

Approvals Issued October – December 2022

	2022		2021	
Licence to carry on a pharmacy business – Individual	34		13	
Licence to carry on a pharmacy business- Company	33		25	
Licence to carry on a pharmacy business – Friendly Societies	0		2	
Licence to carry on a pharmacy department	2		1	
Registration of a pharmacy premises	22		9	
Registration of a pharmacy department	2		0	
Registration of a pharmacy depot	0		0	
Approval To Supply, Compound Or Dispense In Special Circumstances Pursuant To Section 29(1)(b)	11		11	
Approval Of A Person To Carry On Another Business Or Activity In Registered Pharmacy Premises. Section 24	7		3	



Service Standards – approval in principle October – December 2022

	2022		2021	
	Number	Percentage	Number	Percentage
Total number of applications processed (finalised)	91		72	
Number receiving initial assessment within 5 working days	90	99%	72	100%
Number processed within five working days of VPA decision or receipt of outstanding information	86	96%	70	97%
Applications withdrawn	3		0	
Applications denied	0		0	

Investigations with notification

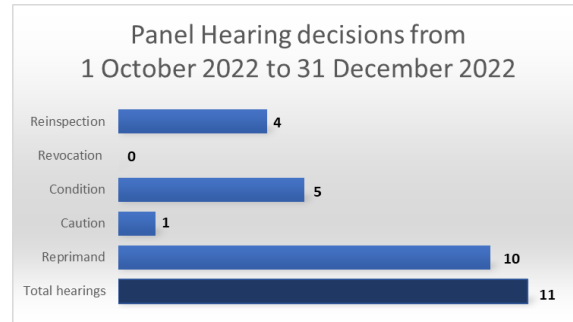
Total complaints received	27
Complaints treated as notifications under <i>Pharmacy Regulation Act 2010</i>	0

Investigations without notification

Number of investigations	20
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Applications received October – December 2022

	2022		2021	
Licence to carry on a pharmacy business – Individual	5		6	
Licence to carry on a pharmacy business- Company	10		6	
Licence to carry on a pharmacy business – Complex Individual	23		9	
Licence to carry on a pharmacy business- Complex Company	24		21	
Licence to carry on a pharmacy business – Friendly Societies	0		1	
Licence to carry on a pharmacy department	1		0	
Registration of a pharmacy premises (include Alterations)	28		29	
Registration of a pharmacy department	3		0	
Registration of a pharmacy depot	0		0	
Approval To Supply, Compound Or Dispense In Special Circumstances Pursuant To Section 29(1)(b)	11		11	
Approval Of A Person To Carry On Another Business Or Activity In Registered Pharmacy Premises. Section 24	7		3	



Registered premises as at 31 December 2022

Pharmacies	1463
Pharmacy Departments	78
Pharmacy Depots	17

Pharmacy ownership audits

There were no pharmacy ownership audits commenced or completed during this period. The VPA is currently assessing 6 pharmacy ownership audits, the outcomes of which will be reported when the audits are completed.

Risk-based focus of inspections in January – March 2023

The current risk-based focus of VPA inspections is compliance with the VPA Standards



Performance measurement framework

The Victorian Pharmacy Authority's performance measurement framework includes information on its activities and intended outcomes.

Defining outcomes

Legislative context

The Victorian Pharmacy Authority (**VPA**) is established under section 81 of the *Pharmacy Regulation Act 2010 (Act)* to regulate the ownership and operation of pharmacy businesses, pharmacy departments and pharmacy depots through the functions specified in section 82 of the Act. These functions include (inter alia):

- a) to license persons to carry on pharmacy businesses or pharmacy departments;
- b) to register the premises of pharmacy businesses, pharmacy departments and pharmacy depots;
- c) to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots.

The objectives of these activities are specified in section 85 of the Act. They are the need to:

- a) control who may own and operate pharmacy businesses in Victoria and
- b) maintain standards relating to
 - the licensing of persons to carry on pharmacy businesses and pharmacy departments and
 - the registration of pharmacy premises, pharmacy departments and pharmacy depots.

The Act recognises that pharmacists play an important role in protecting the public, especially many of the more vulnerable members of our community, and that they are often a first port of call for people seeking health care.

Vision

A safe pharmacy system that is responsive to and satisfies community needs and interests.

Strategic priorities

1. Licensees better supported to engage in good governance and regulatory practice
2. A sustainable, connected and evidence-driven authority
3. A leading pharmacy regulator advocating for best practice approaches to regulation

For more information, the VPA Strategic Plan 2021-2024 is available at www.pharmacy.vic.gov.au.

Performance targets

Consistent with the Statement of Expectations Framework for Regulators, the VPA currently has the following performance targets:

VPA Standards

- Host a stakeholder forum on the VPA Standards to provide information about their purpose and application by 31 October 2022
- Reformat VPA inspection reports by 31 October 2022 to distinguish between requirements under the VPA Standards and other requirements relating to good pharmacy practice
- Update the VPA premises self-audit form to reflect the introduction of the VPA Standards by 31 December 2022

VPA Guidelines

- Seek feedback from consumer groups and/or the general public on VPA guidelines relevant to a consumer's pharmacy experience by 31 October 2022
- Seek stakeholder feedback on draft revised VPA Guidelines; and
- Publish revised VPA Guidelines by 30 June 2023

Stakeholder consultation and engagement

- Publish updated information on the VPA website to clarify the VPA's role and processes for receiving and managing complaints by 31 December 2022
- Implement a new process to obtain feedback from pharmacists on VPA inspections by 31 March 2023
- Implement a revised stakeholder engagement strategy by 30 June 2023

Emerging risks

- Develop by 30 September 2022 a program to invite stakeholders to attend monthly VPA meetings to discuss emerging risks and industry developments

Outcomes statements

The outcomes the Victorian Pharmacy Authority is seeking to achieve are:

- The Victorian community has ready access to a safe pharmacy service through the administration of a licensing and registration scheme and guidelines for pharmacy businesses, pharmacy departments and pharmacy depots; and
- Pharmacy owners and operators are aware of and comply with their legislative and regulatory obligations through engagement with the VPA, primarily via the VPA's inspection and communications programs.

Regulation benefits

These outcomes are realised in several areas as indicated by the potential consequences if the VPA did not exist, which include:

- the risk that pharmacies are owned and operated by persons other than registered pharmacists and pharmacy services are not provided in accordance with professional standards and by adequately trained personnel;
- increased risk of dispensing errors and adverse drug events due to lack of suitable equipment and/or poor pharmacy practice, layout, operational procedures and management;

- harm to members of the community or pharmacy staff due to poor quality medicines;
- exposure to hazardous substances in pharmacies that are not adequately designed, equipped or managed;
- increased risk of misappropriation and unlawful access to drugs of dependence due to lack of security, supervision or poor monitoring and recording;
- greater risk of privacy breaches arising from inadvertent release of patient medicine information due to inadequate privacy control within pharmacies;
- increased levels of criminal activity involving prescription drugs due to poor compliance with standards for security and management of pharmacy premises and compliance with good pharmacy practice.

Quarterly performance report

The following information is included in the VPA's quarterly performance report attached to this document.

Applications received

The table lists the number of applications *received* by category during the period.

Service standards – approval in principle¹

The VPA aims to carry out an initial assessment within five business days of receipt of a complete application. For applications within the delegation of VPA officers, processing should be completed within a further five business days of receipt of any outstanding information. For applications outside delegation, processing should be completed within five business days following a decision of the next monthly meeting of VPA members or receipt of any further required information. The table shows the total number of applications *finalised* followed by the number of these that (i) received an initial assessment within five business days, and (ii) were processed within five working days of a decision of VPA members or receipt of outstanding information.

Approvals issued

The table lists the number of licences issued, premises registered and other approvals granted by category.

Registered premises

Registered premises statistics at the end of the quarter.

Risk-based focus of inspections

Statistics obtained from inspection reports are used to ensure that future inspections focus on areas of significant non-compliance and risk. Based on these statistics and reference to the VPA's risk register, inspectors will pay close attention to the listed high-risk areas.

Inspections conducted

The graph shows the total number of inspections conducted and includes a breakdown by inspection type. Planning inspections refer to inspections of new or altered premises. Cyclical inspections include routine cyclical inspections, review inspections and reinspection. Inspections listed in the table may have been carried out in person or remotely.

¹ Service standards refer to in-principle approvals. The Authority agrees in principle to applications for registration and approves licence applications in principle when applications are assessed as compliant. The actual registration/licence is not granted until a pharmacy is completed/settlement of purchase finalised.

Investigations

The VPA may investigate a matter relating to a licence or a registration based on a notification (complaint) or without notification (usually following a premises inspection). Complaints which fall outside the VPA's jurisdiction are referred to other agencies. The table lists the total number of complaints received, the number of complaints that were treated as notifications under the Act (investigations with notification), and the number of investigations without notification for the period.

Panel hearings

The VPA may convene a panel to hear a matter which has been the subject of an investigation. The graph shows the total number of panel hearings *conducted* during the period and panel decisions which may include cautioning or reprimanding licensees, placing conditions on a licence or registration and revocation of a licence or registration.

Pharmacy ownership audit program

The audit program involves pharmacy ownership audits and financial audits. Ownership audits are conducted by VPA staff to determine if pharmacy ownership and commercial arrangements 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 are examined by an external accounting firm to confirm the stated ownership arrangements and determine if there are undeclared arrangements in place (financial audit).

The tables provide a summary of audits undertaken including outcomes for the period.

The ownership audit outcomes are described by the categories below.

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. Commercial arrangement condition imposed or to be imposed.

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.

For further information on the pharmacy ownership audit program, including program changes, see the Year 1 and Year 2 Evaluation Reports available at www.pharmacy.vic.gov.au (click on Resources, then VPA Pharmacy Ownership Audit Program).

Updated 30 November 2022