



Statement of Regulatory Approach: Risk-Based Approach to Inspections of Registered Premises

Victorian Pharmacy Authority

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TABLE OF CONTENTS

1.	PURPOSE AND SCOPE	4
2.	REGULATORY FRAMEWORK.....	5
2.1	What does the regulatory framework include?	5
2.2	What are the VPA's regulatory functions?.....	5
2.3	What are the VPA's regulatory powers?.....	5
2.4	Which regulatory bodies operate in the pharmacy sector?	6
3.	REGULATORY APPROACH	8
3.1	Vision and purpose	8
3.2	Objectives and outcomes	8
3.3	Guiding principle and values	9
3.4	Risk-based approach to regulation	9
3.5	Risk-based decision-making.....	10
4.	INSPECTION PROGRAM	12
4.1	What is the purpose of the VPA's inspection program?	12
4.2	How is the VPA's risk-based approach applied in relation to the VPA's inspections?	12
4.3	What is the focus of inspections?	12
4.4	What are the types of inspections that the VPA may undertake?	13
4.5	What is involved in an inspection?	14
4.6	What are the possible outcomes from an inspection?	14
5.	PROACTIVE COMPLIANCE	16
	GLOSSARY	17

TABLE OF ABBREVIATIONS

ABBREVIATION	FULL TERM
Act	<i>Pharmacy Regulation Act 2010</i>
AHPRA	Australian Health Practitioner Regulation Agency
APC	Australian Pharmacy Council
Authority	The body established under the <i>Pharmacy Regulation Act 2010</i> with functions and powers under the <i>Pharmacy Regulation Act 2010</i>
HCC	Health Complaints Commissioner
PBS	Pharmaceutical Benefits Scheme
Pharmacy Board	Pharmacy Board of Australia
R&N	Rectify and notify
R&R	Rectify and report
regulatory framework	<i>Pharmacy Regulation Act 2010, VPA Standards and VPA Guidelines</i>
Standards Inspection	An inspection undertaken to assess compliance with the Act, VPA Standards and VPA Guidelines
TGA	Therapeutic Goods Administration
VPA	The organisation and staff that support the Authority to administer the <i>Pharmacy Regulation Act 2010</i>
VPA Guidelines	Current policies of the VPA in relation to matters covered by Standards issued under the <i>Pharmacy Regulation Act 2010</i>
VPA Standards	Standards issued under the <i>Pharmacy Regulation Act 2010</i>

1. PURPOSE AND SCOPE

The Victorian Pharmacy Authority (**VPA**) is the regulator under the *Pharmacy Regulation Act 2010* (**the Act**).

The VPA's functions under the Act include:

- the regulation of pharmacy businesses, pharmacy departments and pharmacy depots through licensing and registration requirements under the Act;
- ensuring that all Victorian pharmacies are owned, operated and controlled by registered pharmacists in accordance with the Act;
- ensuring that registered premises meet the requirements of the Act, standards issued by the VPA (**the VPA Standards**), and guidelines which support the Standards and the requirements of the Act (**the VPA Guidelines**).

This Statement of Regulatory Approach concerns the VPA's inspection program, which is an important component of the VPA's regulatory activities. The purpose of the program is to assess compliance of registered premises with the Act, the VPA Standards and the VPA Guidelines. This, in turn, helps to ensure that the facilities, equipment, security, management and operation of registered premises comply with the Act and good pharmacy practice.

The Statement of Regulatory Approach provides an overview of the regulatory approach taken by the VPA when carrying out its regulatory activity, including inspections of registered premises. It is also intended to support regulated entities to develop a strong and effective compliance culture.

In summary, the Statement of Regulatory Approach covers the following:

- *Regulatory framework*: It provides an overview of the regulatory framework administered by the VPA and explains the role of other bodies involved in the regulation of the pharmacy sector.
- *The VPA's regulatory approach*: It sets out the VPA's vision & purpose, objectives & outcomes and guiding principle & values, which inform the manner in which regulatory activities are undertaken by the VPA. It also explains the VPA's risk-based approach to regulation, which involves using the risk associated with non-compliance with the regulatory framework to guide the prioritisation and focus of the VPA's regulatory activity.
- *The VPA's inspection program*: It describes the VPA's inspection program for registered premises and explains how the VPA's risk-based approach to regulation applies to the program.

2. REGULATORY FRAMEWORK

Key elements of the regulatory framework administered by the VPA form important context for the VPA's regulatory activity, including its inspection program.

2.1 What does the regulatory framework include?

The regulatory framework administered by the VPA comprises the following regulatory instruments:

- *Pharmacy Regulation Act 2010*: The Act sets out the core regulatory requirements applicable to pharmacy businesses, pharmacy departments and pharmacy depots. It also provides the powers and tools available to the VPA to carry out its regulatory functions.
- *Victorian Pharmacy Authority Standards*: The VPA Standards are issued by the VPA under the Act and specify mandatory requirements that apply to licensees and registered premises. The Standards relate to areas associated with the management of registered premises that pose a particularly high risk to public safety.
- *Victorian Pharmacy Authority Guidelines*: The VPA Guidelines support the Standards and the requirements of the Act. They represent current policies of the VPA in relation to matters covered by the Standards. They should be read in conjunction with the VPA Standards, as well as guidelines issued by the Pharmacy Board of Australia and by pharmacy professional organisations.

The above regulatory instruments are collectively referred to in this Statement of Regulatory Approach as “**the regulatory framework**”.

2.2 What are the VPA's regulatory functions?

The VPA has the following main functions under the Act:

- *Licensing*: to license an individual, company and other types of legal entities to carry on a pharmacy business or a pharmacy department.
- *Registration*: to register the premises of a pharmacy business, pharmacy department or pharmacy depot.
- *Standards*: to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots.
- *Advice and information*: to advise the Minister on any matters relating to the VPA's functions and provide information to the Minister.
- *Public register*: to keep a public register of all licensees and registered premises.

2.3 What are the VPA's regulatory powers?

The VPA has the following key powers under the Act that may be relevant in the context of inspections of registered premises:

- *Inspections:* Inspections of registered premises may be carried out by authorised officers of the VPA to determine whether or not the regulatory framework is being complied with.
- *Investigations:* The VPA may investigate a matter where a person has submitted a notification to the VPA about a range of matters, including that a licensee has contravened the Act or the VPA Standards or a registered premises does not meet the requirements of the Act or the VPA Standards. The VPA may also investigate a matter on its own initiative, without notification.
- *Conditions:* The VPA may impose any condition on a licence that it thinks appropriate. Some standard conditions imposed by the VPA are:
 - A condition stating that registration has been granted subject to a satisfactory site inspection.
 - A condition stating that the licensee must undertake a self-audit of the pharmacy using the VPA self-audit tool at a frequency determined by the VPA.
 - A condition requiring the licensee to submit to a reinspection of the pharmacy at their cost.
- *Interview:* The VPA may request a licensee to attend a meeting with members of the Authority to discuss and obtain further information about non-compliances with the regulatory framework identified during an inspection.
- *Revocation of licence and registration:* The VPA has power to revoke a licence or registration on a variety of grounds, including in cases where there has been a failure of good pharmacy practice at registered premises that presents a serious risk to public health and safety.
- *Panel hearings:* The VPA may convene a panel to hear a matter which has been the subject of an investigation. The panel has power to caution or reprimand the licensee or registration holder, to insert conditions into the licence or registration, or to revoke the licence or the registration of premises. Under the Act, the decision of a panel is the decision of the Authority.

2.4 Which regulatory bodies operate in the pharmacy sector?

An overview of the key regulatory bodies and their main areas of responsibility are set out in the table below.

BODY	MAIN AREA OF RESPONSIBILITY
VPA	The VPA is primarily responsible for the regulation of pharmacy premises and ownership in Victoria.
Pharmacy Board of Australia (Pharmacy Board)	The registration of pharmacists and the handling of complaints about the health, conduct or performance of a pharmacist is the responsibility of the Pharmacy Board. The Pharmacy Board is supported by AHPRA.

BODY	MAIN AREA OF RESPONSIBILITY
Australian Health Practitioner Regulation Agency (AHPRA)	AHPRA supports National Boards (including the Pharmacy Board) in their role of protecting the public and setting standards and policies that all registered health practitioners must meet across Australia. AHPRA and the National Boards work together to register and renew registration of health practitioners and, where required, investigate complaints or concerns regarding health practitioners.
Department of Health (Vic)	<p>The Department of Health is responsible for the administration of regulation in Victoria relating to drugs, poisons and controlled substances.</p> <p>The Department of Health is also responsible for the administration of pharmacy-administered vaccination programs. Pharmacists must provide immunisation services in accordance with the applicable regulatory requirements.</p>
Health Complaints Commissioner (HCC)	The HCC is an independent Victorian body that resolves complaints about the provision of health services and the handling of health information in Victoria by registered health services providers, including pharmacists.
Department of Health and Aged Care (Cth)	<p>The Department of Health and Aged Care administers the Pharmaceutical Benefits Scheme (PBS). Among other things, the scheme regulates pharmacy operations in relation to the supply of items listed in the PBS.</p> <p>The Therapeutic Goods Administration (TGA) is the national agency responsible for regulating therapeutic goods, including medicines and medical devices that may be supplied by pharmacists. The TGA oversees a range of rules in relation to therapeutic goods, including their manufacture, import and export, labelling and packaging, and advertising.</p>

Where necessary and in accordance with applicable legislation, the VPA shares information and collaborates with the Pharmacy Board, AHPRA, the Victorian Department of Health and interstate counterparts to enhance regulatory outcomes in the sector.

3. REGULATORY APPROACH

The main aspects of the VPA's regulatory approach that inform the VPA's regulatory activities, including its inspection program, are explained below.

3.1 Vision and purpose

The VPA's vision is for a safe pharmacy system that is responsive to and satisfies community needs and interests.

The purpose of the VPA's regulatory activities is to protect the public by ensuring that:

- pharmacy businesses are owned, controlled and operated only by registered pharmacists; and
- pharmacy premises meet minimum standards and are fit for purpose.

3.2 Objectives and outcomes

In carrying out its statutory functions, the VPA seeks to achieve the following regulatory objectives, which are aimed at reducing the risk of harm and protecting consumers and the public at large:

- to control who may own and operate pharmacy businesses in Victoria; and
- to 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 specific outcomes the VPA is seeking to achieve through its regulatory activities are:

- the Victorian community has ready access to a safe pharmacy service; and
- pharmacy owners and operators are aware of and comply with their legislative and regulatory obligations through engagement with the VPA.

The VPA's regulatory activities help to secure these outcomes by mitigating the following main risks:

- the risk that pharmacies are owned and operated by persons other than registered pharmacists and pharmacy services are not provided in accordance with the regulatory framework and by adequately trained personnel;
- increased risk of dispensing errors and adverse drug events due to the pharmacy layout being inconsistent with safe pharmacy practice and/or a lack of suitable equipment, operational procedures and management;
- harm to members of the community due to poor quality medicines including, for example, compounded medicines that do not meet quality standards and medicines that have not been stored at a suitable temperature;

- 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.

3.3 Guiding principle and values

The VPA's guiding principle is to act in the public interest. The values that underpin all of the VPA's activities are:

- *Responsiveness*: The VPA will be responsive to complaints and enquiries as well as emerging risks and industry developments that are relevant to administration of the regulatory framework and will operate in an agile, flexible and timely manner.
- *Integrity*: The VPA will act with honesty and with integrity to ensure that any real or perceived conflicts of interest are avoided and appropriately managed.
- *Impartiality*: The VPA will discharge its regulatory functions in a fair, neutral and objective manner.
- *Accountability*: The VPA is committed to openness and transparency in its decision-making processes and regulatory actions and welcomes feedback so that it can enhance regulatory performance.
- *Respect*: The VPA will undertake its functions in a respectful, considerate and courteous manner when interacting with its stakeholders and the public.
- *Leadership*: The VPA will show vision, use effective education and communication to enhance outcomes, and commits to keeping abreast of sectoral developments.
- *Human Rights*: The VPA will take into account human rights of stakeholders and the general public in the performance of its regulatory functions.

3.4 Risk-based approach to regulation

There is a range of compliance obligations imposed on licensees and registered premises under the regulatory framework. These compliance obligations are set out in the VPA Standards and elaborated in the VPA Guidelines. In addition, licensees and registered premises are expected to follow good pharmacy practice.

While all compliance obligations imposed under the regulatory framework serve an important purpose, there can be differences in the level of risk associated with any given instance of non-compliance. In addition, there are many entities that are regulated by the VPA. Some pose a higher risk to compliance with the regulatory framework than others. Therefore, the VPA uses a risk-based approach to regulation to ensure that the objectives underlying the regulatory framework are met whilst avoiding undue regulatory burden on regulated entities.

In practice, a risk-based approach means that the VPA focuses its regulatory activities and resources on compliance areas and regulated entities where the relative risks of possible or actual non-compliance are greatest – that is, where the likelihood and consequence of non-compliance with the regulatory framework are the greatest. The VPA considers a range of risk criteria that relate to the specific compliance obligation that has or may have been breached, the actual or possible harm associated with non-compliance, and compliance history and disposition of the relevant regulated entity who is responsible for the breach.

The risk-based approach also helps the VPA to identify the appropriate regulatory response. Generally, the higher the risk associated with non-compliance, the more serious, resource-intensive and timely the regulatory response by VPA. Comparatively less time, effort and resources will be dedicated to regulated entities and compliance areas where the compliance risks are relatively low.

3.5 Risk-based decision-making

The VPA considers three sets of parameters to assess the relative risk of non-compliance in the context of its various regulatory functions; namely:

Nature of non-compliance: The VPA considers whether the breach relates to good pharmacy practice, the VPA Standards and/or the Act. The VPA also considers the number of non-compliances. The relative risk associated with non-compliance with the Standards and the Act is higher compared to non-compliance with good pharmacy practice. Similarly, the risk is greater for a larger number of non-compliances.

NATURE OF NON-COMPLIANCE			
LOW RISK	MEDIUM RISK	HIGH RISK	EXTREME RISK
No instances of non-compliance relating to VPA Standards. Limited instances of non-compliance relating to good pharmacy practice only	Some instances of non-compliance relating to VPA Standards and good pharmacy practice	Significant non-compliance with the VPA Standards and non-compliances may recur over successive inspections	Widespread non-compliance with requirements of the Act and/or VPA Standards

- *Consequences of non-compliance:* The VPA also considers the relative impact of non-compliance, which is assessed in light of the VPA’s vision, goal, objectives and outcomes. The more significant the consequences of non-compliance, the greater the need for regulatory intervention.
- *Risk profile of regulated entity:* The VPA also considers the profile of the regulated entity, particularly factors about the regulated entity that may increase the likelihood of non-compliance in the future. Compliance history and the general attitude of a regulated entity towards compliance is assessed. The greater the likelihood of non-compliance, the greater the need for regulatory intervention.

The three sets of factors are combined to determine the overall risk assessment and regulatory response. Set out below is a summary of the general regulatory responses that correspond to each level of relative risk.

Response Level 1	Low risk	Satisfactory and encourage continuing compliance
Response Level 2A	Medium risk	Room for improvement
Response Level 2B	High risk	Significant room for improvement
Response Level 3	Extreme risk	Refer to Authority

The next section explains how this risk-based approach is applied in the context of the VPA's inspection program.

4. INSPECTION PROGRAM

The key elements of the VPA's inspection program are outlined below, including the manner in which the VPA applies its risk-based approach to inspections.

4.1 What is the purpose of the VPA's inspection program?

The VPA's inspection program plays a critical role in promoting and ensuring compliance with the regulatory framework. While inspections are used to determine whether or not a registered premises complies with the Act, the VPA Standards and the VPA Guidelines, the primary purpose of inspections is to support licensees and holders of registered premises to understand and comply with the requirements of the regulatory framework.

4.2 How is the VPA's risk-based approach applied in relation to the VPA's inspections?

In summary, the VPA uses its risk-based approach to:

- identify when certain inspections are triggered;
- target compliance areas for inspection; and
- determine the outcome from an inspection.

4.3 What is the focus of inspections?

Inspections focus on compliance with the Act, the VPA Standards and the VPA Guidelines, referred to as a "**Standards Inspection**" in this document. However, the scope of an inspection may depend upon the type of inspection (see below for types of inspection).

In general terms, applying the risk-based approach, the following high-risk issues could be assessed during a Standards Inspection:

- *Premises*: Premises are secure and maintained in a clean, hygienic and organised, uncluttered state.
- *Dispensary*: The dispensary is maintained as a private area, dedicated to tasks associated with the dispensing, supply and compounding of medicines and secure storage of medicines and patient records. Prescription medicines are appropriately stored and there is adequate temperature monitoring of drug refrigerators.
- *Management of S8 poisons*: Safes for Schedule 8 poisons comply with legislation and provide adequate storage for S8 poisons on hand at all times and facilitate their accurate selection. Records for S8 poisons are in accordance with drugs and poisons legislation. Medicinal cannabis is an area of current focus.
- *Complex compounding*: Complex compounding (including sterile and medicinal cannabis compounding) is undertaken in accordance with relevant legislation and good pharmacy practice.

- *Staff:* There are enough suitably qualified and trained staff to support service demands and the safe and effective provision of pharmacy services.

4.4 What are the types of inspections that the VPA may undertake?

There are three main types of inspections that are undertaken by the VPA:

- *Proactive inspections:* Proactive inspections are planned and routine inspections for a known cohort of registered premises that are identified using the VPA's risk-based approach. The proactive inspections are used to ensure that each registered premises is inspected at least every three years.
- *Reactive inspections:* Reactive inspections are triggered by complaints or notifications that are made under the Act. Where necessary, the VPA uses its risk-based approach to triage and prioritise its reactive inspections.
- *Targeted inspections:* Targeted inspections are reserved for systemic or emerging risks, which may be undertaken in collaboration with other regulatory bodies.

More details about each type of inspection are set out in the table below. The focus of an inspection will differ depending upon the type of inspection and the particular context in which the inspection is undertaken.

TYPE OF INSPECTION	DESCRIPTION
<i>PROACTIVE INSPECTIONS</i>	
Routine	Each registered premises is routinely inspected at least every three years.
Risk-based	Inspections of registered premises are triggered when the following circumstances exist, based on relative risk: <ul style="list-style-type: none"> - New premises - Change of ownership - Altered premises
Random	Registered premises are randomly selected for inspection, including premises that may have been inspected during the previous 3 years.
<i>REACTIVE INSPECTIONS</i>	
Complaints	Inspections may be triggered by a complaint.
Notifications	Inspections may be triggered by a notification made under the Act.
Review	There are two types of review inspections – inspector-initiated review inspections and reinspection of compliance issues identified following a panel hearing (imposed as a condition by the panel).

TYPE OF INSPECTION	DESCRIPTION
	<p>Inspector-initiated review inspections may occur following a prior inspection to ensure that issues identified in the initial inspection have been rectified or compliance not regressed.</p> <p>Review reinspections may also occur to address compliance issues identified during a panel hearing.</p>
<i>TARGETED INSPECTIONS</i>	
Systemic and emerging risks	Targeted inspections may occur to address systemic and emerging risks.

4.5 What is involved in an inspection?

Officers who are authorised under the Act undertake inspections of registered premises to monitor compliance and support licensees to assess compliance with the regulatory framework. The authorised officers rely upon powers of entry to undertake the inspection.

Following an inspection, the licensee will be issued with a letter, which includes important instructions about the outcomes and action required by the licensee. The letter will attach the inspection report, which summarises any non-compliances identified during the inspection and the outcome from the inspection.

Authorised officers also undertake inspections of other places where medicines are supplied, compounded or dispensed, for example where the VPA has approved registered pharmacists in special circumstances under the Act.

4.6 What are the possible outcomes from an inspection?

The possible outcomes from an inspection are summarised below:

- *Satisfactory and encourage continuing compliance (Support letter):* A support letter notes that no non-compliances were identified during the inspection and informs the licensee that the self-audit tool on the VPA website can be used to assess and assure ongoing compliance with the regulatory framework.
- *Rectify & notify letter (R&N letter):* An R&N letter identifies the non-compliances identified during the inspection and requires the licensee to certify that the non-compliances have been rectified. The inspector will also choose one of following three options for self-audit by the licensee, which will be identified in the R&N letter:
 - recommend a self-audit;
 - require a self-audit twice a year, which must be stored at the relevant pharmacy; or
 - require completion of a self-audit and the actions and next steps must be sent to the VPA.

- *Rectify and report (R&R letter)*: An R&R letter identifies the non-compliances identified during the inspection and requires a report to be provided to the VPA by the licensee detailing how the non-compliances have been rectified. Evidence must be included in the report to demonstrate compliance, such as photographs or other documentary evidence. The R&R letter will include one of the three self-audit options identified above, which has been chosen by the inspector.
- *Refer to Authority*: In cases where serious and/or extensive non-compliances have been identified during an inspection involving breaches of the VPA Standards that would endanger public safety, have occurred repeatedly or where the licensee's response to an R&R letter is unsatisfactory, the matter will be referred to the Authority, after the licensee has been provided with an opportunity to be heard first. The inspection report and any response from the licensee are presented to the Authority for a decision on action, which may include an interview or panel hearing.

The table below summarises the possible outcomes from an inspection based on the relative risk associated with non-compliance detected during an inspection.

RESPONSE LEVEL	OUTCOME
Response level 1	Support letter
Response Level 2A	Rectify & Notify
Response level 2B	Rectify & Report
Response level 3	Refer to Authority

5. PROACTIVE COMPLIANCE

The VPA is committed to working with licensees and registered premises to support their efforts to comply with the regulatory framework, including in the context of the VPA's inspection program. Ultimately, licensees and registered premises are responsible for ensuring compliance with the regulatory framework.

Proactive steps by regulated entities to identify and address any potential or actual non-compliance avoids the need for the VPA to take regulatory action. This can be achieved through the self-audit tool on the VPA's website. Each entity covered by the framework is encouraged to consider and review their regulatory compliance through regular review of their policies, systems, processes and practices using the self-audit tool.

GLOSSARY

TERM	DEFINITION
good pharmacy practice	In relation to good pharmacy practice, the VPA recognises the standards, codes, guidelines and policies issued by the Pharmacy Board of Australia and has regard to standards, codes and guidelines issued by the Pharmaceutical Society of Australia, The Society of Hospital Pharmacists of Australia, Victorian Department of Health and Therapeutic Goods Administration
pharmacy	premises in or from which a registered pharmacist supplies, compounds or dispenses medicines to the public and includes the part of the premises where the registered pharmacist sells or offers to sell goods of any kind, but does not include a pharmacy department or pharmacy depot
pharmacy business	a business carried on at a pharmacy and includes the business of providing pharmacy services and that part of the business where goods of any kind are sold or offered to be sold but does not include a pharmacy department or pharmacy depot
pharmacy department	the part of the premises of a registered funded agency, registered community health centre, private hospital or privately operated hospital within the meaning of the <i>Health Services Act 1988</i> set aside for supplying, compounding or dispensing medicines on order or prescription to patients and staff of the agency, registered community health centre or hospital
pharmacy depot	premises at which— (a) written prescriptions for the supply, compounding or dispensing of medicines may be left for a pharmacist; (b) medicines supplied, compounded or dispensed by a registered pharmacist may be left for collection by or on behalf of the person to whom they are addressed
pharmacy services	includes— (a) the supply, compounding or dispensing of medicines; and (b) advice and counselling on the effective and safe use of medicines
registered premises	premises of a pharmacy business or a pharmacy department that have been registered under section 45 of the Act or a pharmacy depot that has been registered under section 48 of the Act.