Communiqué

31 August 2017

The Victorian Pharmacy Authority (the "Authority") met on 8 August 2017 at the Authority offices.

Complex licence applications

In May 2017, the Authority received advice from the Minister for Health regarding the enforcement of restrictions on pharmacy ownership specified in the *Pharmacy Regulation Act 2010* (the Act). For complex applications, the Minister advised the Authority to examine a suite of documents including bill of sale, mortgage, lease and other commercial arrangements to ensure compliance with the ownership and undue influence provisions of the Act.

Licence applications may be classified as complex if they involve third party commercial arrangements such as franchise agreements or arrangements with banner groups. Complex applications will, in the first instance, be referred to a monthly meeting of the Authority. The Authority will determine if additional information is required from the applicant.

Documents obtained from applicants may be examined by the Authority's lawyers and/or accountants to ensure that a third party does not have an undue influence or proprietary interest in the pharmacy business.

Applicants who lodge a complex licence application may experience an extended processing period and are advised to plan accordingly.

A document summarising the Authority's approach to regulation has been revised in light of these process changes. The updated version is now available on the Authority's website here.

Review of pharmacy business licence application and renewal processes

In December 2016, the Authority commissioned PharmConsult to conduct an external review of its licence application and renewal processes. The objective of the review was to ensure that these processes are adequate to determine compliance with the *Pharmacy Regulation Act 2010*.

It is expected that the review will result in further changes to the Authority's processes to allow it to ensure that the complex commercial arrangements common in the contemporary pharmacy ownership environment comply with the ownership restrictions of the Act.

PharmConsult consulted with pharmacy owners, representatives of pharmacy banner groups, pharmacy organisations, and the Department of Health and Human Services. Consumer groups were not consulted as the review related to matters that would not have a direct effect on public safety or pharmacy services to the public. The Review did not include financial modelling of the impacts of proposed changes. This is expected to be undertaken as the Authority considers the recommendations of the review and selects actions for implementation.

Licensees and other stakeholders will be given adequate notice of any proposed changes arising from the recommendations.

A copy of the Final Report of the PharmConsult review is available on the Authority's website here.

Panel hearings

There were five Panel Hearings in July 2017 into allegations that licensees had failed to meet their responsibilities to comply with the *Pharmacy Regulation Act 2010* and/or good pharmacy practice at registered premises. Panel Hearings are held under sections 57 to 59 of the Act. The decision of the panel is the decision of the Authority.

Case 1

Numerous discrepancies in accounting for Schedule 8 poisons formed part of this hearing. Of note, as also mentioned in Case 3 (below), was a substantial deficit in the volume of methadone concentrate 25 mg/5 mL when compared with the register. Numerous other matters were identified which required remedial action by the licensee. These were:

- Outdated and inadequate references
- Display of Schedule 3 poisons that breached the regulations and guidelines
- Temperature monitoring and control
- Incident records
- Equipping
- Barcode scanning
- Labelling of take-away methadone
- Documentation of dose administration aids (DAAs)

The licensee was reprimanded and a condition inserted into the licence to carry on the pharmacy business that required a self-audit to be conducted quarterly for 12 months and the results, accompanied by a statutory declaration in each instance, submitted to the Authority.

The licensee was required to produce written evidence that references and equipment were up to date. Workload statistics, packing records of DAAs, results of barcode scanning and certification that pharmacists had complied with the Policy for maintenance pharmacotherapy for opioid dependence were to be provided.

The Authority subsequently ordered a re-inspection at the licensee's cost.

Case 2

Storage and recording deficiencies of Schedule 8 poisons were part of this hearing. There were also failures to maintain the prescribed references and inadequacies in recording DAAs. Other deficiencies were:

- Poor lighting in several parts of the premises
- Equipping
- Management of the pharmacotherapy program
- Temperature monitoring
- Signs and displays
- Privacy

The licensee was cautioned and ordered to complete a self-audit to be accompanied by a statutory declaration attesting to its veracity.

Case 3

A significant number of discrepancies in the recording and reconciliation of Schedule 8 poisons was the basis of this hearing. In particular, transactions of methadone concentrate 25 mg/5 mL were grossly deficient. The licensees had also made alterations to the premises by creating a compounding laboratory separate from the dispensary without having submitted an application to, and being approved by, the Authority. The Panel also found that there were privacy issues, inadequate signs identifying the duty pharmacists and unfamiliarity with the operation of the temperature data logger.

The licensees were cautioned and directed to lodge an application seeking approval for the alterations in respect of the compounding laboratory.

Case 4

In this case, the electronic recording and reconciliation of Schedule 8 poisons were grossly deficient. Identifiable Schedule 8 poisons returned by the public were to be recorded and destroyed. Schedule 3 poisons were to be displayed in accordance with the regulations and guidelines.

The licensee was cautioned.

Case 5

Schedule 8 poisons were not adequately secured. A sink in the dispensary was not connected to the sewer despite the licensee having certified that the premises were completed in all respects. Remedial action was required in relation to:

- weighing and measuring equipment
- signs
- procedures in managing and assembling DAAs

The licensee was cautioned and directed to obtain a compliance certificate about the plumbing to be submitted to the Authority.

Toni Riley
Chair