

The constitution of the Board is set out in Part 2, Section 6, of the Act. There are nine members, five of whom are elected by registered pharmacists.

The four appointed members are:

- A pharmacist nominated by the governing body of a university designated by the Minister;
- A barrister or solicitor nominated by the Minister;
- A non-pharmacist to represent the interests of consumers; and
- An officer of the Department of Health or a public health organisation.

Very detailed election procedures are set out in the Elections Regulation. The Regulation contains 26 clauses dealing with procedures for calling of elections, nominations, ballots, scrutiny of ballots and miscellaneous provisions. One of the elected members is appointed as President.

Functions of the Board

The Board has a number of specific functions and an advisory role to the Minister, as set out in Section 5 of the Act. This section sets out nine principal functions of the Board, one of which is a broad function in relation to all matters pertaining to pharmacy authorised or required by the Act. The other functions include promoting and maintaining the highest professional conduct and ethics, providing for education, consulting and advising on training and determining the length and content of training and re-training programmes.

Section 8 enables the Board to establish committees to assist it with the exercise of its functions. There is no requirement for any or all of the members of committees to also be Board members.

Staffing

Section 11 authorises the Board to appoint a registrar and other staff as may be necessary to enable the Board to exercise its functions.

ASSESSMENT

Constitution of the Board

The Review notes that the majority of Board members are appointed. Whilst this is commendable it is nevertheless inconsistent with the Recommendation and the Act should be **amended** to provide for full appointment.

Functions of the Board

On the whole the provisions regarding the functions of the Board and its operation are consistent with the Review's recommendation, but it is noted that they leave considerable discretion to the Board in areas such as professional conduct and ethics, education and training requirements.

Paragraph 5(2)(h) of the Act, relating to advising the Minister in relation to the Act should be **removed** as being inconsistent with that recommendation.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

The registration of pharmacists is set out in Part 3 of the Act. Sections 12 to 19 authorise the Board to maintain a register of pharmacists and set out requirements for registration and related matters. Sections 7 and 19 of the Act authorise the payment of initial and annual fees, which are fixed by the Board.

Section 12 sets out the entries that are to be made in the Register and authorise its publication on an annual basis. Certificates of registration are issued in accordance with Section 17.

Practice protection

Section 26 prohibits a person other than a pharmacist, or a person acting under the personal supervision of a pharmacist, from dispensing or compounding any medicine prescribed by a doctor. Medical practitioners are exempted from this requirement.

Title protection

The use of registered qualifications and titles is covered in Section 30. Pharmacists are reserved the right to use certain specified titles, including “pharmacist” and synonyms. Non-pharmacists who use such titles, or who hold themselves out to be a pharmacists, are guilty of offences against the Act.

Personal requirements for registration

Personal requirements set out in Section 17 of the Act include having attained a minimum age of 18 years, satisfying the Board that they are of good character, and proving to the satisfaction of the Board that they have an adequate knowledge of English.

Professional requirements for registration

Professional requirements for registration are set out in Sections 13 to 16. These specify an approved tertiary course and practical experience in a pharmacy (for a prescribed period as set out in the General Regulation). However, Review understands that the Board also has an additional requirement for a written and oral Pharmacy Board Review to be completed prior to registration. The additional purpose of this requirement is unclear and is not included in the Act or Regulations.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review’s recommendations.

Practice protection

These provisions are consistent with the Review’s recommendations.

Title protection

These provisions are consistent with the Review's recommendations.

Personal requirements for registration

The Review notes that there are minimal personal requirements stated in the Act, but the minimum age requirement is inconsistent with the Review's recommendation and should be **removed**.

Professional requirements for registration

The current requirements, apart from the Pharmacy Board Review, are consistent with the objective of protecting public safety and are therefore a justifiable restriction on competition. Unless the role of the Pharmacy Board Review can be clarified and justified it should be **removed**.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Re-registration

Section 17 (3) gives the Board discretion to refuse registration if a pharmacist has not been registered for more than five years, unless they pass on oral and/or written examination. There are no requirements for pharmacists re-entering practice after any length of absence if registration has been maintained. Nor are there any requirements to notify the Board of any periods of non-practice.

An annual fee is payable as determined and required by Section 19.

Competency based mechanisms

There are no requirements for competency based assessment for re-registration.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

The disciplinary procedures are codified in Part 4 of the Act, sections 19A to 24. The procedures are set out in some detail. The Review notes that the disciplinary process is very clearly described and the rights and responsibilities of the parties in disciplinary processes are included.

Section 19F of the Act allows the Board to decide how to deal with complaints. These range from an investigation to an inquiry or referral to the Board from the Health Care Complaints Commission. The composition of disciplinary committees is set out in Section 19C and

includes a legal practitioner. Schedule 2 of the Act sets out the procedures to be followed in an inquiry by the Board or a Professional Standards Committee appointed by the Board.

The main features of the inquiry process are that it is conducted as in an open court (unless the Board decides otherwise), there is a right of defence, including legal representation, the provision of a written statement of its decision and a right of appeal to the District Court. Committee members must not have dealt with a complaint in their capacity as a Board member. Although the hearings are open to the public, in practice they are not publicly notified.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

VICTORIAN *PHARMACISTS ACT 1974*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacists Act 1974* (the Act) has eight Parts. Regulations consolidated as the *Pharmacists Regulations 1992* (the Regulations) have seven Parts and two Schedules.

The overall objectives of the Act are to:

- Set out the functions, powers and responsibilities of the Pharmacy Board of Victoria (the Board);
- Regulate matters relating to the ownership of pharmacies and the practising of pharmacy in Victoria.

The Regulations deal with matters relating to Board elections, registration procedures, premises approval, registration and other fees, some aspects of pharmacy practice, and pharmacist education and training requirements.

In addition to the Act and Regulations, the Board publishes annually *Guidelines for Good Pharmaceutical Practice* (the Guidelines). The Board uses the Guidelines to advise pharmacists of:

- The Board's interpretation of certain parts of the Act and Regulations;
- How the Board exercises its discretion in regards to certain parts of the Act and Regulations;
- What the Board has determined to be minimum standards of good practice;
- The Board's expectations of pharmacists performance of their duties and responsibilities².

While the Guidelines do not have the status of a statutory instrument, they are approved by the Board rather than by the responsible minister or the Governor. They are more in the manner of professional directives from the Board to registered pharmacists and applicants for registration.

Where they relate to the interpretation of specific provisions of the Act or Regulations, the Guidelines will be taken into account.

2. OWNERSHIP OF PHARMACIES

Matters relating to the ownership of pharmacies generally are covered by Part 5 of the Act. The approval of pharmacy premises is covered by Part 6 of the Act.

² Pharmacy Board of Victoria, *Guidelines for Good Pharmaceutical Practice*, February 1999, para 104.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

Sub-section 21(1) of the Act provides that a body corporate or a natural person who is not a pharmacist shall not “own or have a proprietary or pecuniary interest in a pharmacy practice”. Section 33 of the Act provides penalties for a person who is not a registered pharmacist but who holds himself or herself out to be a pharmacist or that they are carrying on the business of a pharmacist.

The only exceptions to this general requirement are recognised friendly societies “while the society is acting in accordance with this Act” (sub-section 21(4)), and pharmacy departments operated by a registered funded agency, private hospital or privately-operated hospital within the meaning of the *Health Services Act 1988* (Vic) (sub-section 21(5)).

ASSESSMENT

Insofar as they relate to community pharmacies, the provisions of the Act are consistent with the Review’s recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act has no requirement that a person be resident in Victoria in order to own a pharmacy in Victoria.

Section 21(1) of the Act does, however, require that a person must be a registered pharmacist to own a pharmacy in Victoria. The interpretation provisions of section 3 define a “pharmacist” or “registered pharmacist” as a person registered under the Act or its predecessors. Therefore, to be a pharmacy owner in Victoria a person must be registered in the State.

ASSESSMENT

These provisions are consistent with the Review’s recommendations.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Section 21 of the Act provides that a pharmacist may carry on a pharmacy practice either solely or in partnership with other pharmacists. Sub-section 22(1) of the Act requires that a copy of every partnership agreement must be lodged with the Board registrar within two months of its execution.

ASSESSMENT

These provisions are consistent with the Review’s recommendation, but could be **amended** to allow bodies corporate as composed in the Review’s recommendation.

NUMBERS OF PHARMACIES OWNED BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 21(1) provides that no pharmacist, either solely or in partnership, shall own or have a proprietary or pecuniary interest in more than three pharmacies. Sub-section 21(4) links this requirement to pharmacy premises rather than pharmacy businesses in which an interest may be held.

Other provisions in section 21 grandparent arrangements involving more than three pharmacies which may have been in place before the current provisions commenced.

ASSESSMENT

These provisions are inconsistent with the Review's recommendation and should be **removed**.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Section 21 of the Act provides for two exceptions to the pharmacist only ownership requirement, these being:

- Registered societies within the meaning of the *Friendly Societies Act 1986* (Vic); and
- Registered funded agencies, private hospitals and privately-operated hospitals within the meaning of the *Health Services Act 1988* (Vic).

There are no limitations on friendly society pharmacies in terms of their numbers in the State, the numbers that may be operated by any one society and the conditions under which they are approved, established or relocated.

There are no grandparenting or other saving provisions in respect of pharmacies owned or operated by any other non-pharmacist body.

ASSESSMENT

The Act's provisions in relation to friendly society pharmacies are the simplest of any State jurisdiction. They allow friendly societies to operate pharmacies provided the societies themselves meet threshold criteria in other legislation. They assume that if a friendly society is lawfully able to operate pharmacies, then there should be no other constriction on their ability to do so. The Review notes that, notwithstanding this relatively liberal regulation, only 14 friendly societies operate in Victoria, with 47 pharmacies³.

These provisions are consistent with the Review's recommendation.

In respect of pharmacy departments in specified hospital facilities, Victoria is the only State or Territory making statutory provision for the ownership of pharmacy departments in dispensaries in private hospitals and privately-operated hospitals. The Review's reference is

³ Source: Australian Friendly Societies Pharmacies Association *Directory*, February 2000.

to consider the ownership of pharmacies, which relates to community pharmacy premises and businesses. It therefore believes that sub-section 21(5) is beyond the scope of its inquiry.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

As well as prohibiting non-pharmacist ownership of pharmacies, sub-section 21(1) of the Act also proscribes non-pharmacists having a “pecuniary or proprietary interest” in a pharmacy. Neither the terms “pecuniary interest” or “proprietary interest” are defined in the Act, nor is it clarified how the term “proprietary interest” differs if at all from “pecuniary interest”. The Board also does not clarify with matters of pecuniary or proprietary interest in its Guidelines.

For pharmacists, sub-section 21(3) requires that pecuniary or proprietary interests cannot be held in more than three pharmacies. Sub-section 21(7) provides that pharmacist can be required by the Board to give it information about the ownership of, pecuniary or proprietary interests in any pharmacy or pharmacy practice.

In respect of third parties providing financing or loan guarantees to a pharmacy business, sub-section 22(3) provides that no bill of sale, mortgage, lease “or in any other commercial arrangement in respect of the practice of a pharmacist” cannot require:

- The provision of goods or services for the pharmacy business by a specific supplier;
- The right of a third party to “control the manner” in which a pharmacy practice is carried on;
- Right of access to a pharmacy business’s books except for the purpose of the bill of sale or other specified document; and
- The right to receive any consideration from the pharmacy business that varies according to the profits or takings by a pharmacist.

ASSESSMENT

The section 21 distinctions between “pecuniary interest” and “proprietary interest” in the Act are confusing, and hard to delineate.

Given the lack of accompanying definitions in the Act, the Board has great discretion in interpreting and applying the related provisions. The Review understands that “proprietary interest” is interpreted as relating to interests conferring the benefits of ownership, such as a shareholding or directorship in a pharmacy business, and “pecuniary interest” as particular financial or other benefits arising out of an association with a pharmacy business.

This area of Board discretion, and how the Board applies that discretion, are not clarified in its Guidelines.

The section 22 restrictions on financing and leasehold transactions are consistent with similar provisions in several jurisdictions. As they are worded, they work against pharmacy business being freely able to work with non-pharmacist individuals and firms to mutual commercial benefit. The “profit or takings” provision appears to preclude business associations such as franchise agreements involving a share of turnover or profit for the franchiser. The restrictions on terms of leaseholds also appear to make it very difficult for a pharmacy

business to co-locate effectively with a non-pharmacy business such as a supermarket or department store.

These provisions are not consistent with the Review's recommendation and should be **replaced** by:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making a pharmacist's acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Section 23 of the Act requires the Board to approve, rather than register, the premises of pharmacies and pharmacy departments before a pharmacy may be operated from those premises. Sub-section 27(1) complements this by providing that pharmacy can only be practised from approved premises, unless in specially approved circumstances.

Sub-section 24(1) provides that premises will not be approved unless they "comply with the relevant prescribed conditions", and that different parts of the premises "are properly situated and suitable for the purposes for which they are to be used". Section 27 imposes conditions on the conduct of pharmacy business from approved premises, including giving the Board the discretion to prevent any person conducting forms of business not approved by the Board.

Regulation 502 provides, that to approve premises, the Board must be satisfied that they are suitable, secure, hygienic and adequately equipped. Regulation 601 provides that the Board's approval of premises attracts a fee.

Part 6 of the Board's Guidelines, and supplementary appendixes, set out in considerable detail the Board's specifications and expectations of pharmacy premises in terms of the regulatory criteria.

Section 19 of the Act provides that the Board's inspectors may enter pharmacies and examine their records to determine whether the Act and Regulations are being complied with.

There are no express requirements in the Act for the registration or approval of pharmacy businesses.

ASSESSMENT

While it is not described in the Act as such, premises approval as a precondition to operating a pharmacy business is de facto registration. The fact that the undertaking of the approval process attracts application fee supports this perception. The compulsory imposition of the

premises approval process is inconsistent with the Review's recommendation, and should be **removed**.

Beyond that, the setting of guidelines for a safe, secure, hygienic and suitably equipped pharmacy are not inconsistent with the Review's recommendation. This includes the Board's ability to conduct compliance inspections of premises and pharmacy records in accordance with section 19 of the Act.

The Review also suggests, however, that the conditions and specifications presently relating to approving pharmacy premises, for compliance purposes, in the Act and Guidelines should be **simplified** wherever possible. Such simplification should ensure that they concentrate solely on ensuring the safe and competent practice of pharmacy to a minimum standard, and not unduly intrude into wider commercial considerations. The Review notes, for example, that the Board's conferred discretion not to approve pharmacy premises if they are freely accessible to a non-pharmacist business (sub-section 27(2)) may be employed, in theory, to prevent co-locations with non-pharmacy businesses. The Review does understand, however, that the Board has interpreted these provisions practically and generously.

3. REGISTRATION OF PHARMACISTS

Matters relating to pharmacist regulation, pharmacy practice and disciplinary matters, and the constitution and operation of the Pharmacy Board of Victoria are found in Parts I-IV and VI of the Act, and Parts 2-4 and 6 - 7 of the Regulations.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

Part I of the Act relates to the Board, its constitution, powers and staffing. Part 7 of the regulations relates to the election of Board members.

Constitution of the Board

Section 4 of the Act provides for a Board of 10 members, five appointed by the minister and five elected by registered pharmacists. The five appointed members (sub-section 4(1)) are drawn from pharmacists in teaching or research, nominees of the Pharmacy Guild, Pharmaceutical Society, Society of Hospital Pharmacists of Australia, and the Salaried Pharmacists Association⁴. There are no lay or legal practitioner membership requirements.

Functions of the Board

Sub-section 5(1) states that the functions of the Board "shall be to initiate and coordinate policy in regard to the training registration and practice of pharmacists in Victoria and to develop pharmaceutical science with a view to achieving the highest possible standards of human health".

The sub-section provides a list of specific Board functions pursuant to this general objective, effectively covering a broad range of professional activity, including that it may:

- Consult with appropriate bodies on pharmacist training;
- Determine the length and content of training and retraining programmes under the Act;

⁴ Now the Association of Professional of Professional Engineers, Scientists and Managers, Australia (Pharmacists Branch).

- Determine the contents of pharmacy examinations and to direct examinations;
- Providing for the registration and renewal of registration of persons qualified to practise as pharmacists in Victoria;
- Ensuring the highest standards of professional conduct and ethics are maintained in the pharmacy profession;
- Advising the community on the proper use and administration of drugs and medicines; and
- Carrying out “all matters relating to the practice of pharmacists authorised or required by this Act”.

Sub-section 4(2) provides that the Board president be appointed by the Governor in Council from the elected Board members. Sub-section 4(4) provides for three-year renewable terms for Board members. Sub-section 5(2) enables the Board to establish advisory committees and to co-opt any person or persons as members of those committees.

Staffing

Section 6 of the Act provides that the Board may appoint and remove a registrar, inspectors and such other officers as are required for the purposes of the Act, and make by-laws in relation to their powers, duties, functions and remuneration.

ASSESSMENT

Functions of the Board

The listed functions of the Board are wide in relation to the practice of pharmacy and the regulation of pharmacists in Victoria. Its Guidelines are also very comprehensive, and cover aspects of pharmacist conduct and pharmacy practices in minute detail. The Board has the ability, and indeed the statutory responsibility, to oversee all aspects of professional education and training, practice, and professional development. It undertakes these responsibilities with a membership composed entirely of registered pharmacists.

To its credit, the Board has exercised its remit carefully, prudently and responsibly. There is no question of the Board not acting in the public interest as it perceives that interest. There are questions, however, about the breadth of its remit, and its ability to intervene and set standards for all aspects of pharmacy practice.

The Review therefore has reservations about the scope of the Board’s powers and functions under section 5. It believes that a number of the listed functions, such as the control of the practice of pharmacy by registered pharmacists, and setting training and registration standards, should actually be determined by government through wide professional consultation followed by regulation-setting process, and implemented and enforced by the Board. Again that is not to say that the Board itself does not act improperly or without consultation, but rather that this is not its appropriate role.

The Review certainly believes that the Board’s annual Guidelines, which are an admirable consolidation of its expectations and requirements in administering the Act, raise questions of fine interpretation of the Act and Regulations that may need to be endorsed by government from time to time.

In respect of the Guidelines, it may therefore be desirable to make them a statutory instrument, endorsed annually by the Governor in Council, with amendments made during the year approved by the minister. Alternately, detailed specific requirements (for example, for the fitting out of pharmacy premises) should perhaps be incorporated in the Regulations themselves. The Review does not believe that arrangements of this type would hamper unduly the flexibility of regulations or prevent their easy amendment to keep them up to date. To a considerable extent, therefore, the Act, Regulations and Guidelines need to be **revised** to be consistent with the regulatory principles in Recommendation 14.

Constitution of the Board

The Review notes that, under the Act, all members of the Board must be registered pharmacists. In a time of increasing health consumer awareness of their rights, and in the interests of public accountability, this lack of direct community involvement in Board activities is out of kilter with community expectations and with regulatory developments in Victoria and elsewhere.

The present constitution of the Board, including the election of half its members, is inconsistent with the Review's Recommendation 19, and should be **replaced**.

Victorian model legislation

In considering the Act in this regard, the Review had reference to the relevant parts of other Victorian Acts to which that State's template legislation for health professionals has been applied⁵. That model contains provisions relating to the constitution of Boards that:

- Ensure that members are all appointed by the Minister;
- Provide for the appointment of lay and legal practitioner members;
- Provide for the disclosure of interests by Board members in matters before the Board.

In the Review's opinion, the Victorian model health practitioner disciplinary provisions are more consistent with these recommendations than those of the existing Act, and should be considered in any review or replacement of the Board-specific provisions of the *Pharmacists Act*.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

Pharmacy register

Part II of the Act relates to the Pharmacists Register of Victoria, listing all pharmacists qualified for registration in the State. Section 11 of the Act provides that the register may be inspected by any person, and details extracted from it. Schedule 2 to the Regulations requires that the Register record a pharmacist's name and address, and qualifications.

Practice protection

Paragraph 33(1)(a) of the Act makes it an offence for a person who is not a registered pharmacist to practise as or hold themselves out to be a registered pharmacist. Given that section 3 of the Act defines "practice of a pharmacist" as including "the supplying

⁵ The Review used as its main model the *Osteopaths Act 1996* (Vic).

compounding and dispensing of drugs and medicines on an order or prescription”, this seems to prevent the lawful dispensing of a prescription medicine by a medical practitioner or allied health professional such as a nurse practitioner.

Title protection

Paragraph 33(1)(b) of the Act prohibits persons who are not registered pharmacists from using the titles of pharmacist, pharmaceutical chemist and other synonyms, or any title, sign or symbol which may be construed as being able to be construed as implying that they are qualified to practise pharmacy. Similarly, such a person cannot designate premises to be a pharmacy or similar title (paragraph 33(1)(c)).

Personal requirements for registration

In addition to paying the prescribed annual fee and possessing prescribed qualifications and experience, sub-section 12(1) of the Act requires that a candidate is entitled to be registered if “upon personal attendance at the Board’s office he satisfies the Board that he is of good character”. In practice, this is understood principally to involve an interview with the Board’s registrar.

Detailed requirements for registration are contained in the Guidelines (Guidelines 210-209), and vary for Victorian graduates, persons being restored to the register, applicants from other Australian jurisdictions and New Zealand, applicants from the British Isles and other overseas pharmacists.

All applicants are expected to supply the Board with personal details including full name, date of birth place of residence, preferred mailing address, contact telephone number and any languages spoken in addition to English. In addition to good character, Victorian and “other” overseas pharmacists are expected to have a Level 2 Basic First Aid certificate or comparable evidence of first aid proficiency. Victorian graduates are also expected to have evidence of the successful completion of an approved management course.

Guideline 320 provides that pharmacist trainees who are candidates for the Board’s final examination must demonstrate their fluency in spoken and written English.

Professional requirements for registration

Section 12 of the Act empowers the Board to register a person as a pharmacist if they:

- Have completed a prescribed course of practical training for a minimum number of hours;
- Have completed study at the Victorian College of Pharmacy or other prescribed institution; and
- Have passed entrance examinations approved by the Board, including a final examination under the auspices of the Board (section 14), or holds a certificate of competency from a body recognised by the Board and “substantially equivalent to the training and required examination required for registration in Victoria”.

Section 13 authorises the Board to determine the education requirements for a person seeking to study pharmacy, the courses of study leading to annual and final examinations. It also enables the Board to consult with the Dean of the Victorian College of Pharmacy and equivalent persons in other schools of pharmacy in relation to course content.

Some details of education and training requirements are set out in Part 3 of the Regulations, including topics to be included in a course of practical training (Regulation 301), the setting of 2,280 hours as the prescribed period for practical training (Regulation 302), subjects for study at the Victorian College of Pharmacy (Regulation 303) and subjects for the Board's final examination (Regulation 304). Part 3 of the Guidelines sets out further detail again, including requirements specific for overseas-trained pharmacists, and for persons seeking restoration to the Register.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendation.

Practice protection

These provisions are consistent with the Review's recommendation, but there is some uncertainty in relation to dispensing when necessary by medical practitioners and other health professionals. Although it is understood that in practice paragraph 33(1)(a) of the Act has not been applied to the supply of medicines by such persons, a strict interpretation of the term "practice of a pharmacist" as defined elsewhere in the Act could result in the paragraph 33(1)(a) offence being applied to them. It may therefore be prudent to **amend** the Act to eliminate any doubt.

Title protection

These provisions are consistent with the Review's recommendation.

Personal qualifications

The Review notes that considerable parts of laid down requirements for a pharmacist to be registered are not contained in either the Act or Regulations, but in the Board's Guidelines.

Notwithstanding this, the Guidelines' requirement for certain pharmacists to have first aid qualifications is not consistent with the Review's recommendation, and should be **removed**.

Professional qualifications

The Review notes that the Act and Regulations, coupled with the Board's qualifications, give the Board great authority over the setting of professional education and training standards and curricula in Victoria. It is a matter for the jurisdiction to consider whether the extent of this statutory-mandated involvement of the Board is justified.

These provisions are, notwithstanding this observation, consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

The Act stipulates no other requirements for renewed registration as a pharmacist than payment of the prescribed fee (section 15). Regulation 30, however, enables the Board to require to undertake prescribed training for an applicant for restoration to the register if a person:

- Does not apply for registration within two years of otherwise being eligible to apply and has not practised as a pharmacist in that time; or
- Has not practised as a pharmacist for more than two years.

ASSESSMENT

These provisions are consistent with the Review's Recommendation 17. While it falls short of mandatory competence for renewing pharmacists in terms of Recommendation 18, the Act's statutory provision for the Board to impose competency training and assessment requirements on "lapsed" pharmacists wishing to return to practice is consistent with the public's interest in ensuring the safe and competent practice of pharmacy.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

Part IV of the Act relates to the conduct of inquiries and investigations by the Board. Section 17 establishes that the Board's proceedings are subject to the State's *Evidence Act 1958*. Section 17A for a quorum on a disciplinary panel of three members, with additional members able to be co-opted if Board members are unavailable because of a declared interest in the matter, or because specific expertise is needed.

Grounds for disciplinary action

Section 18 provides that the Board may inquire into and punish discreditable conduct by a pharmacist, acting wither on a complaint or its own volition. Sub-section 18(3) states a pharmacist may be penalised if he or she:

- Has been convicted of an indictable offence in Victoria or elsewhere;
- Is physically or mentally unfit to practise as a pharmacist;
- Is drug or alcohol dependent;
- Has been convicted by a court of an offence against the Act, the *Drugs, Poisons and Controlled Substances Act 1981* or their Regulations;
- Is advertising in a prohibited or discreditable manner; or
- Is guilty of "any other conduct discreditable to a pharmacist or which renders him unfit to be registered as a pharmacist".

Findings and review of decisions

Sub-section 18(3) provides penalties ranging from admonishment to the striking of a pharmacist from the Register, and enables the Board to make orders as to the costs of proceedings.

Section 18 also provides for the review, on appeal to the Supreme Court of Victoria, of Board disciplinary decisions. As a procedural measure, Section 18A of the Act provides that a pharmacist's registration may be suspended by the Board pending the outcome of an inquiry, including any appeals.

The Board's Guidelines do not elaborate on disciplinary proceedings and related matters, and there are no specific regulations covering disciplinary matters. This is not to say that the Board's activities in this area of responsibility are not careful, rigorous and consistent, and the Review understands that internal guidelines assist the Board in undertaking its disciplinary responsibilities.

ASSESSMENT

As they stand, the disciplinary provisions of the Act provide a bare bones structure for the conduct of disciplinary proceedings. They imply mechanisms for receiving and investigating complaints, and for conducting disciplinary inquiries and hearings if these are required. They also provide an avenue of appeal from Board decisions.

What is relatively lacking is both detail and relevance to current administrative law practice and procedures in Victoria. While it is sound on most aspects of ground for investigating a pharmacist, the Act is silent on what constitutes "other conduct discreditable to a pharmacist"⁶.

On balance, the Review believes that the Act's existing provisions are not entirely consistent with its recommendation, and should be **replaced**.

In considering the existing provisions, the Review had reference to the disciplinary parts of other Victorian Acts to which that State's template legislation for health professionals has been applied⁷. That model contains a highly detailed and clearly-explained machinery for the handling of complaints and disciplinary matters. Just as importantly, as in section 3 of the *Osteopaths Act 1996* (Vic), the model defines in detail what may constitute "unprofessional conduct", including professional misconduct. Professional conduct itself is, however, not defined.

In the Review's opinion, the Victorian model health practitioner disciplinary provisions on the whole go considerably beyond those of the present Act to meeting its preference for arrangements that are more accessible, public, transparent and open to external review. The model provisions would, therefore, generally be consistent with its recommendation.

As a broad observation, the Review notes that the Act and the model health practitioner legislation are both silent on the matter of awarding costs arising from a disciplinary investigation and hearing by a Board.

It would nevertheless be reasonable, as both a penalty and as a deterrent against incurring conduct disciplinary penalties, for a party found at fault to be liable for the costs of the

⁶ Although the Review understands that this was judicially considered by the Supreme Court of Victoria in *Mercer v The Pharmacy Board of Victoria*, [1968] VR 72, per Pape J, and the *Mercer* judgement is used and guidance by the Board.

⁷ The Review used as its main model the *Osteopaths Act 1996* (Vic).

process, and an order for costs against them made accordingly. Should the Act be **amended** to allow for such a possibility, this amendment would be justifiable in the public interest.

QUEENSLAND *PHARMACY ACT 1976*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1976* (the Act) consists of five Parts. The Act is supplemented by the *Pharmacy By-Law 1985* (the By-Law), which is made by the Pharmacy Board of Queensland (the Board) under section 40 of the Act. Regulations made by the Governor in Council pursuant to section 41A of the Act are contained in the *Pharmacy Regulation 1997* (the Regulation)

The Long Title of the Act identifies its objectives as being:

- Setting out requirements for the qualifications and registration of pharmacists; and
- The regulation of pharmacy practice.

The Terms of Reference for the Review require that only matters in relation to Part 4 of the Act be examined.

As a point of observation, the Act and subordinate legislation are minimal in their specific coverage as aspects of pharmacy ownership and the commercial conduct of pharmacy businesses. The Review understands that forthcoming amendments to Queensland health practitioners legislation may be making substantial changes to the legislation including the *Pharmacy Act*, and its comments here are made anticipating any amendments.

2. OWNERSHIP OF PHARMACIES

Part 4 of the Act deals with pharmacy ownership and related commercial matters, including limitations on ownership and pecuniary interests in pharmacy practices. The By-Law or Regulation do not deal with pharmacy ownership or related matters.

OWNERSHIP OF PHARMACIES (RECOMMENDATION 1)

DESCRIPTION

Sub-section 30(1) of the Act, with limited specified exceptions, restricts the ownership of pharmacy practices to pharmacists.

Section 5 of the Act defines a “pharmacist” as a person currently registered under the Act.

ASSESSMENT

These provisions are consistent with the Review’s recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. The Act effectively requires, however, that a pharmacist owning a pharmacy in Queensland must be registered there.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Sub-section 30(1) of the Act precludes persons who are non-pharmacists from carrying on as an owner of a pharmacy, or otherwise having a direct or indirect pecuniary interest in a pharmacy.

ASSESSMENT

It is understood that sub-section 31(1) has been interpreted in the State as not preventing sole trading pharmacists and pharmacist partnerships but precluding corporations, whether or not there are wholly composed of pharmacist shareholders and directors. The Review notes this, but is still not certain whether such bodies corporate would be precluded by the provision as worded, as the natural persons constituting the body corporate would all be registered pharmacists.

These provisions, with this qualification, are consistent with the Review's recommendation. They could be **amended**, however, to allow definitively for bodies corporate as composed in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PHARMACIST SUPERVISION OF A PHARMACY (RECOMMENDATION 4)

DESCRIPTION

Section 30 (2) of the Act specifies that a pharmacist can own, or have a pecuniary interest in, up to four pharmacies.

There is a savings provision in Section 30 (3B), which allows individuals or associations of persons with ownership or pecuniary interest in four or more pharmacies at the date of commencement of the Act to retain, but not increase, the number of pharmacies they hold.

Sub-section 32(3) makes it an offence for the proprietor of a pharmacy not to have a pharmacy practice carried on under the personal supervision and management of a pharmacist. This ensures that any one pharmacy is always operated under personal pharmacist supervision and direction.

ASSESSMENT

The provisions relating to the number of pharmacies a person or association may own or in which they may have a pecuniary interest are not consistent with the Review's recommendation and should be **removed**.

The provision relating to the direct supervision of a pharmacy by a pharmacist is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Paragraph 30(3)(a) of the Act exempts friendly society pharmacies in existence at the date of the commencement of the Act from its general restrictions on ownership of and pecuniary interest in a pharmacy.

Friendly societies carrying on business when the Act commenced may continue to operate on their sites at that time. Such pharmacies may only relocate to a site "within the locality" if approved by the minister on the recommendation of the Board.

Sub-section 30(7) of the Act provides that the establishment of a new pharmacy by a friendly is only possible if the Board advises the minister that it is appropriate, on the basis of:

- An established need for the establishment of a pharmacy; and
- The composition and membership of the society satisfies prescribed statutory requirements. Paragraph 40(1A)(n) of the Act gives the Board the ability to make by-laws to prescribe "the composition and membership of friendly societies by which the establishment of a pharmacy practice may be approved by the Board".

Other permitted exceptions are limited to those non-pharmacists persons and companies owning and operating pharmacies at the time of commencement of the Act (sub-section 30(3)(a)). As with friendly society pharmacies operating at the time of the Act's commencement, their locations are circumscribed and limited relocations require ministerial approval on Board advice.

ASSESSMENT

There are 24 friendly society pharmacies currently operating in Queensland⁸. The Review understands that there is one grandparented non-pharmacist non-friendly society owner of a pharmacy in the State. It also understands that there have only been a handful of new friendly society pharmacies approved since the Act commenced in 1976.

The restrictions in relation to grandparented owners other than friendly societies are consistent with the Review's recommendation, although the restrictions on their location and relocation are excessive, and should be **removed** in the interests of consistency.

In relation to friendly societies, however, the Act's restrictions are discriminatory insofar as they impose far greater restrictions on one class of lawful pharmacy operator compared to

⁸ Australian Friendly Societies Pharmacies Association, *Friendly Societies Pharmacies Directory*, February 2000.

another. Private pharmacist-owned pharmacies do not have to undergo a ministerial approval process, and Board scrutiny, in the same way that friendly societies are scrutinised. Similarly, private pharmacies are not constrained by State law as to where they may relocate, nor do they require ministerial approval to make what is essentially a matter of commercial and professional judgment.

The Review is particularly concerned by the Act's requirement that a Minister may only decide in respect of a friendly society pharmacy only on the advice and recommendation of the Board. This gives the Board a disproportionate say on specific matters and essentially a right of veto over current or proposed pharmacies not owned by pharmacists.

Of equal concern is the perception that this power could be perceived as being exercised in a partial manner. The Board itself submitted to the Review that "the public is best served by a professional environment in which the ownership and control of pharmacies and the responsibility for the activities within are vested solely in registered pharmacists"⁹. Such statements do not suggest a predetermined approach by the Board when applied to its statutory responsibility to advise ministers on any proposal involving a friendly society pharmacy.

These provisions should be **amended** to be consistent with the Review's recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

Sub-section 30(1) of the Act provides that a non-pharmacist shall not own a pharmacy or have a "pecuniary interest, direct or indirect, in a practice of pharmacy". What constitutes a direct or indirect pecuniary interest beyond ownership is not defined in either section 30 or section 5 of the Act.

Sub-section 30(5) provides that the pecuniary rights of pharmacy employees, and of the grantees of bills of sale in respect of a pharmacy practice, are not affected by sub-section 30(1).

Sub-section 30(6) provides that provisions in commercial arrangements such as bills of sale, mortgages, franchises and agencies are void if they:

- Require goods or services to be obtained from a specific person or body;
- Give a person "other than the person lawfully carrying on the practice" the right to control in whole or part the manner of the practice, to inspect the practice's books (except for the purposes of ensuring compliance with the relevant document); and
- Give other persons rights to a consideration that varies according to the profits or takings of the pharmacy practice.

ASSESSMENT

Insofar as they go beyond restricting the proprietary interests in a pharmacy (that is, who may own, hold shares in or be a director of a pharmacy-operating entity), these provisions are inconsistent with the Review's recommendation.

⁹ Pharmacy Board of Queensland, submission to the Review, page 2.

They could be **replaced** by:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making the a pharmacist's acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

There are no requirements in the Act for the registration of premises or businesses.

WESTERN AUSTRALIAN *PHARMACY ACT 1964*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1964* (the Act) has six Parts and three Schedules. Regulations consolidated as the *Pharmacy Act Regulations 1976* (the Regulations), made pursuant to the Act, have nine Parts.

The overall objectives of the Act are to:

- Set out the constitution, administration and operation of the Pharmaceutical Council of Western Australia (the Council) insofar as these relate to the oversight and administration of professional pharmacy activity in the State; and
- Set out matters, including disciplinary matters, relating to registration and practising as a pharmacist in Western Australia, what entities may carry on business as chemists, advertising, title protection and miscellaneous provisions.

The Regulations spell out detailed constitutional matters of the Council (including rules for the election of Council members and the appointment of a Registrar), examinations and practical training for pharmacists, licences to practise, the registration of pharmacies, and miscellaneous provisions.

The Western Australian Government presently is undertaking a systematic review of its health practitioners legislation, with a view to maximising consistency of regulatory practice across relevant professions, including pharmacy. The Review understands that those restrictions contained in the Act, outside the Terms of Reference for this Review, will be considered later in 2000 as part of this systematic process.

2. OWNERSHIP OF PHARMACIES

Matters related to pharmacy ownership generally are covered in Part V (Miscellaneous Provisions) of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act expresses ownership in terms of describing “persons entitled to carry on business as chemists”. Sub-section 36(1) of the Act provides that the practice of a pharmaceutical chemist may only be carried on by:

- A pharmaceutical chemist (defined by section 5 of the Act as a person registered under the Act or its predecessors)¹⁰; and
- A company or friendly society, provided that the practice of pharmacy is under the immediate supervision of a licensed pharmaceutical chemist.

¹⁰ For ease of reading, this assessment report shortens “pharmaceutical chemist” to pharmacists, which is itself a synonym recognised under the title protection provisions of section 37 of the Act.

Sub-section 36(2) restricts the ownership privilege for companies and friendly societies to those who had it at the time of the Act's commencement, thus grandparenting those entities and restricting the establishment of new pharmacy business to registered pharmacists.

Section 5 of the Act defines “the practice of a pharmaceutical chemist” as:

- The professional dispensing of drugs and medicines; and, where appropriate; and
- The sale of goods and the provision of services in association with the professional dispensing of medicines and drugs.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

Section 26 of the Act requires practising pharmacists to have a licence to practise in Western Australia issued by the Council in addition to being registered.

While section 26 does not prescribe that the holder of a licence has to be a resident of Western Australia, sub-section 26(1) provides that to practise as a pharmaceutical chemist in the State a pharmacist proprietor or employed pharmacist must also be a resident of Western Australia.

ASSESSMENT

Sub-section 26(1) prevents an interstate resident owning or operating a pharmacy in Western Australia. This is the only such restriction in any State or Territory *Pharmacy Act*.

Effectively, it imposes a restraint of trade on non-domiciled persons who otherwise would be eligible to operate a pharmacy in the State, and it appears to be a de facto restraint on interstate commerce. As a residence-based restriction, this provision protects the business of Western Australian pharmacists against interstate-based competition, even though Western Australian pharmacists can establish themselves in pharmacy businesses in any other of the States or Territories.

To the extent that it specified a residence requirement, sub-section 26(1) of the Act is contrary to the Review's recommendation, and the domiciliary requirement should be **removed**. There is further comment on the licensing requirement generally later in this assessment report.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Sub-section 36(1) of the Act, by specifying that a pharmaceutical chemist may carry on a pharmacy business, effectively permits pharmacists to operate as sole traders. Paragraph 36(2)(d), in dealing with the ownership privileges of friendly societies and companies,

specifies that there is nothing to prevent two or more pharmacists forming a partnership operating not more than two pharmacies.

ASSESSMENT

These provisions are consistent with the Review's recommendation, but could be **amended** to allow for the coverage of bodies corporate as composed in the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

Sub-section 28(1) of the Act provides that a pharmacist who, either on their own behalf or "as the agent, employee, partner or other associate of another person or body" carries on the business of, or has a pecuniary interest in, more than two pharmacies, commits an offence under the Act.

Sub-section 38(1) of the Act requires that the practice of a pharmaceutical chemist must be carried on under the personal supervision of the pharmacist or by an assistant who is a pharmacist.

ASSESSMENT

In evidence to the Review, the Pharmaceutical Council of Western Australia advised that restricting holdings to two pharmacies recognises that, ideally, while personal supervision of a pharmacy by a proprietor suggests one pharmacy per pharmacist, giving proprietors a source of ongoing income should they wish to close or sell a pharmacy ensures continuity for the pharmacy business ¹¹.

The Review understands that the two pharmacy rule long predates the present Act. It is the smallest number of owned pharmacies permitted under any of the comparable provisions in other States.

This provision, nevertheless, is inconsistent with the Review's recommendation, and should be **removed**.

The pharmacist supervision requirements are consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 36(1)(b) of the Act provides that a company or friendly society may carry on the business of a pharmaceutical chemist, provided that this is done under the immediate supervision of a pharmacist.

Sub-section 36(2) limits this entitlement to practices being carried on at the time of the Act's commencement, effectively grandparenting the pharmacy holdings of the friendly society or pharmacy to those held at that time. Section 36(2)(b) goes further to restrict these pharmacies

¹¹ Consultations of the Review with the Pharmaceutical Council of Western Australia, 25 August 1999.

to the sites they occupied at the commencement of the Act, unless the Minister decides that it is necessary to move the pharmacy to another location “in the immediate vicinity”.

Section 37 provides that after 1977 amendments to the Act, the pharmacy practices of amalgamating friendly societies could also be amalgamated, subject to the limitations of section 36.

The Act does not enable friendly society or grandparented companies to acquire new pharmacies to replace those that they sell or close.

ASSESSMENT

The Act allows both friendly societies and companies to operate pharmacies, but the terms of its provisions are more restrictive than in several other jurisdictions. While the grandparenting of company-owned pharmacies is consistent with other jurisdictions, the similar grandparenting of friendly societies is not. In practice, the Review is advised that there is one company-owned pharmacy still operating in Western Australia, and one friendly society pharmacy¹².

Sub-section 36(2) is not inconsistent with the Review’s recommendation in relation to the grandparenting of existing friendly societies operating pharmacies.

Paragraph 26(2)(b), in fixing the location of a “grandparented” pharmacy, and only allowing it to move within the immediate vicinity and then only with ministerial approval is, however, a restriction that discriminates against the operator vis a vis private pharmacy providers. This is inconsistent with other parts of the Review’s recommendation, and should be **removed**.

Sub-section 36(2), insofar as it relates to grandparenting company-owned pharmacies, is consistent with the Review’s recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The Act contains a number of provisions relating to pecuniary interests in a pharmacy business.

Sub-section 23(5), relating to the registration of pharmacies, requires the applicant for registration to make a full disclosure of the persons or bodies having an interest in the business or portion of the business, and the extent of such interest.

Sub-section 28 (1) provides that no pharmacist may have a pecuniary interest “whether direct or indirect” in more than two pharmacies. Sub-section 28(2) has a saving provision for pharmacies held under arrangements in place before the commencement of the *Pharmacy Act Amendment Act 1975*.

Sub-section 28(3) provides that any provisions in “a document purporting to have effect in relation to the practice of a pharmaceutical chemist”; a leasehold, licensing or occupancy

¹² Advice from the Pharmaceutical Council of Western Australia, 11 January 2000.

agreement; or a bill of sale associated with a pharmacy business or pharmacy shall be void if they:

- Purport to enable any person than a licensed pharmacist to control the operation of a pharmacy business;
- Enable such persons to receive any consideration from that business that varies according to profit or takings;
- Requires the purchase of goods or services from a specific supplier; or
- Enables access to a pharmacy business's records or documents for purposes other determining "whether or not the grantor of a bill of sale is complying with the conditions of that bill of sale".

Regulation 56(h) provides that the Council shall not register a pharmacy until it is satisfied that the applicant has made a full disclosure of the persons and bodies having an interest in the business applying to operate the pharmacy.

The Act does not define what may or may not constitute direct or indirect pecuniary interest. The relevant provisions appear to assume that pecuniary interest relates to ownership of, or benefiting from the management decisions relating to, a pharmacy practice. The collective purpose of the provisions appears to be to reinforce the basic premise of pharmacist ownership and control of pharmacy businesses.

ASSESSMENT

While they may be intended to protect the integrity of pharmacist proprietorship of pharmacy businesses, the set of provisions in the Act and Regulations are considerably broad in their range. To be implemented, and to determine in some cases what may constitute a direct or indirect pecuniary interest, regulatory and reviewing authorities necessarily have to apply broad discretion in administering these provisions.

Consistent with the Review's recommendations on the pecuniary interest issue, the existing pecuniary interest provisions in the Act could be **replaced** by:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making the a pharmacist's acting under such influence a ground for professional misconduct.

Section 28(3) should be **removed** and not replaced in new legislation. Regulation 56(h) should also be **replaced** with a provision reflecting the above points.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Pharmacy premises

The registration of pharmacy premises is governed by section 23 of the Act and Part VI of the Regulations (Regulations 54-61A).

Section 23 provides that:

- No pharmacy business can be carried out in a pharmacy that is not registered with the Council (23(1));
- Applications for registration of premises may be made to by a pharmacist, company or friendly society, and the Council may withhold registration until prescribed conditions are prescribed with (23(2));
- Registration of premises is annual, remaining in force until 30 June each year, and may be certified by the Council on payment of a prescribed fee (23(3));
- Council decisions relating to registration of premises are appealable to a judge of the Supreme Court of Western Australia (23(4)); and
- Applicants for registration of premises can be required to make a “full disclosure” of the nature and extent of other persons or bodies interests in the business (23(5)).

Section 24 provides that fees for the registration of a pharmacy, as determined by regulation, shall be paid to the Council for the registration to be effective.

Regulation 56(1) sets out the conditions that must be satisfied before the Council registers a pharmacy. These include that:

- Pharmacy premises are “walled, floored and ceiled”, and have a separate entrance from a street or public thoroughfare;
- The premises are well lit and adequately ventilated;
- Fittings and equipment used in the handling and storing of drugs are maintained, clean and in good repair;
- The premises shall not be used in relation to receiving, handling or storing clothing for dry cleaning, laundering or repair;
- The dispensary has a minimum floor space, plumbing services, specified apparatus and reference books;
- Proper and adequate provision is made for the full recording and maintaining of all prescriptions and repeat prescriptions dispensed in the pharmacy; and
- Disclosure of interests in the pharmacy.

Regulation 57 provides discretion for the Council to register a pharmacy “subject to such conditions as it may determine” where either circumstances exist that the requirements of Regulation 56 cannot be complied with immediately, or if in the Council’s opinion it is not in the public interest to require such compliance.

Regulation 58 requires the Council’s approval of structural, layout or floor area alterations of a pharmacy before they are carried out. The Council may withhold approval only if these

plans would, if carried out, mean the pharmacy would cease to comply with any requirements of Regulation 56.

Regulation 71 provides that officers of the Council may inspect the pharmacy or any other premises to which the Act applies.

Pharmacy businesses

The Act does not provide for the registration of pharmacy businesses. As described above, however, the disclosure of details of the pharmacy business, and interests in that business, is a precondition to registering a pharmacy under the Act.

ASSESSMENT

The Act provides for, and the Regulations set out, a series of guidelines and specifications for the fitting out and operation of a safe and effective pharmacy. Provided that they are relevant to the minimum standards needed for the safe and competent contemporary practice of pharmacy, do not interfere unduly in the overall operation of the pharmacy as a commercial business and continue to be approved by the Government, provisions and specifications of this nature are consistent with the Review's recommendation.

It is also noted that the powers of inspection for the Council and its officers could be exercised without the pharmacy premises formally being registered.

Provisions of the Act and Regulations requiring or presuming that a pharmacy be registered by the Council as a precondition to its operation are inconsistent with the Review's recommendation, and should be **removed** to the extent of that requirement or presumption.

Regulations relating to the use of pharmacy premises for non-pharmacy premises, such as the handling of clothing for dry cleaning and similar purposes, need to be examined very carefully to ensure that they do not unduly intrude on the commercial operation of the pharmacy business as a whole, and that they do not relate to activity already regulated elsewhere (eg under public health regulations). If their ongoing presence cannot be justified as central to ensuring the safe and competent practice of pharmacy on the premises, such regulations should be **removed**.

3. REGISTRATION OF PHARMACISTS

Matters relating to pharmacist regulation, pharmacy practice and disciplinary matters, and the Pharmaceutical Council of Western Australia are found in Parts II-V of the Act, and II-VI and VII-IX of the Regulations.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Section 6 of the Act establishes the Pharmaceutical Society of Western Australia, and requires all registered pharmacists in the State to be members of the Society. Section 7 establishes a seven-member Pharmaceutical Council of Western Australia "for the purposes of this Act and the management of the Society".

Part II of the Act deals with matters relating to the constitution and administration of the Council. The key provision is section 10, which provides for both the election of members of the Council by members of the Society, and for the elected Council members to elect their president and deputy president.

Part II of the Regulations (Regulations 5-38) also relate to the constitution of the Council. It sets out procedures for conducting Council elections, conducting Council meetings, and the management of Council funds.

Section 15 of the Act provides for the appointment of a Council registrar and such other officers and examiners as the Council considers necessary for the administration of the Act. Regulations 32 and 33 make a very general description of the registrar's duties in terms of the Act and the Council's determination. Regulation 32 states clearly that the registrar is subject at all times to the Council's direction. Regulation 33 obliges the registrar to consult with the president or deputy president on out of session matters, and follow any instructions that they may give.

ASSESSMENT

The Pharmaceutical Council of Western Australia is unique among Australian jurisdictions as being both the executive body of pharmacists' professional association, as well as being the State's pharmacy regulatory authority under statutory charter. In this regard it has a similar role to Pharmaceutical Societies in the United Kingdom, Ireland and New Zealand.

It is also unique in that it is the only fully elected pharmacy regulatory authority in Australia.

The Council has a long tradition of professional involvement in the administration and regulation of pharmacy in Western Australia. In consultations and discussions with the Review, it stressed consistently that it is committed to protecting the public interest, has the highest objective standards of its members, and is impartial and unbiased in its operation. The Review has no reason to doubt this.

The question for the Review, however, is not simply whether the existing regulatory arrangements work well. It is also to ask whether these arrangements effectively promote the open conduct of professional regulation by ensuring that regulatory machinery and processes are open, fair and accountable to the community, and do not unduly hamper professional or commercial activity.

On these points, the Review believes that the Pharmaceutical Council structure is no longer the ideal way to administer pharmacy legislation in Western Australia. This is because:

- A fully elected Council is directly accountable only to its electors, the registered pharmacists of Western Australia;
- The Council has very wide discretion to act as it sees appropriate on a considerable range of professional matters in the Act and regulations; and
- As the State's peak pharmacy body as well as its regulatory authority, and even with the best intentions of its members, the fully elected Council structure has the potential for conflicts of judgment between the interests of the profession and those of the wider community.

While it commends the Council and its members for their commitment and efforts, the Review must conclude that current provisions regarding the Council and its operation are not consistent with its recommendation. It also concludes that the regulatory machinery should be **reformed** when the Act is reviewed by the jurisdiction in the near future. Such reforms could include:

- The reconstitution of the Council as a Pharmacy Board or like body comparable to those in other States and Territories;
- The appointment of ideally all and at least a significant proportion of the members of the new body by the responsible minister;
- Ensuring that members of the body include representatives of the general community and a legal practitioner;
- A clear setting out of the new body's role, powers (including limitations on its discretion) and responsibilities in the Act and regulations; and
- Ensuring that regulations, by-laws, guidelines and procedural statements that may be proposed by the new body are not effective until they are approved by the Governor-in-Council as statutory instruments.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

Section 20 of the Act requires that the Council keeps “The Pharmaceutical Register of Western Australia” and that the Council registers an eligible applicant, his or her residential or business address, qualifications and date of registration.

The Council may refuse registration under section 22 of the Act. If this occurs, the applicant may appeal against the refusal to a judge of the Supreme Court of Western Australia.

Practice protection

Section 39 of the Act provides that no person shall dispense any medicine or drug if they are not:

- A pharmacist;
- A person who carries out such dispensing under the immediate personal supervision of a pharmacist;
- A medical practitioner; or
- A dentist or veterinary surgeon acting in the course of their profession.

Sub-section 38(2) of the Act makes it an offence, except in an emergency, for a person to accept a prescription other than at a pharmacy where a medicine shall be prepared and supplied.

Title protection

Sub-section 37(1) prohibits a person other than a registered pharmacist assuming or using the title pharmaceutical chemist or other recognised synonyms, or to display any title, term or sign that conveys the impression that a person is a registered pharmacist.

Some of the titles listed in the sub-section, such as druggist, homoeopathic chemist, chemist and druggist are dated and obsolete.

Personal requirements for registration

In addition to paying the prescribed annual registration fee and possessing prescribed qualifications and experience, sub-section 22(1) of the Act requires that an applicant be:

- Aged 18 or over; and
- Able to speak, read and write intelligibly in English.

Sub-section 6(2) provides that every registered pharmacist shall be a member of the Pharmaceutical Society of Western Australia.

Professional requirements for registration

Section 21 of the Act sets out the profession requirements expected of a registered pharmacist. Paragraph 21(1)(a) provides that the general requirements are:

- Completion of at least 2,000 hours practical training in accordance with such conditions prescribed by and in such premises that are approved by the Council;
- Passing examinations prescribed by the Council; and
- Passing a First Aid examination approved by the Council.

The prescribed examination and practical training requirements are set out in Regulations 41-43.

For pharmacists qualified outside Western Australia section 21(d) of the Act provides that they may be recognised for registration in Western Australia if they have been recognised as a pharmacist by “any society, college or board of pharmacy prescribed by the regulations and remain in good standing with that authority. Interstate and New Zealand applicants may be required to demonstrate post-qualification employment experience of at least one year, and all have to sign a statutory declaration that they have study Western Australian law governing the practice and sale of poisons.

Section 21 also contains provision for Council discretion in special circumstances and apprenticeship training predating university pharmacy courses.

Regulation 45 sets out the regulatory authorities whose certification of pharmacists is recognised. They are the Pharmacy Boards of the States and the Pharmaceutical Societies of the United Kingdom, Ireland, Northern Ireland, and New Zealand. The Pharmacy Boards of the Australian Capital Territory and the Northern Territory are not included in the list.

ASSESSMENT

Pharmacist registration

These provisions are consistent with the Review's recommendations.

Practice protection

These provisions provide for classes of health and allied professionals other than pharmacists to dispense drugs and medicines as well as registered pharmacists. In practice these exceptions are limited, but it is noted that they do not include nurse practitioners as is suggested by the Review.

These provisions are therefore consistent with the Review's recommendation.

Title protection

These provisions are consistent with the Review's recommendation. There may be merit, however, to specifying only two titles in the Act consistent with modern usage: pharmacist and (pharmaceutical) chemist, and **removing** other synonyms.

Personal requirements for registration

The English language provision is consistent with the Review's recommendation. The minimum age requirement, however, is not consistent, and arguably is unnecessary. It should be **removed**.

Professional requirements for registration

With the exception of the first aid requirement, these provisions are consistent with the Review's recommendation.

While it is desirable and commendable to ensure a pharmacist has first aid training, having that training is not essential to the safe and competent practice of pharmacy. As a requirement for registration, this provision should be **removed**.

The Review notes the Act's confining of recognised pharmacists to those certified by specified jurisdictions. This potentially discriminates against skills and qualifications certified in other jurisdictions, and therefore an effective barrier to competition for those affected pharmacists.

As indicated in its Report, the Review supports moving to a more competitive registration approach based on certifying an applicant's competency to practise without reference to where he or she was trained or certified.

While specific recognition arrangements are in place, however, the omission of the Pharmacy Boards of the Australian Capital Territory and the Northern Territory discriminates, however inadvertently, against pharmacists registered in those jurisdictions, and is contrary to the spirit of the Mutual Recognition Principles. It is not clear why this is the case, and may be an oversight. Regulation 45 should therefore be **amended** to include the Territory Boards.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Licensing of pharmacists for practice

In addition to registration as a pharmacist, section 26 of the Act requires that a registered pharmacist must also be licensed by the Council in order to practise or carry on business as a pharmacist. Sub-section 26(2) gives the Council the discretion to impose such conditions on the granting of a licence as it considers advisable or necessary in the public interest. No such conditions are set out in the Regulations: they are determined directly by the Council.

A practising pharmacist's licence is renewed annually (sub-section 26(4)). Should a pharmacist wish to return, after an extended absence, to practise as a pharmaceutical chemist, in the sense that practice is defined in section 5 of the Act, they would therefore need apply for a new licence, and thus satisfy the prescribed requirements for the licence.

ASSESSMENT

The licensing requirement additional to registration as a pharmacist is a requirement unique to Western Australia. It was put to the Review that this double requirement for practising pharmacists acts to assure the public of the high quality and competence of their pharmacy care¹³. The licensing requirement also recognises that some pharmacists need the status of registration but do not practise on a day-to-day basis. Such pharmacists would include those in academia or research, in government and industry, or who have retired but otherwise would be ineligible to own pharmacies under the Act.

While commending the good intentions of the Act in this regard, the Review notes that it creates an effective double jeopardy for pharmacists wishing to practise in Western Australia. Not only do they need to satisfy basic registration requirements, they also need to satisfy a "higher" set of licensing requirements. This runs counter to the Review's recommendation that regulated professional requirements only be the minimum needed to ensure the safe and competent practice of pharmacy. Requirements for registration as a pharmacist should be sufficient for this regulatory purpose.

The Act's licensing provisions are therefore inconsistent with the Review's recommendation 17 but may remain valid if, as part of reviewing the Act, Western Australia introduces mandatory demonstrations of competence for re-registering pharmacists along the lines of Recommendation 18. If this does not happen, however, these provisions should be **removed**.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Sections 32-34 of the Act deal with disciplinary proceedings and decisions against registered pharmacists, and against friendly societies and companies permitted to operate a pharmacy. Section 32 sets out disciplinary procedures, and the following sections deal with appeals and actions arising from disciplinary decisions.

¹³ Consultations of the Review with the Pharmaceutical Council of Western Australia, 25 August 1999.

There are no specific regulations relating to conducting disciplinary processes, although it is understood that the Council has its own procedural guidelines to complement the Act.

Handling complaints

The Act is silent on procedures for receiving and investigating a complaint. Section 32's coverage commences only at the point where a party is summonsed to show cause that they should not be dealt with on specified grounds (sub-section 32(3)). Matters relating to the receipt, initial handling and investigation of complaints, and of referred matters such as a criminal conviction of a pharmacist, effectively are at the discretion of the Council and based on established practice rather than set guidelines or standing orders.

Grounds for disciplinary action

The grounds for a summonsed party to show cause are listed in sub-section 36(6). They are that the party:

- Has been convicted of an offence that the Council believes renders them to be unfit to continue to carry on the practice of a pharmacist;
- Is a pharmacist unfit to continue to practise by reason of physical or mental capacity, alcohol or drug addiction;
- Is guilty of carelessness, incompetence, impropriety, misconduct or infamous conduct as a pharmacist;
- Has breached an undertaking given in respect of a previous disciplinary proceeding; or
- Has breached advertising regulations.

Hearing of matters and decisions of the Council

The Act is silent on how disciplinary matters are dealt with by the Council, other than to provide guidance on the treatment of documents and exhibits tendered as evidence, and the protection of witnesses.

The Council itself therefore has considerable discretion in taking action short of formal disciplinary processes, including conciliation of complaints and counselling of pharmacists. In discussions with the Review, the Council highlighted that they seek as a body to work sensitively and appropriately to resolve a matter including, for example, providing informal advice and support to pharmacists dealing with substance abuse. Appearance before a formal hearing as is seen as a last resort¹⁴.

Sub-section 32(7) sets out the penalty options if a party is found liable to be disciplined. These are:

- Erasure from the register;
- Suspension from carrying on practice as a pharmacist for up to three years;
- Imposing fines not exceeding \$500; or
- Censure.

Paragraph 32(7)(c) enables the Council to make costs orders against a party, to impose conditions of a party's licence or registration, or to seek specific undertakings from the party.

¹⁴ Discussions between the Review and the Pharmaceutical Council of Western Australia, 28 November 1999.

Appeals from disciplinary matters

Section 27 of the Act provides for appeals from decisions of the Council, including disciplinary matters, to a Judge of the Supreme Court of Western Australia, whose adjudication is final.

ASSESSMENT

The disciplinary provisions of the Act are a bare framework for a fair, open and accountable disciplinary process. It is not, however, a comprehensive guide to the Council, complainants, parties complained against, or the general public about how the disciplinary system works and how it works effectively to protect the public interest.

The Review accepts, however, that the Council, in developing and applying its own discretion and procedures to supplement the Act, has been and is acting with the public interest in mind, and with professional zeal and integrity. It has sought to fill the gaps in the legislation as practically as possible.

In the Review's opinion, the disciplinary provisions of the Act therefore are inconsistent with its recommendation about the acceptable principles of relevant regulation, and should be **amended** when the Act is reviewed by the State in the near future.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings, including dealing with conflicts of interest for Council members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties;
- Dissemination of disciplinary decisions; and
- Grounds for appeals against by the regulatory authority and the hearing of such appeals.

At minimum, any guidelines or standing orders used by the Council to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. These should cover all stages of a complaints process, including receiving and investigating complaints.

SOUTH AUSTRALIA *PHARMACISTS ACT 1991*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacists Act 1991* (the Act) contains six Parts and two Schedules. The Pharmacists Regulations 1991 (the Regulations) four Divisions and two Schedules.

The principal objectives of the Act are:

- Providing for the registration of pharmacists;
- Constituting the Pharmacy Board of South Australia (the Board) and setting out its composition, functions and powers; and
- Regulating the practice of pharmacy, including pharmacy ownership and related matters, and complaints and disciplinary matters relating to registered pharmacists.

The Regulations include provisions relating to pharmacist registration, prescribed standards for pharmacy premises, prescription and dispensing requirements and restrictions on pharmacists advertising.

2. OWNERSHIP OF PHARMACIES

Pharmacy ownership and related matters are covered in Part 3 of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act deals with which natural persons or companies can own a pharmacy through prescribing who may practise pharmacy. Section 4 of the Act defines “pharmacy” as “the supply of a drug or medicine on the prescription of a...person authorised to prescribe the drug or medicine”. By prohibiting non-pharmacists from this supplying role, the Act determines indirectly that only registered pharmacists may operate a business involving the supply to the public of prescribed drugs or medicines.

Sub-section 18(1) specifies the basic qualifications of a person eligible for a registration as a pharmacist¹⁵. Under sub-section 18(2), a company may be registered as a pharmacist if it satisfies the Board that its memorandum and articles of association satisfy certain requirements. This will be considered further in relation to permitted ownership structures.

Sub-section 26(1) of the Act specifies that only registered pharmacists may practise pharmacy. Sub-section 26(2) contains limited exceptions, including two specified friendly societies.

¹⁵ Registration requirements for individuals are discussed further below in the context of pharmacist registration and related matters.

ASSESSMENT

While they are indirect rather than express in relation to determining who may own a pharmacy, these provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for pharmacy ownership in the Act. A natural person or company does, however, have to be registered under the Act to practise pharmacy in the State.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Provisions relating to ownership and grandparented pharmacies are set out particularly in Sections 18 and 26. In addition, there are number of special obligations for registered pharmacy companies contained in Sections 35 to 39. These include matters such as gaining approval from the Board prior to altering articles of association and that partnerships cannot be entered into without Board approval.

Sub-section 18(2) requires a company registered as a pharmacist to have satisfied the Board that its memorandum and articles of association provide that:

- The sole object of a company must be to practise as a pharmacist;
- The directors must be persons who are registered pharmacists or, if there are only two directors, one may be a prescribed relative (parent, spouse, de facto partner, child or grandchild);
- Shares are owned by a registered pharmacist director or a prescribed relative of that pharmacist;
- Total voting rights in the company are held by registered pharmacists who are directors or employees of the company;
- The directors are not directors of any other company registered as a pharmacist without the Board's approval;
- Shares in the company cannot be transferred beyond the company and members of the company; and
- Shares held by a spouse or de facto partner must redeemed by the company on the dissolution of the marriage or the ending of cohabitation.

The Act does not make specific provision for sole trading pharmacist or partnerships of registered pharmacists. Given that such arrangements are not in breach of section 18 requirements on who may practise pharmacy, there is effectively no restriction on these combinations of persons registered under the Act.

ASSESSMENT

South Australia's registration of companies as "pharmacists" is unique among State and Territory *Pharmacy Acts*. The provision for prescribed relatives to have shares and non-voting directorships in the company is also unique.

While they do not require all the shares of the registered company to be owned by a pharmacist or pharmacists, the requirements of the Act provide for the effective pharmacist ownership of the company through pharmacists' effective and undisputed control of voting rights. This is consistent with the Review's definition of pharmacy ownership by pharmacists.

These provisions are consistent with the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

Sub-section 34 (1) limits a person from carrying on a business of pharmacy at more than four places of business. Eligible friendly societies are restricted to owning a maximum of thirty-one pharmacies. Holdings of more than four pharmacies in place at the time of the Act's commencement are grandparented.

Section 33 of the Act provides that any place open to the public and involving the carrying on pharmacy as defined in the Act must be under the "direct and constant" personal supervision of a registered pharmacist.

ASSESSMENT

The pharmacy holdings provisions are not consistent with the Review's recommendation and should be **removed**.

The pharmacist supervision provision is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 26(2) provides that, other than registered pharmacist persons and companies, the following excepted entities may practise pharmacy:

- Non-pharmacist natural persons or companies carrying on a pharmacy business before present restrictions commenced in 1972 and 1942 respectively;
- The Mount Gambier United Friendly Societies Dispensary Incorporated; and
- The Friendly Societies Medical Association Incorporated.

Sub-section 34(3) provides that the Friendly Societies Medical Association, a group of friendly societies that trades under the name of National Pharmacies, may carry on a pharmacy business at maximum of 31 sites.

ASSESSMENT

These provisions generally are consistent with the Review's recommendations. In relation to the Review's comments about regulating friendly society pharmacies, however, the Act could perhaps be **amended** to:

- Remove the references to specific friendly societies and express eligibility in terms of friendly societies as that are recognised under recent changes to the Corporations Law; and
- Removing the specific limitation on the number of pharmacies held by a particular friendly society group.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

Pecuniary interest is not defined for the purposes of the Act, and there are no prohibitions on non-proprietary pecuniary associations with a pharmacy business.

Regulation 18 is, however, indirectly concerned with supervising pecuniary interest matters. It requires the approval of the Board to carry on business other than the practice of pharmacy at registered premises. A business commonly associated with the practice of pharmacy is possible with the Board's permission, although there is no definition of a commonly associated business. This appears to be left to the Board's interpretation and discretion.

ASSESSMENT

Because of its treatment of who may be registered as a pharmacist, and the requirements imposed on registered pharmacy companies, the Act is quite clear on who may hold a proprietary interest in a pharmacy. Further definition as suggested in the Review's recommendation is not necessary.

The Act's general lack of regulation of pecuniary interests in a pharmacy business is consistent with the Review's recommendation. It may be desirable, however, to **amend** the Act along the lines of the recommendation to include:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making a pharmacist acting under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The registration of pharmacy premises is required by section 32 of the Act. Sub-section 32(2) provides that the Board may register premises if it is satisfied that they are suitable for the purpose of carrying on the business of pharmacy and the annual fee has been paid. Sub-section 32(4) provides for a registration application fee to be paid, and sub-section 32(6) that the registration of premises be renewed annually.

Section 40 gives the Board the power to inspect registered premises, if it has reasonable grounds to suspect proper cause for disciplinary action against a registered pharmacist, that a registered pharmacist is physically or mentally incapacitated, or a person other than a registered pharmacist is guilty of an offence under the Act. Sub-section 40(2) gives Board inspectors the power to enter registered and unregistered premises if he or she reasonably suspects that pharmacy is being practised on those premises.

Regulations 14 to 18 specify prescribed requirements for premises to be registered as suitable. These include the physical characteristics, the display of contact details for a pharmacist with access to the premises, and reference works to be kept at the premises.

There are no requirements for pharmacy businesses to be registered, although this is blurred by the Act's requirement that eligible corporations be registered as pharmacists.

ASSESSMENT

The ability of the Act and Regulations to prescribe standards for pharmacy premises, and to give the Board rights of access and inspection to those premises, are reasonable in protecting the public interest, and are consistent with the Review's recommendation.

The requirement that the premises be registered as a precondition to their operation as pharmacies, however, is not consistent with the Review's recommendation and should be **removed**.

The Review sees the Act's requirement for eligible companies to register as pharmacists as being distinct from this recommendation. They relate to defining a corporate entity that may practise pharmacy, and only indirectly to an individual registered pharmacist. Should the Act or Regulations have required individual registered pharmacists to disclose and register their relevant business interests, this would have been inconsistent with the Review's recommendation.

2. REGISTRATION OF PHARMACISTS

Part II of the Act related to the Pharmacy Board of South Australia as the responsible regulatory authority. The registration of pharmacists and related matters are mainly set out in Part III of the Act. Part IV deals with investigations and inquiries (including disciplinary matters) and Parts V and VI with appeals of decisions and offences under the Act and related matters. Part 2 and Schedule 1 of the Regulations deal with eligibility for registration, including acceptable qualifications.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

The Act

The Act sets out the role, functions and powers of the Board as the regulatory authority. Section 60 of the Act confers regulatory making powers on the Governor in relation to matters including pharmacy practice standards and record keeping, pharmacy premises, professional conduct, and advertising. The Governor's regulatory power relating to fees and charges under the Act may be delegated to the Board.

Constitution of the Board

The constitution of and administrative arrangements for the Board are set out in Part 2, Sections 5 to 14.

Section 6 provides that the Governor appoints all eight Board members. The prescribed membership a legal practitioner, a consumer representative, and nominees of the South Australian branches of the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and the Society of Hospital Pharmacists of Australia. Two other members are nominated by the head of the pharmacy school of the University of South Australia and the Friendly Societies Medical Association Incorporated, and the final member is a registered pharmacist "at large". The Minister appoints a registered pharmacist member as president of the Board under sub-section 6(2).

Section 11 gives the Board the power to establish committees and to co-opt persons to those committees who are not Board members. Section 14 requires the Board to appoint a registrar and gives it discretion to employ such other staff as are necessary for the administration of the Act.

Functions of the Board

Section 15 prescribes the functions of the Board as being:

- The registration and professional discipline of pharmacists;
- Overseeing pharmacy practice standards;
- Keeping under review the law relating to pharmacy and advising the Minister with respect to that law;
- Monitoring pharmacist pre-service and in-service training; and
- Exercising other functions under the Act.

ASSESSMENT

In general, the Act gives the Board very broad responsibilities with relatively little guidance as to how it discharges these. This arrangement places an obligation on the Board with to exercise, with the public's best interests in mind, a considerable degree of discretion in its administration and interpretation of the Act and Regulations.

The advisory role incorporated into the section 15 statement of functions also gives the Board considerable influence in both developing pharmacy policy and in setting as well as administering the rules governing the practice of pharmacy in South Australia.

The Act

Generally, the Act is consistent with principles set out in the Review's Recommendation 14. The distinction between the regulation and standard setting role of the executive government, and the implementation role of the Board is noted. Nevertheless, the Review notes that the powers of the Board to advise the Minister on matters pharmacy law gives the Board a certain degree of specific and direct involvement in the decision making process that goes beyond this separation of responsibilities.

Constitution of the Board

These provisions are consistent with the Review's recommendation.

Functions of the Board

These are consistent with the Review's recommendation, with the exception of paragraph 15(1)(c) of the Act relating to reviewing and advising on pharmacy-related law. This paragraph should be **removed**, as giving the Board a statutory role in executive decision making processes.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

Sub-section 24(1) of the Act requires that the Board registrar keep a registrar of pharmacists. Under section 20, the Board must register a person as a pharmacist if it is satisfied that the applicant is eligible for registration, that is, they have satisfied the prescribed education and training requirements and paid the prescribed registration fee. Section 20 allows for provisional registration, and section 21 enables the Board to impose conditions on a pharmacist's registration.

Practice protection

Section 26 of the Act provides that only persons registered as pharmacists (as discussed in Section 2 above) may practise pharmacy in the State. It also makes the practising of pharmacy by a non-registered person an offence. The Act does not make provision for the emergency dispensing of drugs and medicines by prescribers, including medical practitioners.

Title protection

Section 28 restricts certain titles to registered pharmacists, including companies registered as pharmacists. These titles include "pharmacist", "pharmaceutical chemist", "pharmaceutist" and "dispensing druggist".

Personal requirements for registration

Sub-section a natural person is eligible for registration as a pharmacist if he or she:

- Is 18 years old or over;
- Is a fit and proper person;
- Has prescribed qualifications and experience in pharmacy; and
- Fulfils all other requirements prescribed by the Regulations.

Regulation 5(c)(iii) provides that where an applicant's qualifications have been obtained in a non-English speaking country, the Board must be satisfied that he or she has a sufficient knowledge of English to practise pharmacy.

Applicants for registration are also required to complete an approved first aid course.

Professional requirements for registration

Regulation 5 sets out four sets of professional requirements for registration as a pharmacist:

- An Australian or New Zealand degree or diploma in pharmacy, plus up to one year's practical experience;
- Unconditional registration as a pharmacist in another State or Territory, or New Zealand; or
- A degree or diploma in pharmacy conferred by British and Irish institutions listed in Schedule 1 of the Regulations, unconditional British or Irish registration and at least four weeks supervised practice under an approved pharmacist (defined as a South Australian registered pharmacist or an unconditionally registered pharmacist of another State, Territory or New Zealand); and
- Certification by the Australian Pharmacy Examining Council (APEC) that a person has the necessary qualifications to practise in the State, plus completion of at least the APEC requirements for supervised practice.

In addition to academic and practical training requirements, applicants for registration are required by regulation 5 to satisfactorily have passed a forensic examination conducted by the Board on State law relating to the sale and supply of drugs and poisons.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendation.

Practice protection

These provisions are consistent with the Review's recommendation. It may, however, be desirable to **amend** them to ensure that there are no inadvertent obstacles to dispensing being carried out in limited circumstances (that is, where a registered pharmacist may not be readily accessible) by approved prescribers such as medical practitioners.

Title protection

These provisions are consistent with the Review's recommendation, although the retention of prohibitions on specific titles that are obsolete could be reconsidered.

Personal requirements for registration

The first aid course requirement and the minimum aged requirement are not consistent with the Review's recommendation, and should be **removed**.

Professional requirements for registration

These provisions are consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Section 22 provides for renewal of pharmacists' registration from 31 December to 31 December each year. Sub-section 22(3) provides that applications for renewals of registration must be delivered to the Board registrar not earlier than 1 October and not later than 30 November for the following registration period, but the Board can also decide whether to accept an application made outside this period.

Sub-section 22(4) requires renewal of registration to take place if the application follows these requirements and the prescribed fee is paid.

Particular provisions apply to pharmacists returning after a lapse of registration. Section 29 provides that a person who has not personally practised pharmacy for three or more years cannot himself or herself commence practising pharmacy without the Board's approval. Sub-section 29(2) enables the Board to require such pharmacists to undertake a refresher course or obtain specified qualifications and experience.

The Board also has the ability to impose conditional registration on a pharmacist under section 21 of the Act.

ASSESSMENT

These provisions are consistent with the Review's recommendations. While they fall short of mandatory demonstration of competence for renewing pharmacists, the ability to impose retraining and other requirements on pharmacists returning to personal practice go to the public's interest in ensuring the safe and competent practice of pharmacy.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Investigative and disciplinary procedures are codified in Sections 40 to 59 of the Act. The procedures are set out in some detail and cover pharmacy inspections, incapacity, procedures for inquiries, powers of the Board, costs, appeals and penalties.

Section 40 provides that an investigation may be initiated by the Board if it has reasonable cause to suspect that:

- There is proper cause for disciplinary action against a pharmacist;
- A registered pharmacist may be physically or mentally unfit to practise pharmacy; or
- A person other than a registered pharmacist has committed an offence against the Act.

In respect of the first two points, sub-section 44(1) provides that the Board may act on its own initiative or on receiving a complaint. Sub-section 45(6) defines proper cause for disciplinary action as being:

- Improperly obtained registration;
- Conviction or guilt of offence against the Act, an offence involving dishonesty or an offence punishable by imprisonment for one year or more; and/or
- Guilt of unprofessional conduct, which is not defined.

Section 45 of the Act sets out basic procedures for a disciplinary inquiry, including the giving of written notice to both the complainant and the person being complained about; the right of the person being complained about to have legal representation; and that the accused practitioner has a reasonable opportunity call or give evidence, to examine and cross-examine witnesses and to make submissions to the Board. Section 45 also enables the Board to determine its own inquiry procedures, and requires it to act “according to equity, good conscience and the substantial merits of the case” (sub-section 45(5)).

Sub-section 44(4) provides that the Board, if it is satisfied that there is proper cause for disciplinary action against a registered pharmacist, may impose one of a series of penalties ranging from reprimand to cancellation of registration.

Section 46 sets out the Board’s powers in relation to an inquiry, including powers of summons, swearing of witnesses and requiring answers from witnesses, and recording proceedings.

Section 49 gives right of appeal to the Supreme Court of South Australia against any decision or order of the Board made pursuant to the Act.

ASSESSMENT

These provisions are only broadly consistent with the Review’s recommendations in that they allow for separate investigative and hearing processes for disciplinary matters, provide for accused pharmacists’ rights of response, and include rights of external review of Board decisions.

The Review is concerned that what may constitute professional misconduct effectively is left to the Board’s discretion. While it is important that the public is protected from the unsafe and incompetent practice of pharmacy, it is also important that the powers to determine what may constitute professional misconduct are relatively codified and objective. The Review notes that other jurisdictions, notably Tasmania, have sought to refine similar provisions by setting out grounds for professional misconduct in greater detail.

It is also of some concern that the procedural requirements in the Act are bare bones provisions, and are not as sufficiently comprehensive and open for the public and accused

persons to be assured that complaints are handled consistently and fairly by the Board as an investigating and adjudicating body.

This, however, goes both ways. It is also important that the Board, its members and its staff know what is required of them in disciplinary and professional competence matters. Then the Board can act, and be seen to act, confidently, fairly and consistently in the interests of the persons most directly affected by a given matter, and in the interests of the South Australian community as a whole. This better protects the Board its members and its officers.

Although the Act dates back only to 1991, much work has been undertaken in other States in recent years to revise and overhaul legislation relating to complaints against health practitioners and dealing with disciplinary and professional competence matters openly, consistently and fairly. On balance, the Review believes that while the Act's existing provisions are broadly consistent with the principles of its recommendation, they should be **amended** to make them as fully consistent with these principles as possible, with reference to recent developments in other professions and jurisdictions.

TASMANIAN *PHARMACY ACT 1908*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The Long Title of the *Pharmacy Act 1908* (the Act), describes its objective as being “to establish a board of pharmacy in Tasmania, and to make provision for the registration of pharmaceutical chemists”.

The Act has three Parts and two Schedules. Since 31 December 1998 there have been no regulations under the Act, as the then current regulations lapsed pending the replacement of the present Act with new legislation. The Review notes that the administration of the profession has been carried on as if they were still in place.

The Tasmanian Government currently is developing a *Pharmacists Registration Bill* (the draft Bill), which has been released publicly for comment in exposure draft form. Where awareness of the provisions of the draft Bill has assisted the Review’s consideration of existing provisions, passing references may be made to relevant provisions of the draft Bill in the following sections.

The Review particularly commends the direction being taken in the draft Bill in terms of developing clear and detailed provisions about the operation and powers of the Pharmacy Board of Tasmania (the Board). It notes especially the draft Bill’s codifying of matters relating to complaints about the professional conduct of pharmacists, its setting out of clear and relevant disciplinary procedures and practices, and its clear setting out of the grounds on which regulations may be made under the Act.

The Review’s Terms of Reference exclude the consideration of Tasmanian legislation about the registration of pharmacists and related matters. The following comments on the present Act, therefore, relate only to the ownership of pharmacies against the framework of the Review’s recommendations in Chapter 2 of its Final Report.

2. OWNERSHIP OF PHARMACIES

Matters relating to pharmacy ownership generally are covered in Part III of the Act.

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

Section 30 of the Act provides that, other than registered pharmacists, partnerships composed entirely of registered pharmacists, and recognised friendly societies, no natural person or body corporate may carry on a pharmaceutical business (as owner or otherwise). It also provides that such excluded persons or bodies corporate cannot hold an interest in a pharmacy or the business carried on in a pharmacy.

Sub-section 30(3) provides that a pharmacist whose registration is suspended may retain an interest in a pharmacy or pharmacies during that suspension, if the Board makes an order to that effect under sub-section 17A(8C).

Paragraph 29(1)(d) makes it an offence for a person other than a registered pharmacist to carry on business as a pharmacist or to open a shop or place of business for pharmacy practice.

ASSESSMENT

These provisions are consistent with the Review's recommendation.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act has no express residential requirements for pharmacy ownership. Section 30A requires, however, that a pharmacy must be owned by a registered pharmacist, and section 2 of the Act defines a "registered pharmaceutical chemist" as someone who has a Tasmanian certificate of registration. Therefore, a pharmacist with an interest in a Tasmanian pharmacy must be registered in Tasmania.

ASSESSMENT

This provision is consistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Section 30 of the Act makes it an offence for a natural person or body corporate to carry on a pharmacy business unless the person or body corporate is:

- A registered pharmacist (ie as a sole trader);
- A partnership in which all the partners are pharmacists; or
- A recognised friendly society.

ASSESSMENT

The Review notes that the draft Bill would modify these provisions to allow for individual pharmacist proprietors and bodies corporate of whom each member is a registered pharmacist, and the supervision of the pharmacy practice and business is vested in a registered pharmacist. This broader wording would make possible different corporate structures, including incorporated companies, provided all the shareholders are registered pharmacists.

The present provisions are consistent with the Review's recommendation, and the draft Bills provisions would effectively incorporate the Reviews recommendations on bodies corporate.

NUMBERS OF PHARMACIES OWNED BY A PHARMACIST (RECOMMENDATION 4) AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST

DESCRIPTION

Section 30A of the Act provides that no registered pharmacist shall at any one time either carry on a pharmacy business, or have a direct or indirect interest, in any more than two “ordinary” pharmacies. Section 2 defines an ordinary pharmacy as a pharmacy other than an after hours pharmacy.

After-hours pharmacies are treated differently. Section 2 of the Act requires an after hours pharmacy to be carried on by a partnership consisting of at least five registered pharmacists. Sub-section 30A(2) allows a pharmacist to carry on business or to hold an interest in two after-hours pharmacies, over and above the limitation on owning ordinary pharmacies.

Pharmacy holdings inconsistent with the present rules, but in place when they commenced, are grandparented by sub-section 30(3), until such time as the person gives up their interest in the affected pharmacies, or the pharmacy relocates. The Review understands that this provision is now all but redundant.

Section 31 provides that a pharmacist must ensure that a pharmacy must be supervised by either that pharmacist or another registered pharmacist, or to permit anyone other than a registered pharmacist to vend medicines, or to compound and dispense prescriptions.

ASSESSMENT

The Review is unsure about the necessity for a distinction between ownership privileges for ordinary and after hours pharmacies. It notes, however, that the distinction is expected to disappear in the new legislation, although the present Act’s limitation of holdings to two pharmacies is expected to continue.

In terms of the numerical requirement, however, the provisions are not consistent with the Review’s recommendation, and should be **removed and not replaced** in the new legislation.

The provisions requiring personal pharmacist supervision of a pharmacy are consistent with the Review’s recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

Sub-section 30(2) permits a pharmacy business to be carried on by a friendly society that is recognised by the *Friendly Societies (Tasmania) Code*. Sub-section 30(1) prohibits incorporated and unincorporated associations from owning pharmacies. There are no grandparented provisions in Tasmania.

The Act appears to be worded so that there is no limitation on the number of pharmacies that may be owned by a friendly society, but the Review understands that in practice the two groups operating pharmacies under the Act have two pharmacies each.

ASSESSMENT

The Review understands that friendly societies legislation in Tasmania has been amended to reflect the coverage of friendly societies under the Corporations Law. These provisions are taken as being consistent with the Review's recommendation.

The Review understands that a body similar to a friendly society but a non-pharmacist owned body corporate, the Queenstown Medical Union, was prescribed as eligible to operate pharmacies under the lapsed regulations to the Act. Given that the Union is not a friendly society, its continued operation appears to be inconsistent with the provision for role. If so, its continued pharmacy role would need special provision.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

In dealing with permitted ownership structures, sub-section 30(1) of the Act also provides that no ineligible person or association "shall carry on a pharmaceutical business (whether as owner or otherwise) or hold an interest in a pharmacy or in the business carried on in the pharmacy". Paragraph 29(1)(d) makes it an offence for a person other than a registered pharmacist to carry on the business of a pharmacist.

Section 30D provides that bills of sale, loan documents, leasehold agreements cannot contain terms that:

- Require goods or services necessary for the carrying on the pharmacy business to be bought or otherwise obtained from a specified person;
- Give any party to the agreement, other than the registered pharmacist the power to control the conduct of the business, or access to the accounts of that business; and
- Allow that any party to the instrument receives any consideration from the business that varies according to the business's profits or takings.

ASSESSMENT

The Act does not offer a definition of what constitutes a direct or indirect interest in a pharmacy.

Contextual reading of the relevant sections, however, suggests that these terms that "direct interest" appears to relate to a shareholding in a pharmacy owning entity. "Indirect interest" appears to relate to a non-owning party's ability to influence the direction of a pharmacy business, to derive a share of the business's revenue other than by a contract of supply or service, or both. This would seem to rule out the acceptability of a franchise agreement based on share of turnover or profit.

On this reading, it appears that the sub-section 30(1) reference to "business carried on in a pharmacy" would appear to apply against arrangements such as a full franchise, where a franchise agreement may expect conformity with group practice in terms of matters such as layout, or confer on the franchisor elements of stock management or purchasing. It would not prohibit banner group arrangements where services are provided for a flat fee, and nominally at least participating pharmacist can take or leave elements of the banner package as they see fit.

The Review believes that existing provisions are too vague and go further than is necessary to protect the principle of pharmacist ownership and control of pharmacies and pharmacy businesses. It suggests that the draft bill could **replace** existing pecuniary interest provisions by including:

- A clear statement that no ineligible person or corporation should have a proprietary interest (ie a direct shareholding or directorship) in a pharmacy business;
- If necessary, a definition of proprietary interest to simplify and make consistent the interpretation and administration of relevant provisions of the Act; and
- A provision making it an offence under the Act for any person or corporation to apply improper or inappropriate influence on the professional conduct of a pharmacist, and making the a pharmacist acting under such influence a ground for professional misconduct.

The new Act should also ensure that section 30D of the present Act is **removed**, and not replaced with comparable provisions.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

Pharmacy premises

Section 30B of the Act provides that a pharmacy business can only be carried out in a currently registered pharmacy. Sub-section 30B(3) provides that the Board may register or refuse to register a pharmacy, or it may withhold registration until an applicant complies with such conditions as may be prescribed. Decisions by the Board may be appealed to a magistrate.

Section 30C provides that a pharmacy business can only be carried on in a pharmacy that complies with “the prescribed requirements”, which may include requirements in relation to the pharmacy’s construction, ventilation, lighting, cleanliness, sanitation and fittings.

Section 45 gives inspectors appointed by the Board powers, for the purposes of compliance with the Act, to enter and inspect any premises in an inspector has reasonable grounds for believing that a pharmacy practice or business is being carried on.

Regulations may be made by the Governor under sub-section 38(5) of the Act in respect of the registration of pharmacies and the requirements with which registered pharmacies are to comply. Currently no such regulations are in force.

Pharmacy businesses

There is no requirement under the Act to register a pharmacy business.

ASSESSMENT

The pharmacy provisions of the Act are broad, vague and at the present time unsupported by regulations setting out precisely what conditions or specifications a registered pharmacy must satisfy. While it is understood that the reason for this situation is that regulations lapsed

pending imminent passage of a new Act, the Review is concerned that a prolonged gap in coverage may leave the Board enforcing standards that no longer have statutory force. Regulations of the nature specified in the Act would be justifiable restrictions on competition in interests of public safety, as they would contribute to the safe and competent practice of pharmacy.

The requirement for the registration of pharmacies is, however, inconsistent with the Review's recommendation, and should be **removed**.

The Review notes that, if enacted, the draft Bill would discontinue the present requirement for pharmacies to be registered. The draft Bill does, however, allow the Governor to make regulations in relation to the prescribed requirements for pharmacy premises. It also would retain powers of inspection for the Board, and enable the Board to make by-laws consistent with the new legislation, including in relation to pharmacy premises.

AUSTRALIAN CAPITAL TERRITORY *PHARMACY ACT 1931*

ASSESSMENT AGAINST THE REVIEWS' RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1931* (the Act) has six Parts. There are no Regulations. The main provisions of the Act are the qualifications and registration of pharmacists and the conduct of business by pharmacists. In addition, and the constitution of the Pharmacy Board (the Board) is set out at Section 2 and specifies that the Board is charged with the general administration of pharmacy in the Territory.

2. OWNERSHIP OF PHARMACIES

OWNERSHIP OF PHARMACIES BY PHARMACISTS (RECOMMENDATION 1)

DESCRIPTION

The Act has no express requirement on the ownership of pharmacies. Sub-section 2(4) of the Act defines people who practice pharmacy as those who do so personally on their own account, or as a member of a firm, or those who employ pharmacists. The last provision appears to imply that non-pharmacists, including non-pharmacist companies, can own pharmacies and that they are subject to the Act in relation to the practice of pharmacy.

There is a requirement in sub-section 45(1) for owners of pharmacy business to display the name of the pharmacist in charge at the premises. Sub-section 45(2) contains the penalties that apply to companies and in other cases for contravention of sub-section (1).

ASSESSMENT

The Act appears to make a distinction between the ownership of businesses and the practice or conduct of the business of pharmacy. This view is supported by the provision in Section 45 for the separate concept of a pharmacist in charge as distinct from the owner of a business.

The Review understands that legal opinion obtained by the Board regarding these provisions indicates that there could be some doubt about the ability of non-pharmacists to own a pharmacy business. This advice argues that although a company can own a pharmacy, it cannot be registered as a pharmacist under Section 9 as a company could not meet the requirements of passing an examination and undertaking practical experience. Also, it appears that there would be difficulties in meeting the requirements of the Territories *Drugs of Dependence Act 1989* by a corporate entity or a pharmacy controlled by non-pharmacists. Owning or controlling certain prohibited substances is an offence under this Act, although pharmacists are exempted from these provisions.

On balance, the Review believes that the provisions on the Act cannot be held to rule out the ownership of pharmacies by persons other than pharmacists. If that is so, the current provisions are not wholly consistent with the Review's recommendation but, because they fall *within* and not *outside* the scope of the Review's conclusion on the boundaries of

justifiable regulation of who owns pharmacies¹⁶, any adjustments to current statutory requirements are a matter for the Territory.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

There are no residential requirements for ownership or registration as a pharmacist under the Act. Section 21 lists the details that are to be included in the Register of Pharmacists and includes the person's place of residence, whether within or outside the Territory.

ASSESSMENT

As the Act is silent on these points, it is not inconsistent with the Review's recommendations.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

There are no provisions in the Act relating to ownership structures. Section 43 of the Act authorises the administration of the estate of deceased pharmacists for six months, or more if the Board agrees, provided that the practice of pharmacy in the business is carried on by a registered pharmacist.

ASSESSMENT

The Act does not preclude or prohibit any ownership structures for, or shareholding arrangements in, pharmacy businesses. Generally, this is consistent with the Review's recommendation, but any implied ability for persons and corporations who are not registered pharmacists to be shareholders in a for-profit pharmacy business would be inconsistent with the Review's recommendation.

NUMBER OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

The Act contains no references to pharmacy ownership or the numbers of pharmacies that may be owned by any person, persons or entities.

Paragraph 48(c) of the Act provides that a pharmacist shall not carry on business except under the supervision of that pharmacist or another registered pharmacist.

ASSESSMENT

The Act currently is interpreted as having no limitation on the number of pharmacies that a pharmacist may own. This is consistent with the Review's recommendations.

The pharmacist supervision provisions are consistent with the Review's recommendation.

¹⁶ See also Chapter 1 of Part A of this Report.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATION 5)

DESCRIPTION

The Act contains no references to friendly societies or other ownership structures or arrangements and therefore contains no grandparenting provisions or other exemptions.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

There are no provisions in the Act concerning pecuniary interest.

ASSESSMENT

Unless the Act was amended to clarify its coverage of pharmacy ownership, pecuniary interest provisions are not required. Should such amendments be made, however, they could include:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making the acting of a pharmacist under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The Act has no provisions relating to the registration of pharmacy premises or businesses, although a number of sections provide for the setting and enforcement of pharmacy practice and dispensary standards, and for reasonable inspection of premises.

ASSESSMENT

The Act is consistent with the Review's recommendations.

3. REGISTRATION OF PHARMACISTS

Part 3 of the Act deals with pharmacist registration, and part 4 is concerned with the conduct of pharmacy business, including provisions for the cancellation of registration. Essentially, the two parts provide the Board with the authority to register pharmacists, limit the practice of pharmacy to registered pharmacists, and to determine the professional and personal requirements for registration.

The latter power includes an ability to cancel or suspend registration if a person has engaged in any improper or unethical behaviour, or is not competent to practise pharmacy. The Board also has a discretionary power to impose conditions on registration at Section 22 of the Act. These conditions can include the duration of registration, limitations on practice and conditions relating to any other matters the Board considers appropriate.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

Constitution of the Board

The constitution of and administrative arrangements for the Board are set out in Part 2, Sections 5 to 7. The Board consists of a Chairperson, three other members, all of whom are registered pharmacists and appointed in accordance with the *Health Professions Boards (Procedures) Act 1981* and three who are elected in accordance with the *Health Professions Boards (Elections) Act 1980*, which requires that all candidates be registered pharmacists. The Act is silent in relation to all other aspects of the administration and conduct of the Board, including disciplinary procedures.

Functions of the Board

The Board has a broad role outlined at Section 5, which is the “general administration” of the Act. In practice, the Act requires that the Board and has discretion in a number of areas regarding registration. For example, Section 14 permits the Board to refuse registration to persons convicted of an offence that renders them “unfit in the public interest to practice”. There are also a number of specific powers and functions that the Board is required to perform. These mostly relate to the actual registration and re-registration of pharmacists and generally confine the role of the Board to registration and the practice of pharmacy.

Staffing

There are no provisions relating to staffing apart from Section 7, which provides the ability to create and maintain one or more offices which have duties including the performance of the function of an inspector.

ASSESSMENT

Constitution of the Board

The lack of wider community and legal practitioner representation in Board membership, and the fact that half its members are elected, are inconsistent with the Review’s recommendations, and the existing provisions should be **amended**.

Functions of the Board

Current provisions regarding the Board and its operation are not consistent with the Review’s recommendations and the regulatory machinery should be **revised** to make the provisions more consistent with the principles outlined in Recommendation 14.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Pharmacy register

The registration of pharmacists is dealt with in Part 3 of the Act. The Board is required to keep a Register of Pharmacists in accordance with Section 23, whilst the details to be included in the Register are listed in Section 24. Notification of changes of address, alterations to the Register and the publication of entries in the Register are included in Sections 32 to 34. Certificates of Registration are issued and authorised in Section 31.

Practice protection

Section 42 of the Act makes it an offence for persons other than registered pharmacists to carry on the business of a pharmacist. Section 49 allows dentists, medical practitioners and veterinary surgeons to dispense medicines without becoming registered pharmacists.

Title protection

Prohibition on the use of descriptions or titles by persons other than registered pharmacists in respect of the practice of pharmacy is also included in Section 42.

Personal requirements for registration

There are a number of personal requirements in the Act. These include, conviction of an offence, deregistration outside the Territory, competence and good character (sections 13-16). Additionally, Section 18 requires that application is to be made on the prescribed form and accompanied by the determined fee.

Professional requirements for registration

The qualifications required for registration are covered at Section 9. The requirements specify a tertiary course accredited by the Board, passing an examination conducted by or on behalf of the Board and practical experience or training in practising pharmacy for up to twelve months. There are mutual recognition discretionary provisions at Sections 10 and 11 respectively. The latter permits the board to grant registration for teaching or research positions for people who possess qualifications that the Board considers appropriate.

ASSESSMENT

Pharmacy register

These provisions are consistent with the Review's recommendations.

Practice protection

These provisions are consistent with the Review's recommendations.

Title protection

These provisions are consistent with the Review's recommendations.

Personal requirements for registration

Requirements excess to good character and English language proficiency are inconsistent with the Review recommendations and should be **removed**.

Professional requirements for registration

These provisions are consistent with the Review's recommendations.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

Re-registration

The only re-registration requirement is at Section 28 of the Act, which requires the payment of the determined fee by 31 October each year. There are no requirements to notify the Board of any periods of non-practice nor any other matter. This means that registration can be maintained unless it is cancelled by the Board in accordance with other provisions in the Act relating to registration. These are dealt with in the section on disciplinary processes below.

ASSESSMENT

These provisions are consistent with the Review's recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

The grounds for the cancellation or suspension of registration and the procedures to be followed by the Board are contained in Part 4 of the Act, Sections 35 to 53, which are concerned with the conduct of business as a pharmacist. The Board has both specific and broad powers to cancel registration. These range from withdrawal of the pharmaceutical qualification to habitual drunkenness and improper conduct and incompetence.

The Board can also caution, reprimand and impose fines on pharmacists. The cancellation or suspension of registration can only be imposed following an inquiry, which is required in accordance with Section 41. This Section also applies in cases where pharmacists are cautioned, reprimanded, ordered to undergo medical or psychiatric treatment or counselling or have conditions imposed on their practice.

There are no requirements for the conduct of inquiries and the publication of their findings is at the discretion of the Board (section 44). There are no provisions for the public to make complaints and for them to be investigated, nor is it specified how an inquiry should be instigated or conducted. Appeal rights to the Administrative Appeals Tribunal set out at Section 54, with written notification of Board decisions specified at section 55.

ASSESSMENT

The Act does not provide a comprehensive framework for pharmacist disciplinary system works and how it protects the public interest. The disciplinary provisions of the Act are therefore inconsistent with the Review's recommendation and should be **amended**.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings including dealing with conflicts of interest for Board members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties; and
- Dissemination of disciplinary decisions.

At minimum, any guidelines or standing orders used by the Board to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. These should cover all stages of a complaints process, including receiving and investigating complaints.

NORTHERN TERRITORY *PHARMACY ACT 1996*

ASSESSMENT AGAINST THE REVIEW'S RECOMMENDATIONS

1. OVERVIEW

The *Pharmacy Act 1996* (the Act) has five Parts. There are currently four Pharmacy Regulations.

The purpose of the Act is to register pharmacists and control the practice of pharmacy in the Northern Territory. The main provisions of the Act relate to the administration of the Pharmacy Board of the Northern Territory (the Board), registration requirements for, and the qualifications of, pharmacists, and the conducting of pharmacy businesses. The Regulations relate to meetings of the Board, details to be included in the Register of Pharmacists and the issue of certificates of registration.

By way of a general observation, pharmacy regulation in the Territory is notable for its relative lack of express regulation. While this promotes a professional practice environment, this in itself puts a particular pressure on the Board, which has to use its discretion and interpretative skills to administer the Act. The Act's relatively patchy coverage of key matters, such as pharmacy ownership and disciplinary and professional conduct matters, is noted.

It may be that it is timely for thorough revision of the Act. If this possibility is taken up by the Territory, the Review commends the principles of pharmacy legislation outlined in Recommendation 14 of this Report.

2. OWNERSHIP OF PHARMACIES

OWNERSHIP OF PHARMACIES (RECOMMENDATION 1)

It appears that the Act is concerned with who can practise the profession of pharmacy, rather than ownership of a pharmacy business as such. It is ambiguous in the way it approaches the matter of who can own a pharmacy. Some provisions imply that pharmacists can own pharmacies, and others simply provide that a pharmacy business must be under the management of a registered pharmacist.

Section 39 requires that only pharmacists can carry on business as a pharmacist and that dispensaries are to be constantly under the control of a pharmacist when open for business. Section 32 prohibits anyone other than a registered pharmacist from carrying on the business of a pharmacist. Also contained in Section 32 is a clause regarding the arrangements to be put in place when a pharmacist dies and specifies a transitional time limit of two months before which a registered pharmacist must conduct the business. These provisions could be read as implying only pharmacists are presumed to legally be capable of owning pharmacies.

On the other hand section 34, which relates to the management of a pharmacy, requires the "manager of a pharmacy" to display their name in front of the pharmacy, advise that Board of the pharmacy's location and that he or she is its manager, advise the Board of his or her continuous absence for more than three days, and "who will act as manager of the pharmacy during the absence".

Read in conjunction with sections 32 and 39, however, section 34 seems to imply very strongly that the Act's only interest is that a pharmacy is under the management of a professional pharmacist, and not necessarily that the manager is also the proprietor of the business.

The interpretation section of the Act provides no definition of terms such as "carry on the business of a pharmacist", as "manager of a pharmacy".

ASSESSMENT

The question whether the Act prohibits pharmacies to be owned by persons other than pharmacists is ambiguous at best.

Legal opinion obtained by the Pharmacy Board of the Northern Territory regarding these provisions indicates that it can be strongly argued that the Act implies that a pharmacy must be owned by a pharmacist¹⁷. The opinion canvassed the effects of sections 32 and 39, but notably overlooked the contrary implication of section 34.

Nevertheless, the contention that the Act has an implied assumption that only pharmacists may own pharmacies has some basis on a reading of the Act. Sub-section 32(2), containing transitional provisions for pharmacy businesses on the death of a pharmacist, could be taken to suggest that there was an intent shown by Parliament that only pharmacists can own pharmacies, otherwise this provision would not be needed. It could also be, however, that this sub-section relates only to those businesses that are owned and operated by pharmacists, and not to all pharmacy businesses in the Territory.

But when the pharmacy manager provisions of section 34 are taken into account, the Act can be construed as requiring simply that pharmacies are managed and supervised by registered pharmacists. That a pharmacist also owns a pharmacy is not essential to ensuring the supervision of pharmacy services by a registered pharmacist.

The phrase "carrying on the business of a pharmacist" as used in sub-section 32(1), is also ambiguous. Similar phrases in State *Pharmacy Acts* appear to relate to proprietorship, and in others to the day to day operation of a pharmacy and the provision of professional pharmacy services by pharmacists.

Without clear guidance from the Act itself, it may be that the only ways that this question is resolved definitively are by amendment to clarify the Territory's intentions, or by judicial interpretation if a non-pharmacist proprietor seeks to establish a pharmacy business in the Territory and is challenged by the Board as another party.

On balance, the Review believes that the provisions in the Act cannot be held to rule out the ownership of pharmacies by persons other than pharmacists. If that is so, the current provisions are not wholly consistent with the Review's recommendation but, because they fall *within* and not *outside* the scope of the Review's conclusion on the boundaries of justifiable regulation of who owns pharmacies¹⁸, any adjustments to current statutory requirements are a matter for the Territory.

¹⁷ This legal advice was conveyed to the Review in a letter from the Board dated 16 December 1999.

¹⁸ See also Chapter 1 of Part A of this Report.

RESIDENTIAL REQUIREMENTS FOR OWNERSHIP (RECOMMENDATION 2)

DESCRIPTION

The Act is silent on both whether a pharmacist has to be resident in the Territory to own a pharmacy, and on whether a pharmacist must be registered in the Territory to own a pharmacy.

ASSESSMENT

As the Act is silent on these points, it is not inconsistent with the Review's recommendation.

OWNERSHIP STRUCTURES (RECOMMENDATION 3)

DESCRIPTION

Over and above its unclear provisions on whom may own pharmacies, the Act makes no comment about permitted ownership structures and arrangements for pharmacy businesses.

ASSESSMENT

Because of its silence, the Act does not preclude or prohibit any ownership structures for, or shareholding arrangements in, pharmacy businesses. Generally, this is consistent with the Review's recommendation, but any implied ability for persons and corporations who are not registered pharmacists to be shareholders in a for-profit pharmacy business is inconsistent with the Review's recommendation.

NUMBERED OF PHARMACIES OWNED BY A PHARMACIST AND PERSONAL SUPERVISION OF A PHARMACY BY A PHARMACIST (RECOMMENDATION 4)

DESCRIPTION

The Act is silent on how many pharmacies a pharmacist may own in the Territory, and in which he or she may have a pecuniary interest.

Paragraph 39(c) of the Act provides that a pharmacist shall not carry on business except under the supervision of that pharmacist or another registered pharmacist.

ASSESSMENT

The Act currently is interpreted as making no limitation on the number of pharmacies that a pharmacist may own. This is consistent with the Review's recommendation.

The pharmacist supervision requirement is consistent with the Review's recommendation.

PERMITTED EXCEPTIONS TO PHARMACIST OWNERSHIP (RECOMMENDATIONS 5)

DESCRIPTION

Further to its ambiguity on who may own pharmacies, and the permissible ownership structures for those pharmacies, the Act is silent on who besides registered pharmacists may be the proprietors of a pharmacy. There are no references to friendly societies or any other potential non-pharmacist proprietors in, apart from Section 36 that prohibits persons other than registered pharmacists from holding appointments as pharmacists to a number of agencies, including friendly societies.

ASSESSMENT

In light of the Review's interpretation of other provisions of the Act as not precluding non-pharmacist owned pharmacies, it follows that friendly societies, and non-pharmacist individuals and companies, are not prevented from owning pharmacies in the Territory as the legislation stands.

In practice, it is understood that all community pharmacies in the Territory are currently owned by pharmacists and the issue has not needed to be resolved.

The Act, therefore, is not in itself inconsistent with the Review's recommendation, in the sense that leaves unregulated matters considered by that recommendation.

PECUNIARY INTERESTS IN A PHARMACY BUSINESS (RECOMMENDATION 6)

DESCRIPTION

The Act is silent in this area. This implies that any natural person or body corporate may have lawful pecuniary interest in a pharmacy or pharmacy business.

ASSESSMENT

Unless the Act is amended to clarify its intentions on pharmacy ownership, pecuniary interest provisions are not required. If it is so amended, however, it could include:

- A clear statement that no ineligible person or corporation can have a proprietary interest in a pharmacy business;
- A definition of proprietary interest to simplify and make consistent the administration of these provisions. The working definition of proprietary interest in Chapter 1 of the Review's report may be of guidance in this regard; and
- A provision making it an offence under the Act for a person or corporation to apply improper and inappropriate interference on the professional conduct of a pharmacist, and making the acting of a pharmacist under such influence a ground for professional misconduct.

REGISTRATION OF PHARMACY PREMISES AND PHARMACY BUSINESSES (RECOMMENDATION 7)

DESCRIPTION

The Act has no provisions relating to the registration of pharmacies or pharmacy businesses.

Section 17, however, provides for persons authorised by the Chairman of the Board to enter and examine premises where any pharmacist is carrying on business. Regulation 3 requires the “Professional Address” of pharmacists to be included in a Register of Pharmacists but there is no definition of what constitutes such an address.

Section 34 requires the display of the name of the pharmacy manager. A description of a dispensary is included at Section 39(2), which defines one as a place within a shop where certain drugs or substances are stored. These drugs and substances are defined in other Acts.

ASSESSMENT

These provisions are consistent with the Review’s recommendation.

3. REGISTRATION OF PHARMACISTS

Part 2 of the Act deals with Board matters, Part 3 deals with the registration of pharmacists, whilst part 4 is concerned with the conduct of pharmacy businesses and professional practices, and includes provisions for the cancellation of registration. Essentially, the Act parts provide the Board with the authority to register pharmacists, to limit the practice of pharmacy to registered pharmacists, and to determine the professional and personal requirements for registration.

REGULATORY MACHINERY (RECOMMENDATIONS 14 AND 15)

DESCRIPTION

The constitution of, and administrative arrangements for, the Board are set out in Part 2, Sections 6 to 8A. The Board consists of a Chairman and five registered pharmacists. No members are elected, with the Chairman being the Chief Health Officer, or his or her nominee and five registered pharmacists appointed by the Minister. There are no requirements regarding potential conflict of interest in disciplinary and other matters before the Board.

The role of the Board is not actually codified in the Act. Specific functions are found throughout the Act, the principal ones being the registration of pharmacists (section 21), cancellation of registration, (section 29), and powers to undertake investigations (Sections 9 to 14).

ASSESSMENT

The full appointment of Board members is consistent with the Review’s recommendation.

On the whole, however, provisions regarding the Board and its operation are not consistent with the Review’s recommendation, and indeed with practice either adopted or being

considered for pharmacy regulatory authorities in other States and Territories. The regulatory machinery in the Act should be **amended**. Such amendments could include:

- A clear setting out of the Board's (or new body's) role, powers (including limitations on its discretion) and responsibilities in the Act and regulations; and
- Ensuring that regulations, by-laws and guidelines that may be proposed by the Board or new body are not effective until they are approved by the Administrator-in-Council as statutory instruments.

REGISTRATION OF PHARMACISTS (RECOMMENDATION 16)

DESCRIPTION

Initial Registration

The Board maintains a register of pharmacists, the requirements for which are set out in Section 18 and Sections 26 - 30.

Section 19 describes how a person is registered. The qualifications required for registration are at section 21, and require a candidate passing the examinations prescribed by the Board in any State or by overseas colleges or boards of pharmacy recognised by the Board. Mutual recognition of registration in other States and Territories is provided for in section 20. There is no fee for registration, but one is payable for the issue of a certificate of registration.

Practice Protection

Section 32 makes it an offence to for persons other than registered pharmacists to carry on business as a pharmacist. Retailers of patient or proprietary medicines, defined in section 32(2), are not deemed to be carrying on the business of a pharmacist. Similarly, medical practitioners and veterinary surgeons may dispense medicines and do not need to be registered pharmacists.

Title Protection

The use of certain descriptions or titles, and words of similar meaning, by persons other than registered pharmacists is included in Section 32the Act at section 32.

Personal requirements

Section 21 requires that they be of "good fame and character". Other than this, there are no other personal requirements for initial registration.

ASSESSMENT

Initial Registration

These requirements are consistent with the Review's recommendation.

Practice Protection

These requirements are consistent with the Review's recommendation.

Title Protection

These requirements are consistent with the Review's recommendation.

Personal requirements

These requirements are consistent with the Review's recommendation.

ONGOING PRACTICE (RECOMMENDATIONS 17 AND 18)

DESCRIPTION

The Act contains no re-registration requirements of any kind. This means that a pharmacist's registration continues unless and until it is cancelled by the Board in accordance with the Act. In section 29(1) of the Act grounds for cancellation are set out. These include situations where the original registration was obtained by fraud or misrepresentation, being found guilty of an offence, habitual drunkenness or improper conduct that the Board considers renders a person unfit to practise.

ASSESSMENT

These requirements are consistent with the Reviews recommendations.

DISCIPLINARY PROCESSES (RECOMMENDATION 19)

DESCRIPTION

Disciplinary procedures are codified in Part 2 of the Act, Sections 9-14. These provisions outline the powers of the Board and the procedures it is to adopt in gathering and assessing evidence. Section 29 lists the grounds for cancelling the registration of a pharmacist, whilst Section 30 requires that the Board conduct an inquiry prior to cancellation of registration.

Certificates of registration are to be returned to the Board for cancellation. The grounds for cancellation are outlined above. Persons who appear before the Board are entitled to representation and have the right to examine witnesses. The Board can summon people to give evidence and require them to provide a range of records in their custody or control.

There are no other guidelines for the conduct of inquiries or public notification or the right of the public to attend. Nor are there any appeal rights in the Act, other than a right of appeal against the board's refusal to register a pharmacist. There are no specific grounds or procedures for the public to make complaints to the Board.

ASSESSMENT

The Act does not provide detailed requirements for the making and investigation of complaints. In fact, it does not specify any grounds for the public to make complaints. Nor does it provide a comprehensive guide about how the disciplinary system actually works and how it protects the public interest.

This is not to say that complaints are not dealt with in a rigorous and professional manner by the Board. However, the disciplinary provisions of the Act are inconsistent with the Review's recommendation, and should be **amended**.

Areas to which attention could be given include:

- Who may make complaints, referral of matters by courts and other bodies, and the manner in which complaints and referrals are made;
- Specific grounds for complaint, including setting out in reasonable detail what may constitute professional misconduct;
- Investigating complaints;
- Conciliating complaints and dealing with matters short of a hearing;
- Dealing with complaints by way of formal and informal hearings, and procedures for those hearings including dealing with conflicts of interest for Board members and ensuring that persons investigating a complaint do not adjudicate on the matter;
- The setting of penalties, including appropriate periods of suspension and adequate financial penalties; and
- The dissemination of disciplinary decisions.

At minimum, any guidelines or standing orders used by the Board to investigate, hear and adjudicate on disciplinary matters should be statutory instruments. Regulation making power in relation to “the control of registered pharmacists and the practice of the profession” is already conferred on the Administrator by Section 48 of the Act.