Our Risk-Based Approach to Regulation

The Authority has received Statements of Expectation from the Minister for Health since May 2015. Ministerial Statements of Expectations aim to improve regulatory governance and performance. The Authority also participated in a performance audit of health portfolio regulators carried out by the Victorian Auditor-General's Office in 2014-2015.

Through these processes the Authority has reviewed its activities to improve the administration and enforcement of regulation and engaged in a process of ongoing review.

The Authority administers the *Pharmacy Regulation Act 2010* ("the Act") which regulates pharmacy businesses, pharmacy departments and pharmacy depots. The Authority's vision is for a safe pharmacy system that is responsive to community needs and interests, and its guiding principle is to act in the public interest.

The goals of the Authority are:

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 Authority
Goal 4: National alignment of pharmacy regulation

To achieve these goals the Authority employs a proactive risk-based approach to regulation. Regulatory activities are prioritised towards the most significant risks while aiming to minimise the regulatory burden on licensees. This approach helps ensure a safe pharmacy system and informed stakeholders.

Further information about the Authority's regulatory approach and outcomes can be found in the following documents available on the VPA website at www.pharmacy.vic.gov.au:

- Performance Measurement Framework published within the Quarterly Performance Report
- Ministerial Statements of Expectations and responses

Applications

The Act requires the owners of pharmacy businesses and pharmacy departments to hold a licence and the premises of pharmacy businesses, pharmacy departments and pharmacy depots to be registered.

Applications for pharmacy business licenses, registration of premises and other approvals are considered low-risk when they clearly meet all requirements of the Act and the Authority's guidelines. The Authority delegates the power to issue approvals in respect of low-risk applications to authorised officers of the Authority.

Where possible, the Authority will continue to rely on self-certification by pharmacists to expedite licensing and registration to enable trading to commence without delay.

High-risk (outside delegation) applications are referred to the next monthly meeting of Authority members for a decision.

Complex licence applications

The Authority applies a risk-based approach to the assessment of licence applications. In the case of complex applications, where there are third party commercial arrangements such as franchise agreements or arrangements with banner groups, legal advice may be obtained regarding the proposed commercial arrangements to ensure they do not provide a third party with a proprietary interest in the pharmacy business or undue influence over the operation of the pharmacy.

The Authority may require applicants to provide documents such as a bill of sale, mortgage, lease or other commercial arrangements in respect of a pharmacy business to ensure compliance with the Act.

The Authority's enhanced scrutiny of licence applications involving complex commercial arrangements is ongoing.

The Authority recently engaged PharmConsult to conduct a review of licence application processes. It is expected that further change including amendments to application forms and the introduction of an audit program to ensure ongoing compliance with the Act will be implemented.

Inspection program

The Authority conducts a site visit program that meets legislative requirements and our goals.

Authority pharmacists are authorised to inspect pharmacies, pharmacy departments and pharmacy depots to ascertain whether provisions of the Act are being met. They are required to gather information with reference to the Act, the Guidelines and other relevant legislation and standards in order for the Authority to be satisfied that premises comply with good pharmaceutical practice. Relevant legislation includes:

- *Pharmacy Regulation Act 2010*
- *Drugs, Poisons and Controlled Substances Act 1981*
- Drugs, Poisons and Controlled Substances Regulations 2017

The Authority's Guidelines represent the current policies of the Authority and any departure from them must be justified on a case by case basis.

The Authority recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board of Australia. The Authority has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia.

Premises inspections allow Authority pharmacists to assist licensees and pharmacists to meet their regulatory obligations. Authority pharmacists also reinforce the Guidelines and encourage licensees to self-audit their premises.

Inspections are intended to be informative and not punitive, aiding in the early identification and rectification of matters of concern. Inspectors examine security, workload, privacy, equipment, fittings, compliance with legislation and pharmacy practice standards, and pay particular attention to opioid replacement therapy and dose administration aids.

Following an inspection, the Authority issues an inspection report. The inspection report provides a list of actions that need to be taken in order to comply with legislation and guidelines. If a licensee does not agree with the report they may refer the matter to the Authority in writing detailing the reasons. In most cases the licensee or authorised pharmacist is required to certify that actions have been taken to rectify the deficiencies listed.

Each premises is routinely inspected at least every three years. A second tier of targeted inspections occurs on a risk basis in the following circumstances:

- Change of ownership
- New or altered premises
- Review following unsatisfactory inspection

In the first two circumstances, conditional approvals are granted based on information provided to the Authority and self-certification by applicants. These conditions are removed upon satisfactory inspection. Reviews are conducted on a risk-basis ideally within one year of the previous inspection. Inspection comments considered to be high risk are reviewed annually to determine which premises are reviewed, and inspectors meet quarterly to consider statistics obtained from inspections to determine the focus of future inspections.

Regulatory risks relating to inspections are included in the Authority's risk database to assess the consequences and likelihood of these risks occurring. Risk assessments are used to inform prioritisation of Authority activities including premises reviews and education, with a focus on higher risk and frequently noted deficiencies.

The Authority responds to developments in the profession and changing community needs by continually reviewing its inspection protocols and guidelines and will continue to consult with stakeholders on development of new inspection protocols.

Investigations & panel hearings

The Authority may investigate a matter relating to a licence or premises registration. This may result from an inspection revealing serious deficiencies. In the case of an investigation, a licensee is given the opportunity to respond to the Authority to provide an explanation and detail steps taken to rectify deficiencies before any further action is taken.

Following an investigation, the Authority may decide to take no further action, request the licensee(s) to attend an Authority meeting to discuss the issues, or to convene a panel hearing.

A panel convened by the Authority to hear a matter which has been the subject of an investigation may result in:

- a condition(s) being placed on a licence and/or premises registration;
- a licence and/or premises registration being revoked;
- cautioning or reprimanding of the licensee or registration holder;
- the licence or premises registration continuing.

The Authority may also direct that a site re-inspection be undertaken. In such cases a fee is billed to the pharmacy.

Panel hearings are reserved for matters involving serious failures of good pharmacy practice, alleged breaches of legislation and failures of security and hygiene.

The Authority has resolved to take a firm approach to deficiencies related to drugs and poisons legislation as these present a high risk to the public, with Schedule 8 poison-related deficiencies invariably resulting in a panel hearing. Matters involving alleged breaches are routinely referred to the Department of Health and Human Services, Drugs and Poisons Regulation (DPR) and the Authority works collaboratively with DPR to address the issue of ongoing breaches.

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