



## Business Plan 2020-2021

Victorian Pharmacy Authority

## Business Plan

The Business Plan of the Victorian Pharmacy Authority (the Authority) details the activities the Authority plans to undertake to achieve the Goals and Strategic Priorities in its Strategic Plan and performance targets outlined in the Statement of Expectations (SOE) from the Minister for Health.

It provides a summary of core business activities and priorities to be met to achieve the Authority's regulatory goals, initiatives aimed at improving regulatory performance and responses to any significant changes and challenges in the pharmacy environment.

COVID-19 significantly impacted the Authority's activities in the first half of 2020. This resulted in the suspension of some project work, including initiatives under the Statement of Expectations, to focus activities on the COVID-19 response and ensure the appropriate application of resources and necessary stakeholder engagement to these initiatives.

The Authority relaxed some regulatory requirements to ease the burden on licensees and registered premises during the COVID-19 pandemic and retained statutory fees at 2019-20 levels for 2020-21. Regulatory requirements and the Authority's risk-based approach will be continually reviewed considering further pandemic developments. COVID-19 may further impact planned activities.

## Our mission and objectives

The Authority aspires to achieve a safe pharmacy system that is responsive to community needs and interests.

The Authority is responsible for administration of the *Pharmacy Regulation Act 2010* (the Act). Specific responsibilities include:

- licensing a person to carry on a pharmacy business or a pharmacy department
- registering the premises of a pharmacy business, pharmacy department or pharmacy depot
- issuing standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots
- advising the Minister on any matters relating to its functions and when so requested by the Minister, to give to the Minister any information reasonably required
- keeping a public register
- any other activities conferred on the Authority by legislation

Underpinning all that we do is to act in the public interest to make the pharmacy system safe.

The Authority has set the following goals which form the basis of its Strategic Priorities:

Goal 1: A safe pharmacy system that responds to community needs

Goal 2: Informed stakeholders who engage with good regulatory practice

Goal 3: A sustainable, responsive and performance-focused Authority

Goal 4: National consistency of pharmacy regulation

The Authority's Strategic Plan was reviewed in March 2020 and is available at [www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au).

### **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 trends in non-compliance with relevant legislation and guidelines.
- 2020-21: Continue to implement recommendations of the 2017 Review of Pharmacy Business Licence Application and Renewal Processes in Victoria as outlined in the Authority's Statement of Expectations and communications.

### **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 or poor quality use of 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.

## Statement of Expectations for the Victorian Pharmacy Authority

Ministerial Statements of Expectations aim to improve regulatory governance and performance. The statements articulate government's priorities and objectives for each of its regulators. The Authority's current 2019/21 SOE and its response to the Minister are available on its website at [www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au).

The Authority's current SOE includes the following objectives:

### **Timeliness**

- Continue to implement recommendations of the *PharmConsult* Review of pharmacy business licence application and renewal processes including a program of risk-based audits of pharmacy business ownership and commercial arrangements.
- Identify further improvements to application processes to improve efficiency of regulatory practice and reduce regulatory burden for regulated entities.

### **Risk-based strategies**

- Enhance the Authority's existing pharmacy premises inspection and pharmacy business ownership audit programs to ensure these continue to be risk-based and outcome-focussed and better enable the Authority to target regulatory intervention to improve compliance.

### **Compliance related assistance and advice**

- Revise existing compliance related assistance to aid compliance with pharmacy legislation and guidelines by licensees and other pharmacists.

A copy of the Authority's Action Plan for implementation of the 2019/21 SOE is included at **Appendix 1**.

## Meeting the Authority's goals in 2020-21

### Goal 1: A safe pharmacy system that responds to community needs

- i. Issue and regularly review guidelines that reflect contemporary pharmacy practice and community needs.*
- ii. Conduct a Site Visit Program to ensure that pharmacies meet legislative requirements.*
- iii. Conduct a program to ensure that pharmacies are owned and controlled by registered pharmacists.*

#### *VPA Guidelines*

The Authority reviews its guidelines annually and consults with stakeholders regarding proposed amendments where possible.

- The Authority last issued revised guidelines effective 1 November 2019.
- In late 2019, the Authority commenced a process to issue standards pursuant to section 86 of the Act and plans to develop draft standards by 31 December 2020 for consultation with licensees. The 2020 review of the guidelines may be postponed to align with the development of standards. It is expected that some of the proposed standards may replace related existing guidelines and be supported by amended guidelines.

#### *Site Visit Program – pharmacy premises*

The Authority aims to inspect all registered premises at least every three years. A second tier of targeted inspections occurs on a risk basis following a change of ownership, in cases of new or altered premises, and for review following a previous unsatisfactory inspection.

- A target of 278 cyclical pharmacy visits was initially set for the 2020 *calendar year* to ensure that all pharmacies (including associated pharmacy depots and approved 'special circumstances' dispensing areas) undergo routine inspection at least every three years. This cohort included pharmacies subject to two successive review inspections in prior years.
- A target of 340 planned reviews was initially set for 2020 based on the identification of higher risk deficiencies in 2019 inspections.
- Due to the COVID-19 pandemic, the Authority suspended physical inspections and commenced a program of provisional remote inspections<sup>1</sup> on a risk basis in April 2020.

In 2020-21 we will:

- Continue to undertake provisional remote inspections on a risk basis, including changes of ownership, new or altered premises and in response to complaints, to reduce risks to public safety while restrictions due to COVID-19 continue to apply.

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<sup>1</sup> Pharmacies may be contacted by an authorised officer to arrange a remote inspection and Licensees or Pharmacists in Charge may be required to provide evidence of compliance with good pharmacy practice which may include photographs, copies of written procedures and other documentation.

Inspectors also enquire about physical distancing, infection control and business continuity measures implemented in response to COVID-19 and direct pharmacists to appropriate resources if required.

- Plan for the resumption of physical inspections based on a risk assessment considering factors such as pandemic status and restrictions, health and safety and government policy and directives.
- Undertake a comprehensive review of the risk register associated with compliance with legislation and good pharmacy practice in registered premises to ensure that all risks are adequately captured and assessed.
- Seek feedback from stakeholder organisations, such as the Pharmacy Board of Australia, pharmacy peak body organisations and Medicines and Poisons Regulation, on the risk-based focus of the Authority's inspection program. The Authority postponed the stakeholder consultation process (from the original target of 30 June 2020) in light of COVID-19. The review of the risk-based focus of the inspection program will now align with the review of guidelines and development of Authority standards.
- Develop standards for stakeholder consultation and Ministerial approval.
- Review and plan for the 2021 inspection program.
- Integrate the Australian Health Practitioner Regulation Agency (Ahpra) Practitioner Information Exchange (PIE) software platform into the Authority's database to facilitate the provision of better-quality pharmacist registration data, reducing risks associated with monitoring the registration status of licensees and pharmacists in charge.

#### *Pharmacy ownership – improvements to licence application and approval processes*

In 2017 the Authority engaged *PharmConsult* to review its licence application and renewal processes to ensure these are adequate in the contemporary pharmacy ownership environment. The Final Report of the *PharmConsult* review was published on 31 August 2017 and is available on the Authority's website [www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au).

The Authority is continuing to implement improvements to its processes aimed at ensuring that pharmacies are owned and controlled only by registered pharmacists. Further details can be found in the Authority's current SOE and on the website.

In 2020-21 we will:

- Continue to audit pharmacy business ownership and commercial arrangements to ensure such arrangements comply with the Act.
- Issue a report to stakeholders evaluating the first year of the pharmacy ownership audit program by 31 August 2020. Implement program improvements identified in the evaluation and consult with stakeholders to identify further improvements.
- Issue a report to stakeholders evaluating the second year of the pharmacy ownership audit program by 30 June 2021.
- Continue to undertake in-depth legal reviews of franchise agreements and complex service agreements on a risk basis to ensure such arrangements comply with the Act, requiring non-compliant arrangements to be amended to the Authority's satisfaction to ensure compliance.
- Continue to consult with our interstate counterparts to explore their experience and share information on detecting and dealing with undeclared ownership. This will be done via the Pharmacy Premises registering Authorities of Australia (PPRAA) group.

- Publish information on process changes, guidance documents and general information on compliance with the ownership provisions of the Act for stakeholders in communiqués and circulars.

## Goal 2: Informed stakeholders

- i. Maintain an informative stakeholder engagement plan to:*
  - a. promote good regulatory practice and educate pharmacists about compliance and risks; and*
  - b. inform stakeholders about the Authority's role and regulatory activities.*
- ii. Provide timely, robust information to the Minister, Department of Health and Human Services and other key agencies as required by law.*
- iii. Maintain and foster effective relationships with complimentary regulators and agencies.*

In 2020-21 we will:

- Continue to publish a quarterly circular for distribution to licensees and registered premises.
- Continue to publish communiqués for stakeholders on an ad hoc basis.
- Review and revise the Authority's self-audit form for publication on the website by 30 June 2021 to ensure it is an effective tool to assist licensees and pharmacists to comply with pharmacy legislation and guidelines. [2019/20 target delayed due to pandemic]
- Following consideration of stakeholder feedback, finalise and distribute to pharmacies a compliance and awareness aid to support the appropriate management of Schedule 8 poisons.
- Maintain links with educational institutions which includes delivering lectures on pharmacy legislation to pharmacy students at Monash Parkville, La Trobe Bendigo and RMIT.
- Continue to publish a quarterly performance report providing information on the Authority's activities and intended outcomes. The performance report includes information on applications received, performance against service standards, approvals issued, inspections conducted and information on common high-risk deficiencies, and panel hearings. Data will be reported to the Authority and included in quarterly circulars to stakeholders. The Authority will also report on performance against the key performance indicators outlined in its SOE within this reporting framework on an annual basis.
- Build on existing protocols supporting interaction with other regulators where possible to support a systematic approach to collaboration and information-sharing.
- Liaise regularly with the Department of Health and Human Services and the Office of the Minister for Health to keep them informed about the Authority's activities.

### Goal 3: A sustainable, responsive and performance-focused Authority

- i. Ensure the Authority's strategic and operational performance.*
- ii. Maintain the Authority's financial and information management capabilities.*
- iii. Plan for succession of Authority members and staff.*
- iv. Benchmark VPA processes and identify opportunities to continually improve regulatory performance.*

In 2020-21 we will:

- Engage an expert to:
  - advise on information management systems; and
  - assist with the development of a user requirement specification for the Authority's information management systems to facilitate:
    - Digital transformation
    - Improved record management
    - Improvements to the member database (registration & licensing)
    - Planning for the implementation of a customer relationship management platform/solution to make application processes more efficient and reduce regulatory burden
    - Transitioning 50% of licence/registration application forms to electronic formats by 30 June 2021
    - Improved remote working arrangements for staff working from home and undertaking inspections
    - An upgrade to the VPA website
- Resume recruitment of two pharmacist inspectors (one primarily for inspections of pharmacies, one for pharmacy departments).  
[The recruitment process was commenced in early 2020 but postponed due to the pandemic.]
- Conduct ongoing workforce planning to ensure the staffing needs of the Authority are met on an ongoing basis.
- Undertake an externally facilitated board self-assessment with the aim of identifying improvements in good governance.
- Continue to provide monthly management reports to the Authority on:
  - Performance against the Authority's work plan and implementation of internal audit recommendations, SOE improvements and other objectives.
  - Inspections conducted, licences and registrations granted, and approvals issued.
  - The Authority's financial position, performance against budget, bank reconciliation and investments.
- Continue to conduct risk management audits at least quarterly, reporting to the Audit and Risk Committee and the Authority.
- Ensure internal audit recommendations are implemented in a timely manner.
- Budget and fix Authority fees to ensure that revenue is sufficient to cover the cost of administering the Act.



#### Goal 4: National consistency of pharmacy regulation

- i. Provide leadership in the national consistency of pharmacy regulation and standards for pharmacy premises.*
- ii. Foster the recognition and influence of the VPA in key governmental, professional, educational and community forums.*

In 2020-21 we will:

- Continue to participate in and contribute to the work of the Pharmacy Premises Registering Authorities of Australia (PPRAA) group.
- Continue to host meetings of PPRAA.
- Continue to share information and protocols with interstate pharmacy premises regulators with the aim of adopting uniform, best-practice regulatory approaches and operational processes.
- Continue to support information-sharing between VPA inspectors and interstate pharmacy inspectors.
- Consult with interstate pharmacy premises regulators on the development of Authority standards.

Approved by the Victorian Pharmacy Authority

Date: 14 July 2020

## Appendix 1

# Victorian Pharmacy Authority Statement of Expectations ACTION PLAN: 1 July 2019 to 30 June 2021

The table below outlines the Victorian Pharmacy Authority's Statement of Expectations Action Plan 1 July 2019 to 30 June 2021.

Performance Improvement	Action	Performance Target
<p><b>Timeliness</b></p> <p>Continue to implement recommendations of the <i>PharmConsult</i> Review of pharmacy business licence application and renewal processes including a program of risk-based audits of pharmacy business ownership and commercial arrangements.<sup>1</sup></p>	<ul style="list-style-type: none"> <li>• Undertake pharmacy ownership audits.</li> <li>• Undertake pharmacy financial audits.</li> </ul>	<ul style="list-style-type: none"> <li>• Undertake 100 pharmacy ownership audits annually.</li> <li>• Undertake 10 pharmacy financial audits annually.</li> </ul>
<p><b>Timeliness</b></p> <p>Identify further improvements to application processes to improve efficiency of regulatory practice and reduce regulatory burden for regulated entities.</p>	<ul style="list-style-type: none"> <li>• Transition application forms to electronic formats.</li> <li>• Further develop existing application service standards into a more comprehensive Service Charter outlining the Authority's service commitment.</li> <li>• Send approval letters and licence/registration certificates to applicants by email at the time of issue.</li> <li>• Seek stakeholder feedback on application forms, application processes and service standards.</li> </ul>	<ul style="list-style-type: none"> <li>• Transition 50% of licence/registration application forms to electronic formats by 30 June 2021.</li> <li>• Develop a Service Charter for publication on the Authority's website by 31 December 2019.</li> <li>• Commence routinely sending approval letters and licence/registration certificates to applicants by email at the time of issue by 30 June 2020.</li> <li>• Host a stakeholder forum on application processes and service standards by 31 December 2019.</li> </ul>

<sup>1</sup> *PharmConsult* reviewed the Authority's licence application processes in 2017. Its recommendations included the introduction of a program of risk-based audits of pharmacy businesses which the Authority commenced in 2018. The program includes an ownership audit undertaken by officers of the Authority and, in selected cases, a financial review undertaken by a leading accounting firm on behalf of the Authority to ensure compliance with the Act.

Performance Improvement	Action	Performance Target
<p><b>Risk-based strategies</b></p> <p>Enhance the Authority's existing pharmacy premises inspection and pharmacy business ownership audit programs to ensure these continue to be risk-based and outcome-focussed and better enable the Authority to target regulatory intervention to improve compliance.</p>	<ul style="list-style-type: none"> <li>• Seek feedback from stakeholder organisations, such as the Pharmacy Board of Australia, pharmacy peak body organisations and Medicines and Poisons Regulation Branch, on the risk-based focus of the Authority's inspection program.</li> <li>• Introduce a declaration by licensees at renewal time of compliance in high-risk areas.</li> <li>• Modify the program of pharmacy business ownership audits to clearly differentiate the audit phase from any resulting investigations into pharmacy business ownership or commercial arrangements. This will facilitate publication of audit outcomes to promote compliance with the ownership provisions in the Act.</li> </ul>	<ul style="list-style-type: none"> <li>• Feedback will be sought 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 will then be communicated to stakeholders.</li> <li>• Renewal applications will include a declaration of compliance in high-risk areas commencing with 2020 renewals (by 30 June 2020).</li> <li>• The Authority's pharmacy business audit program will include a clearly differentiated audit phase and post-audit investigation phase by 31 December 2019.</li> </ul>
<p><b>Compliance related assistance and advice</b></p> <p>Revise existing compliance related assistance to aid compliance with pharmacy legislation and guidelines by licensees and other pharmacists.</p>	<ul style="list-style-type: none"> <li>• Review and revise the Authority's self-audit form to ensure it is an effective tool to aid compliance by licensees and other pharmacists with pharmacy legislation and guidelines.</li> <li>• Provide current relevant guidance to licensees following inspections.</li> </ul>	<ul style="list-style-type: none"> <li>• The self-audit form will be reviewed and revised for publication on the Authority's website by 30 June 2020.</li> <li>• Inspection-related guidance documentation will be reviewed and revised by 31 December 2019 with a view to expanding the range of guidance provided.</li> </ul>

	<ul style="list-style-type: none"><li>• In consultation with Medicines and Poisons Regulation Branch and pharmacy peak bodies, develop a compliance and awareness aid for the management of Schedule 8 poisons in pharmacies, recognising existing levels of non-compliance and the significant risks to public safety.</li></ul>	<ul style="list-style-type: none"><li>• A compliance and awareness aid for the management of Schedule 8 poisons in pharmacies will be developed in consultation with stakeholders, published and distributed to pharmacy premises by 30 June 2020.</li></ul>
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