

Year 3 and Program Evaluation Report

Pharmacy Ownership Audit Program

Victorian Pharmacy Authority

Report to 30 June 2022

Victorian Pharmacy Authority
PHARMACY OWNERSHIP AUDIT PROGRAM
YEAR 3 AND PROGRAM EVALUATION REPORT

EXECUTIVE SUMMARY

The Victorian Pharmacy Authority (**VPA**) is committed to ensuring that all pharmacies in Victoria are owned, operated and controlled only by registered pharmacists in accordance with the *Pharmacy Regulation Act 2010 (Act)*.

A program of risk-based audits of pharmacy businesses was a key recommendation of the 2017 *PharmConsult* review. The Pharmacy Ownership Audit Program (**program**) was introduced to address a perception among pharmacists with whom *PharmConsult* met, that there have been and continue to be breaches of the Act in relation to silent or undeclared interests in pharmacy businesses.

The VPA commenced the program in December 2018 for a minimum of three years with the requirement to monitor, evaluate and report outcomes. Reports evaluating the first two years of the program are available on the VPA website (www.pharmacy.vic.gov.au).

The program has included set annual targets of ‘ownership audits’ and ‘financial audits.’ Ownership audits are conducted by VPA staff to determine if the ownership and commercial arrangements comply with the Act. Financial audits are conducted by an external accountancy firm for a subset of the ownership audits to confirm the veracity of the information and documentation submitted by licensees.

The VPA undertook 140 ownership audits, including 21 financial audits over the 3-year course of the program using risk-based selection criteria. Of the 131 ownership audits and 15 financial audits completed, there were two cases of non-compliance with the requirements of the Act arising from licensees acting on the advice of their financial advisors.

Considering the high demand on resources and licensees, and that audit outcomes have not reflected the perceptions held by pharmacists, the VPA has decided that maintaining annual audit targets is not an efficient use of the program.

Instead, the VPA will undertake pharmacy ownership audits and/or financial audits based on notifications or intelligence from its regulatory activities (e.g., information arising from inspections or licence application processes) and discontinue auditing on the basis of annual targets.

In parallel, the VPA will continue its risk-based program of comprehensive reviews of franchise and other complex commercial agreements to ensure compliance with the ownership and undue influence provisions of the Act. These initiatives along with the VPA’s comprehensive licence application processes will help detect and deter unlawful pharmacy ownership arrangements.

The VPA will continue to consult with stakeholders to gain insights on pharmacy commercial arrangements, emerging risks and industry developments to help improve the program.

INTRODUCTION

Legislation

Ownership of a pharmacy business

The *Pharmacy Regulation Act 2010* (**the Act**) regulates who may own or have a “proprietary interest” in a pharmacy business. To that end, section 5 of the Act provides that:

- 1) A person must not own or have a proprietary interest in a pharmacy business unless the person is:
 - a) a registered pharmacist;
 - b) a company registered under the Corporations Act—
 - i. whose directors are all registered pharmacists;
 - ii. in which all of the shares and the beneficial and legal interest in those shares are held by registered pharmacists.¹

“Proprietary interest” is defined under s 3 of the Act as meaning:

“a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, or member or shareholder of a company and as the trustee or beneficiary of a trust.”

Section 5(2) of the Act states that a registered pharmacist and a company referred to in subsection (1)(b) must not own or have a proprietary interest in more than 5 separate pharmacy businesses.

Undue Influence/control of a pharmacy business

The Act also places restrictions on who can control or influence the way in which a pharmacy business is carried on.

In particular, section 11 of the Act relates to undue influence over a pharmacy business. It provides that:

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

- a) the right to control the manner in which the pharmacy business is carried on; or
- b) the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or
- c) the right to receive any consideration that varies according to the profits or takings in respect of the business—

is void.

¹ Section 5(1)(c)-(f) sets out various exceptions to s 5(1)(a)-(b) that relate to friendly societies.

Pharmacy Ownership Audit Program

In December 2016, the VPA commissioned *PharmConsult* to conduct an external review of its licence application and renewal processes. As part of its review, *PharmConsult* recommended the introduction of a program of risk-based [ownership] audits of pharmacy businesses to be undertaken for a short term initially (e.g., three years) with a requirement to monitor, evaluate and report outcomes. The Final Report *Review of the Pharmacy Business Licence Application and Renewal Processes in Victoria* (18 July 2017) is available on the VPA website.

During the review, 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.

Following a pilot, the VPA commenced the program in December 2018 by selecting 100 ownership audits and 11 financial audits to be undertaken in the 2019 calendar year (**Year 1**).

In each case, an **ownership audit** carried out by VPA staff examined the pharmacy ownership and commercial arrangements (following a process developed in consultation with the VPA's lawyers and accountants) to ensure they are consistent with VPA records/stated arrangements, and that they comply with the ownership and undue influence provisions of the Act.

Additionally, the financial records of a subset of pharmacies selected for ownership audit were examined by an accounting firm to confirm the stated ownership arrangements and determine if there are undeclared arrangements in place (**financial audit**).

If ownership auditing identifies potential non-compliance, the VPA obtains legal advice pending further action. This may include a panel hearing or legal proceedings.

Thirty-five ownership audits and two financial audits were completed in Year 1. It was evident that the initial annual target of 100 ownership audits would not be achieved with existing resources. The VPA decided on the following actions in response to audits undertaken in the first year of the program:

1. Review selection criteria for audit to ensure that audits are undertaken on an appropriate risk basis.
 - a. Remove *Association with franchise/banner group* and *Licensees residing interstate* as selection criteria.
 - b. Consult with stakeholders to help identify possible additional criteria for audit.
2. Apply additional resources and tools to (a reduced number of) ownership audits – this may include carrying out premises inspections in parallel with ownership audits to examine documents such as electronic funds transfer (EFT) records, Medicare payment advice, invoices for goods received.
3. Reduce the base number of ownership audits to be undertaken annually.
4. Maintain and consider increasing the number of financial audits subject to consideration of further audits findings.
5. Accelerate the formal legal review of franchise agreements and other complex commercial agreements to ensure compliance with the Act.
6. In cases where information is not provided or is incomplete without reasonable excuse, advise licensees that continued failure to provide information may lead to prosecution.

It should be noted that separately, and prior to the *PharmConsult* review, the VPA had commenced a risk-based program of comprehensive reviews of pharmacy franchise and other complex commercial agreements to ensure compliance with the ownership and undue influence provisions of the Act (**franchise reviews**).

The selection criteria *Association with franchise/banner group* was removed after Year 1 because there was little value in auditing pharmacies on this basis if a comprehensive review of commercial agreements had yet to be undertaken. Pharmacies operating as a franchise or in association with a banner were still selected for audits provided that they met one of the other selection criteria. Information obtained through an ownership audit may also lead to a franchise review.

In the second year of the program the VPA continued its assessment of the remaining audits selected on commencement of the program.

The VPA then revised the annual target to 40 ownership audits for 2021 (**Year 3**), including 10 financial audits. This was outlined in the Year 2 Evaluation Report. These audits were selected on the basis of a revised risk-based audit selection criteria following the Year 1 Evaluation Report and stakeholder consultation. The revised selection criteria were as follows:

- i. Association with medical centre/clinic.
- ii. Commercial arrangement or association with a person who has a proprietary interest in five pharmacies.
- iii. Recent graduate pharmacist(s) as licensees.
- iv. Other on order of the VPA.
- v. Licensees who have held a licence for five or more years. This is a new criterion because some of the commercial agreements associated with these licences may not have been reviewed at the time of application because these predates VPA's current application review processes.
- vi. Pharmacies with trust structures in the case of a financial audit. This is a new criterion following the outcome of a financial audit in 2019 that identified the distribution of profits via a trust to family members who were not eligible to have proprietary interest.
- vii. Pharmacies operating under a franchise/banner group that are yet to be selected for a financial audit provided they also meet at least one other selection criteria. This is a new criterion to confirm the stated ownership arrangement of a pharmacy operating under a franchise/banner group using financial information.

The outcomes of the audits completed are summarised in the next section.

OUTCOMES

1. Year 3 Outcomes

The VPA set an annual target of 40 ownership audits, including 10 financial audits for 2021. The following tables outline the progress and outcomes of the ownership and financial audits that were selected.

Progress of Ownership Audits				
Time	Number of Ownership Audit Requests Sent	Number of Responses Received	Number of Ownership Audits Commenced	Number of Ownership Audits Completed
1Q 2021	4	-	-	-
2Q 2021	-	4	3	-
3Q 2021	11	11	1	-
4Q 2021	25	22	28	13
1Q 2022	-	2	4	10
2Q 2022	-	-	3	8
Total	40	39	39	31

Progress of Financial Audits				
Time	Number of Financial Audit Requests Sent	Number of Responses Received	Number of Financial Audits Commenced	Number of Financial Audits Completed
1Q 2021	4	-	-	-
2Q 2021	-	4	3	-
3Q 2021	2	2	1	-
4Q 2021	4	2	3	-
1Q 2022	-	1	1	2
2Q 2022	-	-	1	2
Total	10	9	9	4

Outcome of Ownership Audits Completed	
Compliant	9
Compliant (noting review of established commercial agreement pending)	13
Compliant (noting potential non-compliance with s11)	7
Compliant (noting potential non-compliant clauses in the trust deed)	1
Non-compliant	1
Total	31

Outcome of Financial Audits Completed		
Compliant	Non-compliant	Total
4	0	4

Key:*Compliant*

Ownership arrangements consistent with stated arrangements and compliant with the Act.

Compliant (noting review of established commercial agreement pending)

Ownership arrangements consistent with stated arrangements. No evidence of non-compliance but formal legal review of established commercial arrangements for compliance with Act still pending.

Compliant (noting potential non-compliance with s11)

Ownership arrangements consistent with stated arrangements. Pharmacy operated pursuant to commercial arrangements that have been subject to a formal legal review for compliance with the Act and required amendment. Potential non-compliance with control and undue influence provisions identified due to documents not being agreed precedent versions. [Process requiring licensees/franchisors to update pre-existing arrangements ongoing]

Compliant (noting potential non-compliant clauses in the trust deed)

Ownership arrangements consistent with stated arrangements. No evidence of non-compliance but noting potential non-compliant clauses in the trust deed.

Non-compliant

Ownership arrangements not consistent with stated arrangements (e.g., undeclared interests) or otherwise not compliant with the Act.

2. Program Outcomes

The VPA undertook 140 ownership audits, including 21 financial audits over the course of the program, of which 131 ownership audits and 15 financial audits have been completed. All audits selected in Year 1 have been completed. The following tables outline the outcome of the audits that have been completed since the start of the program.

Program Outcome - Ownership Audits Completed	
Compliant	44
Compliant (noting review of established commercial agreement pending)	57
Compliant (noting potential non-compliance with s11)	23
Compliant (noting potential non-compliant clauses in the trust deed)	2
Compliant (noting review of established commercial agreement pending and potential non-compliant clauses in the trust deed)	4
Non-compliant	1
Total	131

Program Outcome – Financial Audits Completed		
Compliant	Non-compliant – payment to non-eligible beneficiary	Total
14	1	15

EVALUATION

1. Year 3 evaluation

The VPA selected forty ownership audits, including 10 financial audits for 2021.

Findings from the third year of the program are summarised below:

- Thirty-one ownership audits were completed, and 30 of these did not detect any unlawful ownership.
- The ownership arrangements of one ownership audit were found to be non-compliant. It was identified that the licensee failed to apply for a new licence when they switched to a corporate structure. The licensee also failed to comply with the licence condition requiring them to inform the VPA of any changes to the commercial arrangements pursuant to which the pharmacy business is conducted prior to the changes taking effect.
- One audit identified potentially non-compliant clauses in a trust deed. There was no evidence of non-compliance, and the stated ownership arrangement was confirmed.
- Seven ownership audits involved franchisees operating pharmacies pursuant to franchise agreements which required amendment to ensure compliance with the Act. A process to update to compliant versions is in place. The audits otherwise confirmed the stated ownership arrangement.
- Thirteen ownership audits involved established commercial arrangements that have not undergone a franchise review. A process is in place for prioritisation of these reviews. The audits were otherwise consistent with the stated ownership arrangements.
- One audit did not commence prior to 30 June 2022 because the licensee failed to provide the information required for the audit despite a lengthy engagement and multiple time extensions. The VPA warned the licensee that it will commence proceedings in the Magistrates Court if there is continued failure to produce the information and documents.
- The VPA continues to set clear expectations in its correspondence to licensees regarding the turnaround time to respond to audit requests for information. Most licensees have provided the requested information within a reasonable timeframe with some extensions requested and granted.
- Four out of the 10 financial audits completed did not detect any unlawful ownership. The remaining six financial audits were pending completion by the external accountancy firm. Financial audits typically require at least six months to a year to complete owing to the volume and complexity of information undergoing assessment. It is also dependent on whether licensees provide further information in a timely matter.

2. Program evaluation

The VPA committed to a program of risk-based audits of pharmacy businesses for at least three years. The VPA selected 140 ownership audits and 21 financial audits over the course of the program according to the audit selection criteria.

Findings from the program are summarised:

- The VPA completed 131 ownership audits and 15 financial audits by 30 June 2022. The remaining audits have commenced, and on initial assessment have not found cause for concern in relation to compliance. Of the audits completed, there were two findings of non-compliance:
 - i. Year 1 finding: A financial audit of one pharmacy identified the distribution of the profit of a partner to trust beneficiaries not eligible to have a proprietary interest. In this case a panel hearing was convened, and the licensee reprimanded. The licensee had also taken steps to amend the trust to ensure compliance with the Act.
 - ii. Year 3 finding: An ownership audit of one pharmacy identified that the ownership arrangement was not consistent with the licence. The director of the company was granted a licence to carry on the pharmacy business as a natural person but failed to apply for a new licence when they switched to a corporate structure. A panel was convened, and the licensee reprimanded. In this case, the licence could have been revoked or the company prosecuted for carrying on the pharmacy business without a licence.

In both cases, the Panel noted licensees' explanation that they had acted on the advice of their financial advisors. Licensees were reminded that they should take the necessary steps to satisfy themselves that ownership and commercial arrangements comply with the Act and not rely solely on their advisers.

Both audits involved licensees who have held a licence for five or more years and this appears to be a useful audit selection criteria. Licensees with long tenures may have commercial agreements that have changed since the time the licence was granted but failed to seek the VPA's approval prior to entering new agreements. Further, their commercial agreements may not have been assessed with the same lens as applications in recent years where a more comprehensive licence application assessment process is applied.

There are licensing implications of carrying on a pharmacy business as a company versus a natural person because they are different legal entities. The VPA has provided information on this matter including a case study in a dedicated communique (published 4 December 2020). Similar cases of non-compliance have been identified outside of the program and have been highlighted in the VPA circulars as a reminder to pharmacists.

- Six ownership audits identified trust deeds with potentially non-compliant clauses. The stated ownership arrangement was confirmed and the licensees were required to amend the trust deeds to compliant versions.
- The VPA required licensees to provide documents such as electronic funds transfer (EFT) records, Medicare payment advice, bank statements relating to

EFT and Medicare deposits and invoices for goods received on a case-by-case basis. This has been a helpful tool to verify ownership arrangements.

- Continuing the program in its current form with set annual targets is not likely to be productive given:
 - i. The number (two cases) and extent of non-compliance detected to date were due to licensees acting on inadequate advice given by financial advisors and does not reflect the perceptions held by pharmacists with whom *PharmConsult* met regarding unlawful ownership conducted with intent and disregard for the Act.
 - ii. That it is resource and time intensive.
 - iii. The regulatory burden on pharmacists.
 - iv. The VPA continues its existing franchise reviews outside of the program involving comprehensive reviews of franchise agreements and other complex commercial agreements on a risk basis for non-compliance with the ownership and/or undue influence provisions of the Act.
- The program should transition away from annual targets. The VPA believes there is better value in using audits as a regulatory tool to investigate potential non-compliance where:
 - i. Ownership and financial audits are undertaken on order by the VPA e.g., based on intelligence or notifications.
 - ii. Ownership audits are undertaken on order by management e.g., based on information obtained during an inspection or as part of a licence application.
 - iii. Financial audits may initially be focused on certain commercial arrangements of concern while maintaining the option to undertake a comprehensive audit of all arrangements based on initial findings. This would be done on a risk basis. This supports assessment efficiency and reduces the regulatory burden on pharmacists.
- Using audits as a regulatory tool means audits are conducted on a risk basis and this serves as a deterrent against unlawful ownership arrangements.
- Further, the VPA has additional measures in place to detect and deter breaches of the Act in relation to undeclared interests:
 - i. Increased scrutiny of complex commercial agreements through the VPA's current licence application assessment process.
 - ii. Comprehensive reviews of new and established commercial agreements including franchise agreements on a risk basis.
 - iii. Ongoing consultation with stakeholders for insights on pharmacy commercial arrangements, emerging risks and industry developments to improve the program.

- iv. The VPA has and continues to highlight requirements of pharmacy ownership according to the Act including penalties associated with breaches in its circulars.
- v. There is a standard condition on all licences requiring the licensee to inform the VPA of any changes to the commercial arrangements pursuant to which the pharmacy business is conducted prior to the changes taking effect.

The VPA will report on the outcomes of the remaining ownership audits and financial audits in the VPA circular when the information is available.

DECISIONS

The VPA made the following decisions based on the outcomes of the program:

1. Remove annual ownership and financial audit targets.
2. Ownership audits are to be selected on order by the VPA or management based on credible information raising concerns about the lawfulness of the ownership arrangements.
3. Financial audits are selected on order by the VPA based on credible information raising concerns about the lawfulness of the ownership arrangements.
4. Financial audits may be conducted as a comprehensive financial audit or may be commenced with a focus on certain commercial arrangements of concern while maintaining the option to undertake a comprehensive audit of all arrangements based on initial findings. This would be done on a risk basis.

Victorian Pharmacy Authority

13 December 2022