

#### Approvals issued October - December

	2020	2019
Licence to carry on a pharmacy business – Individual	25	41
Licence to carry on a pharmacy business- Company	23	22
Licence to carry on a pharmacy business – Friendly Societies	-	-
Licence to carry on a pharmacy department	-	-
Registration of a pharmacy premises	13	17
Registration of a pharmacy department	-	-
Registration of a pharmacy depot	-	1
Approval to supply, compound or dispense medicines in special circumstances pursuant to section 29(1)(b)	10	10
Approval of other person to carry on business or activity in registered premises (Section 24)	30	4

#### Service Standards – approval in principle October - December

	2020		2019	
	Number	Percentage	Number	Percentage
Total number of applications processed (finalised)	92		82	
Number receiving initial assessment within 5 working days	92	100%	77	94%
Number processed within five working days of VPA decision or receipt of outstanding information	90	98%	82	100%
Applications withdrawn	0		0	

#### Applications received October - December

	2020	2019
Licence to carry on a pharmacy business – Individual	5	9
Licence to carry on a pharmacy business- Company	10	5
Licence to carry on a pharmacy business – Complex Individual	31	38
Licence to carry on a pharmacy business- Complex Company	14	19
Licence to carry on a pharmacy business – Friendly Societies	1	2
Licence to carry on a pharmacy department	-	-
Registration of a pharmacy premises (includes alterations)	35	32
Registration of a pharmacy department	2	-
Registration of a pharmacy depot	-	-
Approval to supply, compound or dispense medicines in special circumstances pursuant to section 29(1)(b)	12	9
Approval of other person to carry on business or activity in registered premises (section 24)	30	3

#### Registered premises

Pharmacies	1442
Pharmacy Departments	75
Pharmacy Depots	18

#### Risk-based focus of inspections

The Authority is currently reviewing the risk-based focus and plans to undertake stakeholder engagement in this area shortly.

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



#### Investigations with notification

Total complaints received	7
Complaints treated as notifications under <i>Pharmacy Regulation Act 2010</i>	0

#### Investigations without notification

Number of investigations	3
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#### Panel hearings

No panel hearings were held during the period.

#### Pharmacy ownership audits

Number of ownership audits commenced	10
Number of ownership audits completed	10
Number of financial audits completed	0

#### Outcome of ownership audits completed

Compliant	6
Compliant (noting review of established commercial agreement pending)	4
Compliant (noting potential non-compliance with s11)	0
Compliant (noting potential non-compliant clauses in the trust deed)	0
Compliant (noting review of established commercial agreement pending and potential non-complaint clauses in the trust deed)	0
Non Compliant	0
<b>Total</b>	<b>10</b>

## 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. [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).
- 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. [Delayed due to coronavirus (COVID-19) pandemic – consultation expected to be undertaken by 31 December 2020]
- 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. [Delayed due to coronavirus (COVID-19) pandemic]
- 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. [Delayed due to coronavirus (COVID-19) pandemic – expected to be completed by 31 December 2020]
- Transition 50% of licence/registration application forms to electronic formats by 30 June 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 principle<sup>1</sup>

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.

### Inspections conducted

The graph shows the total number of inspections conducted followed by a breakdown by inspection type. Planning inspections refer to inspections of new or altered premises. Cyclical inspections include routine cyclical inspections, review inspections and full re-inspections.

### Risk-based focus of future 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 from the previous quarter and reference to the Authority's risk register, inspectors will pay close attention to the listed high-risk areas.

### 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.

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<sup>1</sup> 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.

## 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 followed by panel decisions which may include cautioning or reprimanding licensees, placing conditions on a licence or registration and revocation of a licence or registration. A Panel may also refer a matter back to the Authority for consideration of further action such as premises re-inspection.

## 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 Evaluation Report available [here](#) on the Authority's website.

Updated 2 November 2020.