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Final Report

Review of the Pharmacy Business Licence Application and Renewal Processes in Victoria

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Executive Summary

Introduction

The Victorian Pharmacy Authority ('VPA' or 'the Authority') is responsible for the administration of the *Pharmacy Regulation Act 2010* (the Act) which provides for the regulation of pharmacy businesses, pharmacy departments, and pharmacy depots.

The Act requires the owners of pharmacy businesses, pharmacy departments, and pharmacy depots to hold a licence and the premises of pharmacy businesses, pharmacy departments, and pharmacy depots to be registered.

Through this project, the Authority wished to examine if risks relating to eligibility to be granted a licence, and third party commercial arrangements, are adequately managed; and, if its current application of resources is proportional to the risks.

The Authority considered a thorough review of pharmacy business licence application and renewal processes was required to assess if the information acquired during these activities is adequate for determining whether applications met legislative requirements.

PharmConsult was engaged to provide independent specialist advice concerning these matters and undertake this project (the 'Project' or 'Review').

Objectives and approach

The objective of the Project was to review pharmacy business licence application and renewal processes to ensure that the information disclosure requisites are adequate for the Authority to determine applications in the contemporary pharmacy ownership environment.

The approach *PharmConsult* took to achieve the objectives was to:

- appraise the current licencing and renewal processes and documents relevant to these processes;
- conduct a series of stakeholder consultations regarding pharmacy business licence and renewal processes in two phases;
- summarise the findings and draw conclusions about the current pharmacy business licencing and renewal process from this consultation; and
- make recommendations for potential changes to the pharmacy business licencing and renewal processes.

Key Findings

First phase consultation

The key findings included:

- stakeholders had limited understanding of the Authority's functions under the Act but nonetheless, felt the VPA lacked resource or was limited in its reach for various reasons or was somewhat powerless;
- undue influence, as defined by the Act, is a concept poorly understood;
- in addition to conducting audits, stakeholders proposed various changes to the processes the Authority uses to review licence applications; and
- although application forms were considered fit for purpose in their current state, a number of suggestions were made in regard to additional information the Authority should collect to be able to make informed determinations about proprietary interest (particularly in relation to undeclared interests) and undue influence in relation to a pharmacy business.

Second phase consultation

Five scenarios, the first relating to the current application and renewal process and four developed from the findings of the phase one consultation relating to potential changes to the application process, were presented to stakeholders for comment.

The aim was to test the perceived impacts of these potential changes to the Authority's processes.

The key finding was that stakeholders preferred a blend of components of the scenarios as the most effective way to enable the VPA to fulfil its responsibilities under the Act.

Summary

There appears to be:

- limited understanding by pharmacists of the Act;
- perceptions that the VPA has neither the will nor the ability to take action in the face of (perceived) breaches of the Act; and

- perceptions that the registration of pharmacists protects public safety while the registration of pharmacy premises and licencing of pharmacy businesses adds little in the way of minimising harm to consumers.

PharmConsult believes these perceptions need to be addressed in concert with any change to the pharmacy business licencing application and renewal processes, and that any major changes to the VPA's processes should be communicated to all stakeholders at least 12 months prior to introduction.

Recommendations

PharmConsult considers the findings of the research support the recommendation of the following options for change which are aimed at improving the perception stakeholders possess about the ability of the VPA to fulfil its role under the Act.

Recommendation 1

A program of risk-based audits of pharmacy businesses should be introduced, and that the audit program:

1) in the first instance, be for a short term (e.g. three years) with a requirement to monitor, evaluate and report outcomes;
2) require accountant(s) preparing the most recent tax return for the pharmacy business to make a declaration that the distributions of funds from the pharmacy business comply with the Act; and
3) require legal counsel preparing changes to commercial arrangements in the preceding year declare that the business arrangement documents comply with the Act.

Recommendation 2

The pharmacy business licence application process should be modified in the following ways, requiring or using:

1) certification of compliance with the Act by the legal counsel preparing the pharmacy business' commercial agreements;
2) high-risk applications for pharmacy business licences receive greater scrutiny with an independent expert committee available to assess the degree of risk associated with applications, handle appeals in respect to risk determinations, and make binding decisions about the applicable licence fees;
3) the establishment of applicant identity using a 100-point check;
4) application forms more explicit in the description of penalties; and
5) application forms with improved declarations clarity, particularly utilising checklists with only dichotomous (yes or no) answers.
6) Where other professionals (e.g. lawyers and accountants) are required to make a declaration, these forms should also utilise checklists with only dichotomous (yes or no) answers.

Recommendation 3

The pharmacy licence renewal process should also be modified. The modified process would need renewal forms to be developed that:

1) require licensee declarations in relation to changes to the commercial or business arrangements of the pharmacy and use a checklist in respect to the declarations with only dichotomous (yes or no) answers;
2) contain explicit description of penalties; and
3) use a checklist with dichotomous (yes or no) answers where other professionals must make a declaration.

The modified process would use:

4) licensee declarations to risk-stratify renewal applications for a targeted audit program (see Recommendation 1); and
5) the application of a condition upon all renewed licences requiring that the VPA be notified of changes to a pharmacy business' commercial or business arrangements.

Recommendation 4

The Authority explore the experience, if any, of the other regulators' efforts to detect and deal with undeclared ownership.

1. Introduction

The Victorian Pharmacy Authority

The Victorian Pharmacy Authority is responsible for the administration of the *Pharmacy Regulation Act 2010* which provides for the regulation of pharmacy businesses, pharmacy departments, and pharmacy depots.

The Act requires the owners of pharmacy businesses, pharmacy departments, and pharmacy depots to hold a licence and the premises of pharmacy businesses, pharmacy departments, and pharmacy depots to be registered.

The VPA has the following functions:

a) to license a person to carry on a pharmacy business or a pharmacy department;
   i. to register the premises of a pharmacy business, pharmacy department or pharmacy depot;
   ii. to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots;
   iii. to advise the Minister on any matters relating to its functions;
   iv. to give to the Minister any information reasonably required by the Minister;
   v. to keep a public register; and
   vi. any other function conferred on the Authority by or under the Act or any other Act.

Risk management and public safety

In terms of public safety, the Authority has assessed the risks relating to the eligibility to be granted a licence, as defined in the Act, and facilities and management, as critical.

In terms of public safety, the Authority has assessed the risks relating to pharmacy businesses' commercial arrangements with third party service providers as moderate.

Through this project, the Authority wished to examine if risks relating to eligibility to be granted a licence, as defined in the Act, and third party commercial arrangements, are adequately managed; and, if its current application of resources is proportionate to the risks.

This project

The Authority considered a thorough review of pharmacy business licence application and renewal processes was required to assess if the information acquired during these activities is adequate for the Authority to determine if applications met legislative requirements.

PharmConsult was engaged to provide independent specialist advice concerning these matters and undertake this Review.

2. Objectives

The objective of the Project was to review pharmacy business licence application and renewal processes to ensure that the information disclosure requisites are adequate for the Authority to determine applications in the contemporary pharmacy ownership environment.

3. Methodology

To achieve the objectives of the Project, it was agreed *PharmConsult* would employ a qualitative research methodology for stakeholder consultation because of its flexibility, exploratory nature, and its relatively unstructured approach to gathering information.

It was agreed consultation with stakeholders would be phased and stakeholders would be selected in order to maximise the range of opinions on the matters being investigated.

Consultations with stakeholders were to be conducted as face-to-face interviews.

3.1. Project establishment

This stage involved:

a) a meeting between *PharmConsult* and a Project Reference Group created by the Authority, to ensure that there was a clear and shared understanding of:
   i. the Review;
   ii. the proposed methodology;
   iii. foreseeable project risks and potential solutions; and

b) to discuss or to confirm:
   i. the appointment of a Project Sponsor as the single point of contact for *PharmConsult* for this Project;
   ii. the frequency and type of communication and reporting throughout the Project;
   iii. any barriers that the Project may encounter and potential solutions to these;
   iv. the ability of, and timelines for the VPA to provide the information and data which *PharmConsult* required;
   v. the types of stakeholders to participate in the consultation process;
   vi. the format of reports; and
   vii. other information relevant to the Project.

3.2. Review of current licence application forms and processes

During this stage *PharmConsult*:

a) reviewed the relevant sections of the Act, namely:
   i. Section 5 regarding ownership of pharmacy businesses; and
   ii. Section 11 regarding undue influence;

b) reviewed information and correspondence provided by the VPA including:
   i. responses to questions in relation to ownership and undue influence, and
   ii. information provided by the VPA on approaches which other states take to ownership and influence issues;

c) reviewed licence application forms effective from January 2017 and current determination processes;

d) identified potential deficiencies in documentary evidence and information provided in regard to ownership and undue influence;

e) reviewed current surveillance processes including the VPA's available reference datasets from;
   vii. the Australian Health Practitioner Regulation Authority (AHPRA); and
   viii. the Australian Securities and Investments Commission (ASIC);

f) investigated requirements for additional documentary evidence and information; and

g) examined suggestions that the VPA received from stakeholders such as the Victorian Department of Health and Human Services and other materials received from the Pharmacy Guild of Australia, and other entities.

3.3. First phase stakeholder consultation

It was agreed seven stakeholder meetings would be conducted for this stage of the Project with the aim being to gain first-hand information on current attitudes and opinion associated with the pharmacy business licence application and renewal process in Victoria.

3.3.1. Discussion guide and consultation planning

During this stage *PharmConsult*:

a) developed a draft discussion guide for use during the first phase of consultation;

b) obtained feedback from the VPA on the draft discussion guide;

c) amended the discussion guide until agreement was reached on the content of the guide;

d) sought the Authority's endorsement of the final version of the Phase One Discussion Guide; and

e) contacted stakeholders to organise meetings.

3.3.2. Consultation

During this stage *PharmConsult*:

a) met with seven individual stakeholders or groups of stakeholders for depth interviews;

b) received stakeholder opinion using the agreed semi-structured interview format documented in the Phase One Discussion Guide; and

c) recorded and analysed stakeholder opinion including any issues raised which had relevance to the Project.

3.3.3. Preliminary feedback

After the early phase interviews were completed, *PharmConsult* met with the VPA and provided a verbal update of findings to that stage.

3.4. Mid-project meeting

During this stage *PharmConsult*:

a) presented the preliminary Draft Report to the Project Sponsor in advance of meeting with the Project Reference Group;

b) met with the Project Reference Group to discuss the preliminary findings;

c) considering compliance, resource, and regulatory burden perspectives, modelled the potential impacts of licence application and renewal process changes;

d) discussed the matters and issues on which opinion would be sought during the second phase of the consultation process; and

e) discussed and received feedback from the Project Reference Group on the structure and proposed content of the Draft Report.

3.5. Second phase consultation

During this stage *PharmConsult*:

a) developed a draft discussion guide which included a number of scenarios for potential changes to VPA process on which opinion would be sought during the second phase of the consultation process;

b) received feedback from the VPA on the draft discussion guide and the scenarios;

c) amended the discussion guide until agreement was reached on the content of the guide;

d) requested the VPA to sign off on the Phase Two Discussion Guide; and

e) contacted stakeholders to organise meetings.

At the completion of the second phase of consultation, *PharmConsult* provided verbal feedback to the VPA on the outcomes of the interviews.

3.6. Analysis and synthesis of findings

During this stage, *PharmConsult* analysed and interpreted the findings from the information review and each phase of consultation and provided advice in regard to its:

a) investigation of the requirements for and merits of obtaining and scrutinising additional documentary evidence and information during the licence application and renewal process; and

b) consideration of options for future processes including targeted and random surveillance audits.

3.7. Draft and Final Reports

During this stage *PharmConsult* consolidated the work of the previous stages into a Draft Report.

The Draft Report was presented to the Project Reference Group to enable:

a) discussion of the findings; and

b) the receipt of feedback from the Project Reference Group on the Draft Report;

Upon consideration of the feedback, *PharmConsult* amended the Draft Report as required, and prepared and presented this Final Report to the Project Sponsor.

4. The Victorian Pharmacy Authority

The Pharmacy Board of Victoria formerly regulated both pharmacists and pharmacy businesses in the jurisdiction until the *Health Practitioner Regulation National Law* came into effect on 1 July 2010 providing for a number of health professions, including pharmacy professionals, to be regulated, registered, and accredited nationally.

The regulation of pharmacy premises and businesses is not included in the Health Practitioner Regulation National Law and these matters remain the responsibility of pharmacy premises and business approval authorities in each jurisdiction.

The Victorian Pharmacy Authority is the successor in law to the Pharmacy Board of Victoria and is responsible for administration of the Pharmacy Regulation Act 2010 under which, pharmacy premises and businesses are regulated in the state of Victoria.

The Pharmacy Regulation Act 2010 (the Act) provides for the regulation of pharmacy businesses, pharmacy departments and pharmacy depots and requires the owners of pharmacy businesses, pharmacy departments and pharmacy depots to hold a licence and the premises of pharmacy businesses, pharmacy departments and pharmacy depots to be approved and registered.

4.1. Overview of the VPA

The Authority consists of six members nominated by the Minister for Health and appointed by the Governor in Council. Four members are registered pharmacists, one is a lawyer and one is a community member.

The Authority has the following functions:

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

b) to register the premises of a pharmacy business, pharmacy department or pharmacy depot;

c) to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots;

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

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

f) to keep a public register (of pharmacy businesses); and

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

Given the Authority's functions under the Act, the VPA has both a supportive role for pharmacy businesses by:

a) issuing Authority guidelines (the Guidelines); and

b) assisting pharmacists to comply with legislation and guidelines;

and a scrutinising and regulatory role when the VPA:

c) processes applications to register pharmacy premises and licence pharmacy businesses;

d) manages pharmacy business licencing;

e) conducts pharmacy business, pharmacy department and pharmacy depot inspections;

f) conducts investigations relating to the Act; and

g) convenes panel hearings.

4.1.1. Supporting pharmacy business

The VPA provides information for licensees and pharmacists practising in registered premises with the aim of assisting them in their professional practice and to comply with Act.

To this end, the VPA:

- endeavours to have at least one pharmacist present at the Authority offices on all working days to answer queries;
- publishes and distributes a monthly communique and a quarterly circular to highlight emergent matters to pharmacists and licensees;
- develops and issues the Guidelines which represent the current policies of the Authority and form the basis of the inspection program (see 4.1.2); and
- maintains its publications, the Guidelines, other application and notification forms and further information in a repository at the VPA website (www.pharmacy.vic.gov.au).

4.1.2. Scrutinising pharmacy business

The VPA categorises applications for pharmacy business licenses, registration of premises, and other approvals as low- and high-risk. Applications clearly

meeting all requirements of the Act and the Guidelines are deemed low-risk while those failing this standard are deemed high-risk.

Power to issue pharmacy business application approvals is delegated to authorised officers of the Authority when an application is low-risk. This delegation enables trading to commence at the pharmacy business, pharmacy department or pharmacy depot without delay while high-risk applications are referred to the next monthly meeting of Authority members for a decision minimising delays while providing greater oversight of the application.

A routine site visit program provides for each registered premises to be inspected at least every three years. During site visits, the assessment focuses on:

- security;
- workload;
- customer and patient privacy;
- equipment and fittings; and
- compliance with legislation, pharmacy practice standards, and guidelines.

After completion of a site visit, an inspection report is issued advising if any actions need to be taken in order to achieve compliance with legislation and guidelines. Where deficiencies are noted during a site visit, in most cases, the licensee or authorised pharmacist will be required to certify rectification.

The VPA also undertakes targeted inspections following a change of ownership, the completion of new or altered premises, or following an unsatisfactory inspection to ensure the certified rectification steps have been taken.

Inspections revealing serious deficiencies may result in the VPA conducting an investigation. Following an investigation the VPA has the option of:

- when an explanation including details of rectification has been provided and is complete, taking no further action;
- requesting the licensee(s) attend an Authority meeting to discuss the issues; or
- convening a panel hearing.

Panel hearings are reserved for matters involving serious failures of good pharmacy practice, alleged breaches of legislation and failures of security and hygiene. Deficiencies relating to storage or recording of Schedule 8 poisons are considered to present a serious risk to the public. In addition to routinely referring incidents relating to Schedule 8 poisons to the Drugs and Poisons Regulation Unit of the Victorian State Government Department of Health and Human Services, the VPA will invariably address alleged breaches by convening a panel hearing.

Panel hearings generally, may result in:

- the continuation of a licence or premises registration;
- a condition or conditions being placed on a licence or premises registration or both;
- a revocation of a licence to conduct a pharmacy business or a premises registration or both; or
- cautioning or reprimanding the licensee or registration holder.

4.2. The powers and responsibilities of the VPA

The Authority's guiding principle is to act in the public interest to deliver a safe pharmacy system to meet the community's needs.

The Authority prioritises its regulatory activities according to the most significant risks to the public whilst seeking to minimise the regulatory burden placed on licensees.

As with other health portfolio regulators, the VPA receives Statements of Expectations from the Victorian Minister for Health each year. In 2014-15, the VPA, along with a number of health portfolio regulators, participated in a performance audit carried out by the Victorian Auditor-General's Office, which resulted in enhancements to regulatory performance and risk-based regulation.

The Authority responds to developments in the profession and recognises the registration standards, guidelines, codes, and policies issued by the Pharmacy Board of Australia and has regard to the standards, codes, and guidelines issued by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia.

The Act grants the Authority the powers necessary to enable it to perform its functions. In carrying out its functions and exercising its powers, the VPA must:

- consult with the Minister and have regard to the Minister's advice;
- have regard for the need to control who may own and operate pharmacy businesses in Victoria; and
- have regard for the need to maintain standards relating to the licencing of pharmacists to carry on a pharmacy business.

Described in the Act are powers enabling the VPA to:

- refuse to grant a licence and to revoke licences and for the VPA to do so without notice to reduce or prevent a serious risk to public health and safety (e.g. where there has been a failure of good pharmacy practice at a registered premises);
- require a licensee to give the VPA any information or produce any documents relating to pharmacy business ownership noting it is an offence to refuse to do so or to mislead the VPA when doing so;
- during opening hours, enter the premises of any pharmacy and examine any room to inspect medicines, other goods, equipment, and documents, and to make copies of documents;
- investigate matters relating to a pharmacy licence or a registration without notification if the VPA believes there is evidence to do so; and
- convene a panel, which must follow procedural rules, to hear matters relating to an investigation.

4.3. Current VPA determination processes

4.3.1. Licence applications

Application for a licence to operate a pharmacy business begins with the completion of the relevant part of a six-part application form. The six parts relate to the type of applicant, whether a registered pharmacist, company of registered pharmacists, or a 'Friendly Society' (defined in the Act).

These forms provide information in regard an applicant's obligations under the Act and under the *Evidence (Miscellaneous Provisions) Act 1958* and in regard penalties that may be applied if either of these are breached.

From the information provided in each of the forms and from the VPA's connections to AHPRA, the Australian Securities and Investment Commission (ASIC), and Medicare, and from its own database of Victorian pharmacy businesses, the VPA:

a) reviews the pharmacist's registration status with the Pharmacy Board of Australia (PBA);

b) reviews the registration status of nominated pharmacist partners with the PBA;

c) for companies of pharmacists, reviews:

   i. company data submitted to ASIC to ensure there is consistency with the details provided in the members' applications;

   ii. company member and office holder PBA registration; and

   iii. the licence applications submitted by the other company members to ensure there is consistency with the details provided;

d) using its registered pharmacy business database, assesses the network of interests in pharmacy businesses to:

   i. ensure no pharmacist (neither applicant nor nominated partners nor company members) has a proprietary interest in more than five Victorian pharmacies;

e) assesses whether people other than pharmacists have beneficial interest in a pharmacy business requiring changes to be made to Trusts (for example) if this is the case; and

f) assesses the risk of the exertion of undue influence, as it is defined in the Act requiring changes to be made to commercial arrangements where undue influence could result from the described obligations.

Where the VPA has had to seek a formal legal opinion and address, through extensive negotiation with a licensee, matters relating to complex commercial arrangements and undue influence, this has cost in the order of $40,000 per application in recent years.

Currently the pharmacy licence renewal process involves only:

- the VPA issuing an invoice; and
- the licensee paying the invoice.

At all other times the VPA:

- continuously monitors the registration status of pharmacy owners;
- reviews information that becomes available from time to time; and
- may test the veracity of this information with other sources e.g. Medicare (approved pharmacy premises), AHPRA and ASIC.

The VPA maintains an ASIC alert subscription to monitor, on an ongoing basis, any changes to relevant pharmacy company structures. ASIC information and alerts provide detail of:

- company addresses and changes of address;
- names of company members and officeholders;
- changes to company members and officeholders;
- changes to company share structure; and
- deregistration of a company.

5. First phase stakeholder consultation

5.1. Overview of consultation

During the seven phase one interviews, 17 stakeholders provided opinion to the Review in face-to-face interviews.

Involved were the Victorian State Government Department of Health and Human Services (DHHS), Pharmaceutical Society of Australia (Victorian Branch), Pharmacy Guild of Australia (Victorian Branch), one friendly society and three organisations representing seven pharmacy banner groups. Of the 17 stakeholders participating in phase one consultations, 10 were pharmacists.

An unsolicited written submission was also received from an independent pharmacy owner.

5.2. Approach

In February and March 2017 *PharmConsult* conducted seven qualitative interviews with government, pharmacy business owners, pharmacy professional advocacy groups and pharmacy marketing groups known as banner groups.

The aim was to gain first-hand information on current attitudes and opinion associated with the pharmacy business licence application and renewal process in Victoria.

The face-to-face discussions were largely exploratory in approach and relied on a relatively unstructured, flexible approach to gather information. Nevertheless, the Phase One Discussion Guide which was used ensured all issues were covered in interviews. See Appendix 1 for detail of the Phase One Discussion Guide.

5.3. Findings

5.3.1. Perceptions of the VPA

Overview of responses

The stakeholders were asked about their knowledge of VPA functions and how the Authority's role differed from the role of the PBA. The majority of stakeholders broadly knew the functions of the VPA and the PBA. Some had a detailed knowledge of the VPA activities and personnel as they had frequently interacted with the Authority. Only a few were confused about VPA and PBA functions.

Approximately half of the stakeholders indicated they had regular dealings with the VPA. Those with regular contact included stakeholders from DHHS, and pharmacy business owners who submitted pharmacy business registration and licence applications and renewals. Expressing some distance from the day-to-day functions of the VPA, a few banner groups reserved opinion on the grounds of their unfamiliarity.

All who had contacted the VPA, however, were satisfied with their interactions and found the VPA responsive and informative.

In relation to pharmacy business ownership, stakeholders were more critical of the VPA with a few suggesting the Authority was unwilling to address lingering concerns that pharmacists had interest in more than five pharmacy businesses.

Expressing a strong feeling that information was withheld from the Authority or that the VPA was misled by the information submitted during licencing application and approval processes, professional advocacy group stakeholders and some banner groups expressed the opinion the VPA was failing to satisfactorily investigate matters they perceived to be breaches of the Act.

All stakeholders acknowledged they had no evidence of breaches of the Act with most suggesting they based their perception that breaches occurred on the claims they had heard, or on supposition from media reports, or on the size of some banner groups.

In the main, stakeholders held the opinion the VPA reviewed only proffered documentation and did little to investigate the detail expressing a concern the

VPA had limited resources at its disposal and suggesting the VPA was somewhat powerless to fully administer the Act.

The functions of the VPA and risk to the public

Despite their belief that cases of non-compliance with the Act existed in Victoria, all stakeholders expressed the opinion that the professional integrity of pharmacists was not in doubt and public safety was not threatened.

A minority of stakeholders, one professional advocacy group and one banner group, expressed the opinion that public safety and matters of pharmacy ownership were quite separate issues.

5.3.2. Compliance with the Pharmacy Act

Overview of responses

A general disquiet prevailed among the majority of stakeholders, due to their belief that non-compliance with the Act existed in Victoria.

Again, it is worth noting that despite this, no stakeholder was willing or able to provide an example of actual non-compliance with Act. A number of stakeholders made general statements to the effect that they presumed non-compliance existed but were unable to provide definitive evidence of this.

Eligibility

The VPA uses the application process to determine whether applicants are eligible to be licensed to carry on a pharmacy business. The majority of stakeholders thought the information collected in business application forms was appropriate and adequate. A few thought the breadth of information collected was the most appropriate of all the Australian authorities.

In the Act, eligibility refers to whether an applicant satisfies the requirements under section 5; that is, they are a registered pharmacist or an eligible company or friendly society. Only eligible persons may have a proprietary interest in a pharmacy business, and eligible persons must not own or have a proprietary interest in more than five separate pharmacy businesses.

A majority of stakeholders suggested that the reliance solely on this process had limitations in regard to assessing undeclared interests and that an audit process was required to ensure compliance with the Act.

While most stakeholders recognised the limited resources of the VPA and the exacting nature of investigating compliance issues, they believed this did not relieve the VPA of a need to investigate or audit certain pharmacy businesses as a responsibility under the Act.

Stakeholders expressed the concern that certain pharmacy business arrangements would not be identified during the current application process. Stakeholders speculated that:

- the information provided to the VPA was inaccurate in some cases as pharmacists had been heard boasting of owning more than five Victorian pharmacies;
- sham pharmacy business agreements were provided to the Authority only to gain a licence approval;
- financing arrangements existed enabling new pharmacists to enter into pharmacy business ownership but these effectively gave control or profit to a larger pharmacy group or pharmacist circumventing the five pharmacy ownership limit;
- some agreements or contractual arrangements were withheld from the VPA so the VPA could not fully assess proprietary interests; and
- undisclosed ownership arrangements for an ‘absentee’ owner existed in parallel with the arrangements disclosed to the VPA.

Undue influence

Undue influence, as defined in the Act, was poorly understood by most stakeholders. Some stakeholders thought it would be useful to provide specific examples of the types of commercial agreements that would be deemed as exerting undue influence in the context of carrying on a pharmacy business in Victoria and consequently void those agreements.

Stakeholders speculated or offered examples of hearsay about undue influence. These included:

- services or lease arrangements which provided a right to future ownership of the business;
- an absence of one large pharmacy group’s businesses in lists of pharmacies for sale;
- agreements requiring members of a banner group to use only the banner group’s endorsed tax accountants;
- management fees paid to non-financial institutions or third parties in lieu of funding guarantees for pharmacy businesses; and
- certain employee agreements.

Licence renewal

The majority of stakeholders viewed the invoice renewal process as inadequate as a means to ensure Victorian pharmacy businesses remained compliant with the Act. Currently, once an application has been approved, any changes to the information provided in the original application have not been additionally required by the VPA.

It was viewed as appropriate for the VPA to collect all documentary changes from the time of a pharmacy business' last statutory declaration. Nevertheless, most accepted the reality, that in many cases, businesses may have been operating for 10 to 20 years without their changed commercial arrangements ever having been seen or reviewed by the VPA.

Stakeholders regarded the possibility of application documentation that had been submitted but later changed without informing the VPA, represented a loophole that needed to be closed. It was suggested that this could be done through an audit process.

Audit

Many stakeholders thought that to administer the Act effectively, there was a need for the VPA to conduct investigative audits of the commercial arrangements of pharmacy businesses.

Many thought any additional costs of audit activities should be borne by all pharmacy businesses with a proportionate increase in registration fees.

It was suggested by one stakeholder that a showcase trial would demonstrate the VPA's willingness to take action under the Act in regard to non-compliance and encourage pharmacist 'whistle-blowers' to come forward with evidence. Some stakeholders held the view that showcase audits or investigations would make more pharmacists aware of their obligations under the Act.

5.3.3. Penalties

Overview of responses

Although stakeholders generally poorly understood the penalties which applied for non-compliance with the Act or for providing wrong or misleading information to the VPA, few thought fines were strong deterrents when advised of their nature.

Stakeholders knew that penalties could be applied but not the magnitude or nature of those penalties.

One stakeholder noted, making a wilful false statement in a statutory declaration was the jurisdiction of the Courts and doubted the VPA had the power to bring a matter of this nature before them.

Following prompting with the detail of the penalties, most stakeholders considered:

- the fines too financially insignificant to be a deterrent; but
- the prospect of imprisonment or revocation of a licence a high deterrent.

All stakeholders, however, agreed it was a good idea to publicise and include the penalties at appropriate points in the application forms.

Many stakeholders also expressed the opinion that:

- they doubted the VPA would ever cancel a pharmacy business licence;
- they had never heard of a case of a pharmacy business licence being revoked; and
- the VPA had little ability to enforce the Act.

Many thought the large pharmacy groups had the financial means to stay 'one-step ahead' of greater scrutiny. They also thought that the breaches the interviewees presumed existed had been in place for so long that the VPA had little opportunity to enforce the Act retrospectively.

5.3.4. Additional information required by the VPA to make determinations

Overview of responses

All but one stakeholder thought the current application forms fit for purpose.

The majority of stakeholders thought the information collected in pharmacy business application forms was appropriate and adequate. One stakeholder with experience from interactions with similar entities to the VPA in other jurisdictions thought the breadth of information collected by the VPA was the most appropriate of all the Australian pharmacy regulators.

Proposed application form changes

Stakeholders were asked what if any additional information should be collected by the VPA in the application form and what other procedures the Authority could employ to improve the business application and renewal process.

Individual responses in regard to application form changes included that new application forms should:

- be fact-based and should not require applicants to draw conclusions about whether the interest of a person, company or other entity constitutes a proprietary interest as defined in the Act;
- better inform applicants of their responsibilities under the Act;
- include a detailed list of the types of proprietary and beneficial interest arrangements that might arise when establishing a pharmacy business;
- require applicants to disclose the proportion of proprietary interest they hold in the business;
- identify the people or organisations that may exert influence over the pharmacy business;
- identify financial arrangements including loan or security agreements with non-institutional lenders;
- identify profit or revenue sharing arrangements including any agreement with a fee or payment linked to revenue, earnings or any other financial metric;
- identify agreements providing for Call options, first right of refusal or other rights to acquire shares in a pharmacy business in specified circumstances; and
- identify lease arrangements that exert undue influence or enable effective pharmacy businesses control.

Proposed process changes

Individual responses in regard to changes to the application process included suggestions that the VPA should:

- verify ownership details with additional authorities or relevant bodies such as Medicare, the Australian Tax Office and the Australian Community Pharmacy Authority;
- ensure all relevant business agreements lodged with the VPA are scrutinised by the VPA's legal counsel;
- require the applicant's legal counsel to certify that the pharmacy business' agreements comply with the Act; or
- require pharmacy franchises to declare and demonstrate compliance with the Australian Competition and Consumer Commission Franchise Code of Conduct.

5.3.5. Summary

a) In terms of the VPA's functions, stakeholders' understanding varied from excellent to limited.

b) In terms of dealings with the VPA, where stakeholders had interacted with the VPA, impressions of the VPA were very good.

c) In terms of capacity to administer the Act, general opinion was that the Authority lacked resources or was limited in its reach for various reasons or was somewhat powerless.

d) No stakeholder was willing or able to provide an example of actual non-compliance with Act but all largely believed it occurred.

e) Undue influence, as defined by the Act, was poorly understood by stakeholders.

f) Stakeholders also poorly understood the magnitude of penalties but all thought it a good idea to publicise the penalties at appropriate points in the application and renewal forms.

g) It was a strongly held opinion by most that the most important process change that could be implemented by the Authority would be for it to conduct pharmacy business audits, both targeted and random.

h) Although application forms were considered fit for purpose in their current state, a number of suggestions were made in regard to additional information the Authority should collect in relation to determinations about eligibility and detection of undeclared interests.

i) In addition to conducting audits, a few proposals were made concerning changing the processes the Authority uses to review licence applications.

j) Exploration of the value and utility of these proposals for changes to application forms and VPA processes occurred during a second phase of consultation.

6. Second phase stakeholder consultation

6.1. Overview

In phase two consultation, seven face-to-face interviews involving 14 stakeholders were conducted.

The DHHS, the Pharmaceutical Society of Australia (Victorian Branch) and the Pharmacy Guild of Australia (Victorian Branch) were again included in the sample along with pharmacy business owners. In total 11 pharmacists were included in the sample and seven of these owned Victorian pharmacy businesses.

6.2. Approach

In May and June 2017 *PharmConsult* conducted seven qualitative interviews in the second phase of consultations, to test five scenarios: the first relating to the current application and renewal process and four relating to potential changes to the application process that were developed from the findings of the phase one consultation process. The aim was to identify the perceived impacts of the proposed changes to the Authority's processes.

Stakeholders were invited to comment and elaborate upon each scenario when they thought it necessary and scored each scenario on a number of attributes.

The scores aimed to gauge the impact on the ability of the VPA to:

- perform its functions under the Act, identify undue influence, and determine eligibility (as defined in the Act) to own pharmacy businesses; and

to gauge the impact on:

- the time, effort, and finances of the VPA and of applicants; and
- public safety.

This information provided additional support to the findings commentary but was not collected for statistical analysis due to the small sample size. See Appendix 2 for detail of the Phase Two Discussion Guide.

6.2.1. Public safety and the VPA

Stakeholders rarely mentioned the concept of public safety during this phase of consultation and the scoring, in the format offered, forced some reflection on the subject. In *PharmConsult's* opinion, stakeholders failed to see a correlation between the activity of the VPA and matters of public safety.

Findings from the earlier phase of consultation revealed stakeholder disdain for the notion the VPA should prioritise public safety in its risk-based approach to administering the Act. During this second phase of consultation, one stakeholder implied the PBA had greater influence on public safety than the VPA and the Authority inadvertently threatened public safety by allowing pharmacists registered in the 'non-practising' category to be licensees. (The Act does not preclude pharmacists holding non-practising registration being licensed).

Recognising no pharmacy business customers nor consumer stakeholders were consulted during the Project, *PharmConsult* notes that a discord exists between Ministerial and other stakeholder expectations of the Authority, and that this is pertinent and remains unexplored.

6.3. Findings

6.3.1. Scenario A: The status quo

This scenario presented the status quo i.e. described the current processes used by the VPA to evaluate each application, and at licence renewal to ensure that stakeholders had a clear understanding of these.

Most stakeholders thought current processes were inadequate to enable the VPA to perform its functions under the Act in the current pharmacy business environment. The majority also thought the status quo should not be maintained.

Many believed the VPA seemed to be more focussed on 'bricks and mortar' with its premises inspections and less on unlawful interests in pharmacy businesses or upon undue influence in the pharmacy ownership environment. Moreover, some believed this was a reflection of the skill set of the Authority as pharmacists rather than other professionals such as lawyers or accountants.

6.3.2. Scenario B: New information gathered

This scenario presented the idea that the VPA could, to improve the process, collect additional information or declarations at the time of application and this could include a:

- certification of applicant identity using the familiar 100-point system;
- declaration that the ownership of the pharmacy and any commercial arrangements comply with the Act plus a declaration of intent to conduct the pharmacy business in accordance with the Act; and
- criminal history declaration, as being found guilty of an offence affecting suitability to hold a pharmacy licence constitutes grounds upon which VPA might revoke a licence.

In addition the application forms might also include:

- decision support regarding concepts of proprietary interest, and undue influence; and
- detail of the penalties associated with breaches of the Act or providing false or misleading information.

No one objected to the addition of a 100-point identity check and most thought it a logical and necessary inclusion. Some wondered why it had not been included previously.

Similarly, no one objected to the idea of a declaration of ownership and intent. However, there was concern that it required a pharmacist applicant to make judgements about matters of law.

A declaration of criminal history was thought by most to be a duplication of effort since APRHA collects this information at pharmacists' annual registration renewals.

Confirming the findings in the earlier consultation, the provision of decision support at relevant points in the application form and information on penalties was regarded as a positive move allowing applicants to be better informed.

Overall, stakeholders thought these changes:

- placed virtually no additional burden on applicants or the VPA; but
- offered little improvement in terms of public safety.

Additional comments

In addition, the following comments were made:

- criminal history checks could or should be extended to all persons receiving a distribution of funds from a pharmacy business including all members of related trusts; and
- penalties, in the main, were thought inadequate and inconsequential to the very large businesses associated with community pharmacy in Victoria.

6.3.3. Scenario C: Certified applications

This scenario presented the idea that in addition to current processes, applicants could be required to have their legal counsel certify or declare that the business and commercial agreements associated with the pharmacy comply with the Act.

At first presentation, this idea produced little interest from stakeholders but most returned to this concept during later discussion to describe it as a positive step forward.

Some thought the larger business groups could afford 'clever lawyers' to work out how to circumvent this step to their advantage and initially queried the usefulness of this move. However, as discussions progressed, often during the other scenarios, stakeholders made positive remarks about the impact of this proposed change.

Most thought this addition would have a positive impact on the ability of the VPA to perform its functions, identify undue influence, and detect unlawful arrangements. Additionally the change was expected to have a positive impact on public safety but potentially have a negative impact on applicants in terms of the additional burden.

Additional comments

In addition, the following comments were made:

- The scenario resulted in speculation about which party to the process the VPA could prosecute if the certification or declaration was false.
- It was suggested that if pro-forma commercial agreements were issued by the VPA, i.e. a one-for-all approach, it would relieve the VPA of the need to make exhaustive appraisals of pharmacy business documentation.
- The suggestion of certification of agreements by legal counsel spurred the idea that the accountant(s) for pharmacy businesses might or should

certify at renewal time, based on the most recent tax return that the disbursement of pharmacy business income complies with the Act.

6.3.4. Scenario D: Streamed applications

This scenario presented the idea that the VPA could escalate its application review depending on the complexity of the applicant's business arrangements. The scenario proposed a sliding scale for application fees according to the escalation process with a base fee consistent with the current amount and a maximum fee, nearly eight times as much, based on what it has recently cost the Authority in legal fees to obtain legal advice in order to make determinations on very complex pharmacy business arrangements.

This scenario was well accepted by stakeholders and the idea of a user-pays fee was welcomed as it was thought unfair for pharmacists with simple business arrangements to have to subsidise the review of others' more complex agreements. A risk-based and well-publicised set of criteria for escalation were considered essential to the successful implementation of a change of this nature.

This change was thought likely to have a positive impact on the ability of the Authority to detect undue influence.

Additional comments

In addition, the following comments were made:

- This arrangement would be strengthened by the addition of a certification made by the applicant's legal counsel that all contracts relevant to the application had been submitted to the Authority.
- The introduction of additional fees based on the VPA's decision as to the complexity of business arrangements would need an appeal process allowing an applicant a right of reply to the VPA's decision. It was suggested by a number of stakeholders that the appeal should be heard by an independent review committee with the power to make binding decisions. The committee could be comprised of a lawyer, forensic accountant and a community pharmacist experienced in pharmacy ownership and business arrangements.

6.3.5. Scenario E: Renewal changes and audit

Two renewal scenarios were presented for discussion. The first related to the renewal process and the second to the concept of risk-based audit.

At renewal

This scenario presented the idea that the VPA, instead of using a simple invoice and payment process at the licence renewal anniversary might implement a requirement for the submission of a renewal form that contained various declarations.

The nature of declarations required on this form might be to the effect that:

- the licensee intends to conduct the pharmacy business in accordance with the Act;
- the licensee's criminal history did not render them unsuitable to own a pharmacy business under the Act; and
- changes to the licenced pharmacy's commercial and business agreements had been submitted to the Authority.

As with Scenario B, all stakeholders thought this to be a positive step imposing minimal burden upon both the VPA and applicants. Some suggested a checklist involving dichotomous (yes or no) answers would simplify the implementation of this concept and the completion of the renewal form.

The experience of a similar body in another jurisdiction that had implemented a requirement for the submission of changed commercial agreements at renewal was relayed to stakeholders. The requirement caused significant additional resource burden for the pharmacy business authorising body. Interestingly, stakeholders thought a change of this nature may over-burden pharmacy business owners since exiting old franchise agreements and entering new agreements was met with few obstacles and although this is a common occurrence in community pharmacy, individual owners might have difficulty identifying relevant documents.

Audit

This scenario presented the idea that the VPA might use a risk-based approach to initiate audits to determine compliance with the Act. To be conducted for a three-year period with the results aggregated and potentially reported, the success of the audit program could be evaluated after which a decision could be made on its continuation. It was proposed this process change might result in a base renewal fee increase of approximately $100, depending on the nature of the eventual audit program.

All stakeholders commended the suggestion of audits and thought this process change would positively affect the ability of the VPA to perform its functions and enhance public safety.

Additional comments

In addition, the following comments were made:

- A singular renewal anniversary date for all pharmacy businesses was thought to be a barrier to the implementation of a change of this nature and it was suggested that renewals be staggered over a 12-month period instead.
- The ownership and control of medicine and other stock in a pharmacy business and the identity of the party or entity possessing the ultimate right to approve the sale of a pharmacy business represented two pieces of information stakeholders thought pertinent to the Authority's ability to determine undue influence.

6.3.6. Stakeholder's preferences

Stakeholders unanimously agreed a blend of features from all of the scenarios provided sound options for process change at the Authority.

7. Audit and assessment of VPA determination processes

7.1. Approach

PharmConsult undertook a review of VPA forms and processes to:

a) understand the operations of the VPA; and

b) identify potential deficiencies in documentary evidence and information required by the Authority in regard to undue influence and pharmacy business ownership.

PharmConsult reviewed documents including:

- the Pharmacy Regulation Act 2010 in relation to pharmacy business ownership, undue influence and penalties;
- the contents of pharmacy business licence application forms VP11, VP12 and VP13 in each of their states prior to and post-amendment in December 2016;
- other correspondence received in relation to or provided in response to questions regarding undue influence or pharmacy business ownership; and
- examined suggestions provided in writing to the VPA from various stakeholders in regard to pharmacy business application processes.

PharmConsult met with the Authority to gain an understanding of:

- the relative advantages and disadvantages of the systems for making determinations regarding pharmacy business licence applications in Victoria and the other Australian states; and
- the processes for determining eligibility, as defined in the Act, and for ongoing surveillance of compliance with the Act including the use of reference datasets from the Australian Health Practitioner Regulation Authority and the Australian Securities and Investment Commission.

These activities informed exploration of stakeholder opinion regarding the information the VPA requires carrying out its functions and the manner in which the Authority deals with matters of risk management and public safety in the following audit.

7.2. Assessment of determination processes

In auditing the VPA pharmacy business licence application and renewal forms and processes, *PharmConsult* considered:

a) the Pharmacy Regulation Act 2010;

b) the implications of change in terms of regulatory burden for applicants;

c) the implications of change in terms of the resource burden for the VPA;

d) change and implementation feasibility;

e) the benefits and advantages of the change; and

f) the disadvantages of change or the risks associated with the change including matters relating to public safety.

PharmConsult also took into consideration the Authority's desire to examine if risks relating to:

- eligibility to be granted a licence, as defined in the Act; and
- third party commercial arrangements;

were currently adequately managed; and,

- if its current application of resources was proportionate to these risks.

7.3. Summary

The VPA has administered the Act and has operated for over five years. This review of VPA processes, in light of the Authority's experience and emerging pharmacy ownership arrangements, is timely and warranted.

Stakeholder perceptions are that the complexity of pharmacy business models has increased and that the skill set of the Authority is now not matched to the task of making determinations about pharmacy business interests and undue influence.

There appears to be:

- limited understanding by pharmacists of the Act;
- perceptions that the VPA has neither the will, the ability, nor the resource to take action in the face of (perceived) breaches of the Act; and
- perceptions that the registration of pharmacists protects public safety while the registration and licencing of pharmacy businesses adds little in the way of minimising harm to consumers.

7.3.1. Pharmacy licence application and renewal processes

PharmConsult believes these perceptions need to be addressed in concert with any change to the pharmacy licencing application and renewal processes.

Any major changes to VPA's processes should be communicated to stakeholders, pharmacists (and lawyers and accountants if affected by the changes) at least 12 months prior to introduction.

The recommendations provided in Section 8 are based on *PharmConsult's* interpretation of the information and opinion received in two phases of consultation with a group of stakeholders not including consumers.

PharmConsult provides these recommendations having formed an opinion on the adequacy of current pharmacy licence application and renewal processes and the information gathered during these processes that are intended to enable the Authority to do its job effectively.

As no evidence of breaches of the Act on the grounds of ineligibility, unlawful interests or undue influence was provided to substantiate stakeholder's perceptions, *PharmConsult* could propose that the Authority make no change to pharmacy business licence application and renewal processes or forms.

Nevertheless, the perception among the pharmacists with whom *PharmConsult* met, was that there have been, and continue to be breaches of the Act in regard to eligibility and undeclared interests. *PharmConsult* found this belief both widespread and strongly held, within the sample of stakeholders with whom we spoke in both phases of consultation.

It is *PharmConsult's* belief that the issue of most concern to the stakeholders consulted, is that of undeclared ownership and a lack of resource application to this perceived risk.

Stakeholders understood that only registered pharmacists and eligible companies or friendly societies may have a proprietary interest in a pharmacy business, and those eligible persons must not own or have a proprietary interest in more than five separate pharmacy businesses. Stakeholders were direct in expressing their sentiment and perceptions in relation to this matter.

By contrast, undue influence was poorly understood and seemingly, of less importance to the pharmacists consulted. Little discussion of the assurance of public safety as an Authority role in administering the Act was entered into.

It is also *PharmConsult's* opinion that because of these widely held perceptions, possibly misconceptions in view of the lack of evidence of breaches; it is nevertheless both important and timely for the VPA to make changes to its processes.

A change in process is required to deal with the perception that the VPA:

- neither uses adequate process, nor
- has the resources to detect breaches of the Act in relation to unlawful interests;

and, because of;

- the increasing financial pressures under which many community pharmacies operate and the temptation that these pressures might exert on some pharmacists to be non-compliant;
- the increasing complexity of business and commercial arrangements; and
- an increasing use of these complex arrangements.

PharmConsult believes the changes proposed, if implemented will:

- restore the confidence of many in the pharmacy community in the VPA's ability to do its job effectively;
- increase the reluctance among pharmacists or non-pharmacist companies to consider deviation from the requirements of the Act;

- deal with the perceptions that the current VPA processes are inadequate when handling the complex business arrangements associated with franchises, banner groups or other collective activities; and
- provide an effective mechanism to deal, in the future, with the increasing number of complex business and commercial arrangements which the Authority is likely to assess.

7.3.2. Pharmacy business inspection program

Concerning the Authority's pharmacy inspection program, although no questions were asked nor comments made during stakeholder consultation, it is *PharmConsult*'s opinion inspections remain an important activity. The current application of resource to risks as documented by the Authority also received no stakeholder commentary, as what most concerned the stakeholders consulted was the risk of undeclared ownership of pharmacy businesses.

Ensuring that pharmacies are maintained in a way that is compliant with the Act and which gives confidence to the public that pharmacies are operated professionally and in a safe and proper manner (albeit a belief not tested with consumers) should be upheld. As such, *PharmConsult* proposes its recommendations for change be implemented without decreasing the number and frequency of inspections.

8. Recommendations

PharmConsult considers the findings of the research support the recommendation of the following options for change which are aimed at improving the perception stakeholders possess about the ability of the VPA to fulfil its role under the Act.

Recommendation 1

A program of risk-based audits of pharmacy businesses should be introduced, and that the audit program:

1) in the first instance, be for a short term (e.g. three years) with a requirement to monitor, evaluate and report outcomes;
2) require accountant(s) preparing the most recent tax return for the pharmacy business to make a declaration that the distributions of funds from the pharmacy business comply with the Act; and
3) require legal counsel preparing changes to commercial arrangements in the preceding year declare that the business arrangement documents comply with the Act.

Recommendation 2

The pharmacy business licence application process should be modified in the following ways, requiring or using:

1) certification of compliance with the Act by the legal counsel preparing the pharmacy business' commercial agreements;
2) high-risk applications for pharmacy business licences receive greater scrutiny with an independent expert committee available to assess the degree of risk associated with applications, handle appeals in respect to risk determinations, and make binding decisions about the applicable licence fees;
3) the establishment of applicant identity using a 100-point check;
4) application forms more explicit in the description of penalties; and
5) application forms with improved declarations clarity, particularly utilising checklists with only dichotomous (yes or no) answers.
6) Where other professionals (e.g. lawyers and accountants) are required to make a declaration, these forms should also utilise checklists with only dichotomous (yes or no) answers.

Recommendation 3

The pharmacy licence renewal process should also be modified. The modified process would need renewal forms to be developed that:

1) require licensee declarations in relation to changes to the commercial or business arrangements of the pharmacy and use a checklist in respect to the declarations with only dichotomous (yes or no) answers;
2) contain explicit description of penalties; and
3) use a checklist with dichotomous (yes or no) answers where other professionals must make a declaration.

The modified process would use:

4) licensee declarations to risk-stratify renewal applications for a targeted audit program (see Recommendation 1); and
5) the application of a condition upon all renewed licences requiring that the VPA be notified of changes to a pharmacy business' commercial or business arrangements.

Recommendation 4

The Authority explore the experience, if any, of the other regulators' efforts to detect and deal with undeclared ownership.

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Appendix 1: Phase One Discussion Guide

Note: This discussion guide represents a guide rather than a set of specific questions. The purpose of the guide is to provide a framework for discussion, and to provide a list of the issues to be covered. Accordingly, the exact wording of questions will vary, and the order in which topics are discussed may vary across interviews.

Introduction

Thank you for making the time to meet with me today.

Confidentiality: Remind respondent that responses are treated in confidence and data will be aggregated, that is, individual information will not be provided to the client.

Background

PharmConsult has been commissioned by the Victorian Pharmacy Authority (the VPA or the Authority) to review its pharmacy business licence application and renewal process to ensure the information required is adequate to enable the Authority to determine applications in the contemporary pharmacy ownership environment.

I wish to make it clear; this review is not about pharmacy deregulation or changes to the Pharmacy Regulation Act 2010 (the Act). This discussion will focus on the activities of the VPA and how it can most effectively perform its function as described in the Act with the limited resources it has at its disposal. As such, the quality of the information it collects from applicants is critical to the VPA meeting its responsibilities.

Scope:

In this interview, we will focus on the following topics:

Eligibility - this relates ultimately to the suitability of the applicant / licensee to obtain, possess, and distribute drugs. The Authority / VPA has procedures in place to ensure that applicants for a licence to carry on a pharmacy business are eligible and licence holders remain eligible pursuant to the requirements of the Act. This applies to a natural person (pharmacists), pharmacist corporations and friendly societies.

Undue influence - this relates primarily to the commercial and accounting arrangements of the licensee and whether these arrangements meet the requirements of the Act; i.e. they do not give a third party a proprietary interest in or the power to control the operation of the pharmacy business.

Penalties - this relates to penalties for providing false and misleading information to the Authority, and to offences under the Act for non-compliance with the ownership provisions.

At this stage, it is timely to remind you of the VPA functions as this has a strong bearing on the scope of our discussions today.

VPA functions:

The VPA has the following functions:

- to license a person to carry on a pharmacy business or a pharmacy department;
- to register the premises of a pharmacy business, pharmacy department or pharmacy depot;
- to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots;
- to keep a public register;
- to advise the Minister on any matters relating to its functions;
- to give to the Minister any information reasonably required by the Minister; and
- any other function conferred on the Authority by or under the Act or any other Act.

The Authority's functions include monitoring compliance and conducting investigations. Thus, the VPA has to ensure it is collecting adequate, appropriate, and accurate information on pharmacists and pharmacies in order to carry out its role.

The best way to start is to first find out a little about your background(s).

Respondent background

The purpose of this discussion is to contextualise the opinion and information provided by the respondent(s) in relationship to the environment in which they work or operate.

Can you please tell me (each in turn; if paired depth or mini focus group interview):

- Where you work, your current position and how many years you have worked in this position?
- Do you hold any professional (e.g. Pharmacy Guild of Australia) or business positions (banner groups) relevant to pharmacy which is in addition to your current work role?
- Have you applied to the VPA for an approval to carry on a pharmacy business; if so how many times have you done this, and when was the last time you did this?

The overall perception of VPA

The purpose of this discussion is to gather insights and information on the respondent's knowledge of the VPA and its role, responsibilities and activities.

Knowledge of VPA

Explore respondent's knowledge of VPA now and in the past.

What do you understand to be the functions of the VPA?

How does the VPA's role differ to the Pharmacy Board of Australia?

How satisfied are you with the interactions you have had with the VPA?

Opinion of VPA

Explore respondent's view as to how well the VPA is fulfilling its responsibilities.

Out of 10 (where 0 is a low score and 10 is a high score) how well do you think VPA is performing its functions

What are the reasons for this score?

Are there any areas in which the VPA could improve? Explore in detail, request specific examples.

What other comments would you like to make concerning the VPA?

Now keeping in mind the scope of this review, we need to discuss some issues with the first being your perception that pharmacy businesses comply with the Act.

Assessing Compliance

The aim of this discussion is to: determine if the respondent believes or perceives that breaches of the Act occur; examine perceived breaches in more detail; determine if changes to the application process could prevent these; and explore what these changes might be.

The overall function of the VPA is to reduce risk to public health and safety in relation to the way pharmacy businesses and pharmacy departments operate.

To do this the VPA currently

- collects information on pharmacy ownership eligibility;
- examines commercial relationships with other parties;
- inspects premises; and
- issues guidelines for pharmacy premises and ownership.

The VPA prioritises its activities according to an assessment of risk to public health and safety.

I would like to get your thoughts on situations where pharmacy businesses might not comply with the Act and how this could be prevented in the future.

Do you know of examples of pharmacists:

- Owning more than the permitted number of pharmacies?
- Owning businesses with unusual company structures?
- Engaging in other activities that might breach the Act?

In this discussion, explore how the VPA could close any loop holes or what if any activity the VPA could undertake to better ensure compliance.

Explore if there is other information that needs to be collected through the application process by showing respondents the questions asked on Authority forms VP11, VP12 or VP13.

Now let's have a look at the VPA activities in more detail (and use the example of natural person pharmacists, companies of pharmacists or friendly societies if mentioned).

Eligibility

The aim of this discussion is to ascertain if the respondent(s) feel the information collected by the VPA to determine the eligibility of applicants is sufficient.

Natural persons - VP11

Currently during the application process, the VPA collects the following information on VP11 (visual cue sheet provided to respondents) for natural person pharmacists seeking a license:

- name, registered address and registration number of applicant;
- address of the premises at which the pharmacy business is to be carried on;
- if relocating, the address of the existing business;
- status as sole proprietorship or partnership;
  - if applicable the names of the partners; and
  - a copy of the partnership agreement;
- other persons, registered companies or other entities (other than partners) having a proprietary interest in the pharmacy business;
  - if applicable, the names and registration numbers of those persons and the nature of this relationship;
- the applicant's proprietary interests in any other pharmacy business;
- the nature of any agreement with any company or person related to the carrying on of the pharmacy business (franchisor, licensor, marketing company, management company etc.); and
  - if applicable, a copy of those agreements;

and whether right to;

  - control the manner in which the pharmacy business is carried on;
  - access books or accounts; or
  - receive any consideration regarding profits or takings;

is conceded through those agreements.

VP 11 also requests information on whether a trust operates in association with the pharmacy business and if applicable, its name, a copy of all trust deeds and beneficiaries of each trust.

Is there other information which should be collected by VPA to gauge eligibility?

How should this be requested in an application form?

Companies of pharmacists - VP12

Currently during the application process, the VPA collects the following information on VP12 (visual cue sheet provided to respondents) for an applications relating to a company of pharmacists:

- in addition to the information gathered on VP 11;
- name of company and address of registered office;
- number of shares issued;
- name, address and pharmacy registration number of all directors;
- name, address and pharmacist registration number of all persons who hold or have a beneficial interest in shares and the number of shares each holds;
- a copy of the Current ASIC Company Extract;
- address of the premises at which pharmacy business is to be carried on; and
- the business or trading name and address of every other pharmacy business that the applicant company owns or in which it has a proprietary interest.

Is there other information that should be collected by VPA to gauge eligibility?

How should this be requested in an application form?

Friendly societies - VP13

Currently during the application process, the VPA collects the following information on VP13 (visual cue sheet provided to respondents) for an application relating to a friendly society:

- in addition to the information gathered on VP 11;
- name of company and address of registered office;
- name, registration number and address of all directors;
- evidence that immediately before 1 July 1999 the company was registered or incorporated as a friendly society under a Friendly Societies Code or Territory that was in force at that time;

- a copy of the ASIC Company Extract;
- a copy of the company's constitution or memorandum and articles;
- a statement or other evidence to demonstrate that:
- the company is not carrying on business for the dominant purpose of securing a profit or pecuniary gain for its members; and
- any object of intention of the company to provide a dividend to its shareholders or members is limited to and not dominant purpose of the company; and
- the property and income of the company is applied towards the objects of the company; and
- list of the business or trading name and address of every other pharmacy business that the applicant owns or in which it has a proprietary interest.

Is there other information that should be collected by VPA to gauge eligibility?

How should this be requested in an application form?

Licence Renewal process

The purpose of this discussion is to explore if a change to the renewal process may increase compliance with the Act.

Currently the VPA uses a simple invoice system with confirmation of a pharmacist's registration status when renewing a licence. The Pharmacy Council of NSW require pharmacy owners to submit an annual declaration of pecuniary interests in the hope that any changes are notified to the regulator.

What additional information might be collected by the VPA during licence renewal?

What information about changes in proprietary interest might be collected?

What information about changes in commercial arrangements (e.g. contracts, leases, franchise arrangements) might be collected?

What other information might be collected at renewal to assist the VPA to gauge ongoing eligibility?

How should this be requested in an application form?

Influence on pharmacy businesses

The aim of this discussion is to gain some insight into possible undue influences, which might affect pharmacy businesses, and possible actions that might be taken by the VPA to minimise the chances of this happening.

In the carrying on of a pharmacy business, circumstances, where a third party, such as a franchisor, service provider, a shopping centre owner, a marketing company or others might inappropriately influence the pharmacy business can arise.

What instances or examples do you know of where undue influence might have been exerted on a pharmacy business owner?

Given the discussion to date, how appropriate is the information collected on the forms in assisting the VPA determine if undue influence might be exerted on a pharmacy business owner?

How could the forms be modified or procedures at the VPA changed to better assist in determining if the potential for a pharmacy business to be placed under undue influence exists?

Penalties

The aim of this discussion is to identify if the penalties, which might be applied to applicants and licensees providing false or misleading information, or committing an offence under the Act, are sufficiently understood or serious enough to act as a deterrent.

At the end of each application, the applicant(s) make a statutory declaration to state that all information provided is correct.

Are you aware of the penalties for committing an offence under the Act?

If not prompt with:

In regards to section 5 or 21, relating to ownership and establishment of pharmacy businesses, breach of the Act could result in penalties of 240 penalty units for a natural person (=$37,310.40) or 1200 penalty units for corporations (=$186,552) or revocation of the licence to carry on a pharmacy business or both.

Are you aware of the penalties for providing false or misleading information?

If not prompt with:

Under section 27 of Evidence Act 1958 it is an offence to make a wilful false statement in a statutory declaration and a person can be liable, upon conviction, to be imprisoned for up to 15 years.

Under section 9 of the Act, it is an offence to fail or refuse to give the Authority any information required under section 8 or refuse to produce documents required under section 8 or wilfully mislead the Authority when giving the information. Penalties are 60 penalty units for natural person (=$9,327.60) and 300 penalty units for corporations (=$46,638).

What are your thoughts on whether the penalties act as a deterrent?

What are your thoughts on the ability of the VPA to enforce the Act including penalties?

Should these penalties be publicised or printed on the application forms so pharmacists will see the penalties for misleading the Authority?

Other issues

Are there any other issues you want to raise or highlight which are relevant to this Review?

Summary

Review the discussion with the respondent(s) by summarising very briefly their thoughts on the following: their opinion on and experience with the VPA; examples of businesses seemingly not complying with the Act; ways in which VPA could address through changes to application forms or processes these breaches; examples of undue influence; ways in which VPA could through changes to application forms or processes minimise the chances of undue influence arising; and the influence of penalties.

Thank you for participating in this interview.

Appendix 2: Phase Two Discussion Guide

Introduction

Thank you for finding time to meet with me today.

> Confidentiality: Remind respondent that responses are treated in confidence and data will be aggregated, that is, individual information will not be provided to the client.

Background

PharmConsult has been commissioned by the Victorian Pharmacy Authority (the VPA or the Authority) to review its pharmacy business licence application and renewal process to ensure the information required is adequate to enable the Authority to determine applications in the contemporary pharmacy ownership environment.

You may or may not know that *PharmConsult* has already completed one round of consultations with stakeholders to receive their opinions on the functions of the VPA and its administration of the Pharmacy Regulation Act 2010 (the Act). Phase one of consultations focused on issues of eligibility for ownership and undue influence in the contemporary pharmacy ownership environment, and the penalties that can be applied by the Authority under the Act.

The purpose of this second round of consultations is to gain an understanding of the perceptions of key stakeholders of the perceived impact of potential changes to the pharmacy business licence application and renewal processes or application forms.

To achieve this, we would like to present six scenarios to you and request your comments and ratings on each as to your perception of the impact of the change in terms of a number of factors.

The factors are:

- the ability of the VPA to perform its functions under the Act;
- the ability of the VPA to prevent the occurrence of undue influence in pharmacy businesses;
- the ability of the VPA to determine eligibility for a pharmacy business licence;
- the burden upon the resources (effort, time, and finances) of applicants;
- the burden upon the resources (effort, time, and finances) of the VPA, and
- the benefit to the public or the enhancement of public safety.

To provide background to these factors, I would like to remind you of a few things about the VPA's functions and responsibilities, and aspects of eligibility and undue influence.

VPA Functions

The VPA has the following functions:

- to license a person to carry on a pharmacy business or a pharmacy department;
- to register the premises of a pharmacy business, pharmacy department or pharmacy depot;
- to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots;
- to keep a public register;
- to advise the Minister on any matters relating to its functions;
- to give to the Minister any information reasonably required by the Minister; and
- any other function conferred on the Authority by or under the Act or any other Act.

The Authority's functions include monitoring compliance and conducting investigations.

Eligibility

A person may apply for a licence to carry on a pharmacy business if the person is:

- a registered pharmacist; or
- a company registered under the Corporations Act whose directors are all registered pharmacists and in which all the shares and the beneficial and legal interest in those shares are held by registered pharmacists; or
- a Friendly Society as defined by the Act.

A registered pharmacist and the companies referred to must not own or have a proprietary interest in more than five separate pharmacy businesses

Undue influence

A provision in a bill of sale, mortgage, lease or in any other commercial arrangement in respect of a pharmacy or pharmacy business is void if it gives to any person other than the person licensed to carry on the pharmacy business the right to:

- control the manner in which the pharmacy business is carried on;
- access books of accounts or records kept for that business other than for monitoring compliance with conditions set out in the relevant document; or
- receive any consideration that varies according to the profits or takings in respect of the business.

In effect, a commercial arrangement should not include such a right.

Presentation of scenarios

The aim of presenting these five scenarios is to gain comment on each of them in terms of impact on stakeholders namely, applicants and renewing businesses, the public and the Authority.

We would like to explore five different scenarios relating to application or renewal processes and forms to understand how you feel about their impact on pharmacy business stakeholders. Two scenarios are focused on aspects of information collection on the application forms, two scenarios concern processes involved in the review of applications, and one scenario explores information gathering at renewal and the idea of auditing pharmacy business compliance.

The status quo

The interviewer is to provide respondent(s) visual cues as follows: Scenario A: Status quo visual and forms VP11 and VP 12 as updated December 2016.

At application:

The applicant completes the relevant application form.

From the information provided and from the VPA's connections to AHPRA, ASIC and Medicare and from its database of Victorian pharmacy businesses, the VPA:

- reviews the pharmacist's registration status with AHPRA;
- reviews data submitted to ASIC;
  - noting that at the initial application stage for companies of pharmacists using VP12, the ASIC Company Extract is reviewed for consistency with the details provided in the application;
  - an ASIC alert subscription ensures any changes to the company are monitored on an ongoing basis; and
  - ASIC information includes address and change of address; names of company members and officeholders; changes to company members and officeholders; changes to share structure; and, deregistration;
- reviews company member and office holder registration with AHPRA Pharmacy Board of Australia;
- reviews partner pharmacist's registration status with AHPRA and confirms licence applications submitted by partners;
- assesses from its registered pharmacy business database, the network of interests in pharmacy businesses to ensure no pharmacist (applicant or nominated partners or company members) has interest in more than five Victorian pharmacies;
- assesses the risk of the exertion of undue influence, as defined in the Act, on the carrying on of the pharmacy business, and requires changes to be made to commercial arrangements where undue influence exists;
  - noting that where the VPA has had to seek a formal legal opinion and address, through extensive negotiation with a licensee, matters relating to complex commercial arrangements and associated undue influence, this has cost in the order of $40,000 per application in recent years; and
- assesses if people other than pharmacists have beneficial interest in a pharmacy business (which requires changes to be made to Trusts if this is the case).

At renewal, the process involves only:

- the VPA issuing an invoice; and
- the Licensee paying the invoice.

The VPA is able to monitor pharmacist registration status, and monitor any changes of company details with ASIC.

At all other times the VPA:

- reviews information that becomes available from time to time; and

- may test the veracity of this information with other sources e.g. Medicare (approved pharmacy premises), AHPRA, ASIC.

For discussions after Scenario A, the interviewer should rotate the scenarios to avoid bias. Present relevant visual cue sheets and ask respondents to score scenarios before moving to the next.

New information gathered

In this scenario, the application processes would remain unchanged (i.e.as described in the status quo) except that the information gathered in application forms would also require:

- 100 Points of identification;
- a declaration that the ownership of the pharmacy and any commercial arrangements comply with the Act, and intent to conduct the pharmacy business in accordance with the Act; and
- a criminal history declaration as a finding of being guilty of an offence affecting suitability to hold a licence constitutes grounds upon which the VPA may revoke a licence.

The application forms would provide:

- decision support regarding proprietary interest and undue influence; and
- detail of the penalties associated with breaches of the Act or giving false and misleading information.

Certified applications

In this scenario, nothing changes from the status quo except applicants will be expected to have their legal counsel certify that all business and commercial agreements comply with the Act.

Certification will be at the applicant's expense (the VPA would issue a new standard or guideline to support this change).

Streamed applications

In scenario, nothing changes from the status quo except the VPA would escalate its review depending on the complexity of the applicant's business arrangements;

This may include having agreements reviewed by their independent legal counsel. This would involve a sliding scale of fees and the following has been provided as a guide:

- Base fee: $259.55
- Complex commercial arrangement application fee: ca. $2,000.

If respondents ask why the fee would be of this magnitude, explain the estimated fee is based on the assumption that the cost of legal advice is $100,000 per year and assumes 50 applications per year are associated with complex commercial arrangements. The estimate represents a guide for the purpose of discussion only.

Renewal changes and audits

Currently, the renewal process is very simple: the VPA issues a licence renewal invoice and the licensee pays the renewal. The VPA reviews pharmacist registration and ASIC notices but an audit of businesses is not currently conducted and declarations are not currently required.

Declarations at renewal

In this scenario, the VPA would issue the licence renewal invoice and the licensee would be required to pay this but in addition, return a number of declarations regarding:

- the intent to continue to conduct the pharmacy business in accordance with the Act;
- the licensee's criminal history (similar to that of AHPRA's notification) declaration; and
- changes to commercial and business agreements*.

*Note: discuss the issues related to the period of time this notification might relate to including the information both the VPA and the applicant retain.

In discussing this option explore the burden for applicants and the VPA; whether there is benefit in safety enhancements for the public and whether this option is any more or less suitable as a mechanism to gather data on changing commercial arrangements over time than to conduct audit.

Audit

Using a targeted risk-based approach, the VPA would select for audit, certain applications for renewal for compliance with the Act. The audit would be conducted by officers of the VPA.

The process would be conducted initially for three years during which time the results would be aggregated (and potentially reported). The value of the program of auditing would be assessed after three years and a determination made then on the benefit and cost of continuing the audits.

Base annual licence fees (as a result of conducting these audits) would increase by ca. $100.

> Only if respondents ask why the fee would be of this magnitude, explain that the estimate is based on $100,000 legal fees and $20,000 administrative costs (one senior staff member conducting audits one day/week), i.e. $120,000 divided by 1400 licence renewals is approximately $100.

Review of preferred changes

So that preferences for changes can be gauged, ask:

Picking one scenario or blending two or more scenarios, please describe your ideal application and renewal process.

Why did you choose this?

Picking one scenario or blending two or more scenarios, please describe the ideal application and renewal process for providing benefit to the public or the enhancement of public safety.

Why did you choose this?

Picking one scenario or blending two or more scenarios, please describe the ideal application and renewal process for the VPA to perform effectively its functions under the Act.

Why did you choose this?

Summary

> Review the discussion with the respondent(s) by summarising very briefly their thoughts on the impacts of potential changes and their ideal scenario or blend of scenarios.

Thank you for participating in this interview.

Scenario impact assessment sheet: *provide sheet to respondent and ask them to score (i.e. circle a number) for each scenario as each is presented*

+1 = positive impact 0 = neutral impact -1 = negative impact

Scenario	Impact on the ability of the VPA to perform its functions under the Act	Impact on the ability of the VPA to identify undue influence in pharmacy businesses	Impact on the ability of the VPA to determine eligibility to own a pharmacy business(es)	The impact on the time, effort and finances of applicants			The impact on the time, effort and finances of the VPA			The impact on public safety
				time	effort	finance	time	effort	finance	
(A) Current process and forms (status quo)	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1
(B) Amended forms to gather additional information	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1
(C) Certification by applicant's lawyer	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1
(D) Streamed review based on complexity of the business' agreements	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1
(E) Renewal changes New declarations required	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1
(E) Renewal changes Targeted risk- based audits at renewal	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1	+1 0 -1