

Approvals issued April - June 2021

	2021	2020
Licence to carry on a pharmacy business – Individual	25	20
Licence to carry on a pharmacy business- Company	15	16
Licence to carry on a pharmacy business – Friendly Societies	0	0
Licence to carry on a pharmacy department	0	2
Registration of a pharmacy premises	10	10
Registration of a pharmacy department	0	1
Registration of a pharmacy depot	0	0
Approval To Supply, Compound Or Dispense In Special Circumstances Pursuant To Section 29(1)(b)	7	8
Approval Of A Person To Carry On Another Business Or Activity In Registered Pharmacy Premises. Section 24	11	2

Service Standards – approval in principle April – June 2021

	2021		2020	
	Number	Percentage	Number	Percentage
Total number of applications processed (finalised)	65		69	
Number receiving initial assessment within 5 working days	56	86%	61	88%
Number processed within five working days of VPA decision or receipt of outstanding information	63	97%	69	100%
Applications withdrawn	1		1	

Applications received April – June 2021

	2021	2020
Licence to carry on a pharmacy business – Individual	1	9
Licence to carry on a pharmacy business- Company	5	4
Licence to carry on a pharmacy business – Complex Individual	12	18
Licence to carry on a pharmacy business- Complex Company	16	12
Licence to carry on a pharmacy business – Friendly Societies	0	0
Licence to carry on a pharmacy department	1	2
Registration of a pharmacy premises (include Alterations)	21	24
Registration of a pharmacy department	3	4
Registration of a pharmacy depot	0	0
Approval To Supply, Compound Or Dispense In Special Circumstances Pursuant To Section 29(1)(b)	7	8
Approval Of A Person To Carry On Another Business Or Activity In Registered Pharmacy Premises. Section 24	11	2

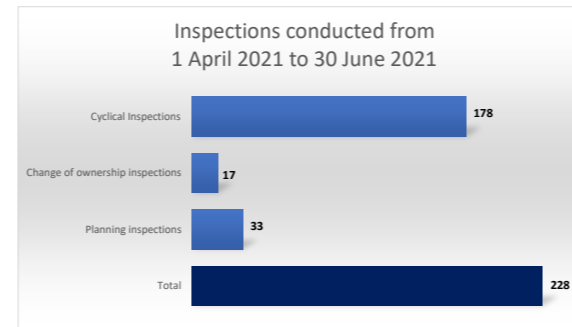
Registered premises as at 30 June 2021

Pharmacies	1445
Pharmacy Departments	75
Pharmacy Depots	18

Risk-based focus of inspections

The Authority is currently reviewing its risk-based focus following recent stakeholder consultation.

Inspections listed in the following table may have been carried out remotely.

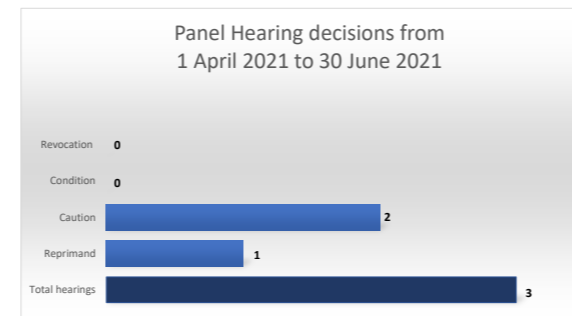


Investigations with notification

Total complaints received	20
Complaints treated as notifications under <i>Pharmacy Regulation Act 2010</i>	0

Investigations without notification

Number of investigations	8
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Pharmacy ownership audits

Number of ownership audits commenced	3
Number of ownership audits completed	2
Number of financial audits completed	0

Outcome of ownership audits completed

Compliant	1
Compliant (noting review of established commercial agreement pending)	0
Compliant (noting potential non-compliance with s11)	0
Compliant (noting potential non-compliant clauses in trust deed)	0
Compliant (noting review of established commercial agreement pending and potential non-complaint clauses in trust deed)	1
Non Compliant	0
Total	2

Outcome of financial audits completed

No financial audits were finalised during the quarter.

The Authority has commenced selecting pharmacies for the next round of audits following consultation with stakeholders regarding the pharmacy ownership audit program.

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 (the Authority) is established under s81 of the *Pharmacy Regulation Act 2010* (the Act) to regulate the ownership and operation of pharmacy businesses, pharmacy departments and pharmacy depots through the functions specified in s82 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 s85 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.

Purpose

To ensure a safe pharmacy system that is responsive to community needs and interests.

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 Authority, primarily via the Authority's inspection and communications programs.

Key benchmarks

Quarterly: Review statistics obtained from pharmacy site visits and use these statistics to regularly recalibrate priorities within the Authority's inspection program.

Annually: Review of trends in non-compliance with relevant legislation and guidelines.

Statement of Expectations 2019-21:

- Undertake 100 pharmacy ownership audits and 10 financial audits annually. [Target modified – refer to VPA Pharmacy Ownership Audit Program - Year 1 Evaluation Report - July 2020]
- Clearly differentiate the pharmacy ownership audit phase from any post-audit investigation by 31 December 2019 (to facilitate publication of audit outcomes). [Completed]
- Develop a Service Charter for publication on the Authority's website by 31 December 2019. [Completed]
- Host a stakeholder forum on application processes and service standards by 31 December 2019. [Completed]
- Review and revise inspection-related guidance documentation by 31 December 2019 with a view to expanding the range of guidance provided. [Completed]
- Commence routinely sending approval letters and licence/registration certificates to applicants by email at the time of issue by 30 June 2020. [Completed]
- Obtain feedback from stakeholder organisations on the risk-based focus of the Authority's inspection program by 30 June 2020. Any resulting changes to the inspection program to be communicated to stakeholders. [Target postponed in accordance with VPA Business Plan 2020-21 ([here](#)) due to coronavirus (COVID-19) pandemic, to undertake a detailed analysis of inspections and comprehensive review of risk register and to align with the development of Authority standards and review of VPA guidelines; survey sent to stakeholders on 29 June 2021.]
- Incorporate a declaration of compliance in high-risk areas commencing with 2020 renewal applications (by 30 June 2020). [Completed]
- Review and revise the Authority's self-audit form for registered premises for publication on the Authority's website by 30 June 2020. [Target postponed in accordance with VPA Business Plan 2020-21 ([here](#)) due to coronavirus (COVID-19) pandemic. This allowed the self-audit form to be comprehensively reviewed and reformatted as a fillable PDF document. The updated self-audit form was uploaded to the VPA website on 30 June 2021 (see VPA Circular No 25 [here](#)).]
- In consultation with stakeholders, develop a compliance and awareness aid for the management of Schedule 8 poisons in pharmacies, for publication and distribution to pharmacy premises by 30 June 2020. [Target postponed in accordance with VPA Business Plan 2020-21 ([here](#)) due to coronavirus (COVID-19) pandemic. *Managing Schedule 8 poisons - a reference guide for pharmacists* was published and sent to all registered premises in December 2020 (see Circular No 23 [here](#)).]
- Transition 50% of licence/registration application forms to electronic formats by 30 June 2021. [Completed – 7 of the 12 application forms were uploaded to the VPA website on 30 June 2021 (see VPA Circular No 25 [here](#)). Eight further notification forms are expected to be added in August 2021.]

Regulation benefits

These outcomes are realised in several areas as indicated by the potential consequences if the Authority 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 Authority's quarterly performance report.

Applications received

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

Service standards – approval in principle¹

The Authority aims to carry out an initial assessment within five business days of receipt of a complete application. For applications within the delegation of Authority 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 Authority 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 Authority 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 Authority's risk register, inspectors will pay close attention to the listed high-risk areas.

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.

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.

Investigations

The Authority 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 Authority'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 Authority 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 Authority staff to determine if pharmacy ownership and commercial arrangements are consistent with Authority 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 [here](#) on the Authority's website.

Updated 3 August 2021.