Communiqué

21 December 2017

This communiqué is issued by the Victorian Pharmacy Authority (the "Authority") to keep stakeholders informed about the Authority's regulatory activities.

Revised licence application forms

The Authority has updated its application forms for a licence to carry on a pharmacy business. Affected forms are VP11 – to be used when the applicant is a registered pharmacist, and VP12 – when the applicant is a company registered under the Corporations Act.

New forms include requirements for additional documents relating to pharmacy commercial arrangements and 100 points of identification. The updated forms are now available on the Authority's website here. Old forms lodged after 31 December 2017 will not be accepted.

Panel Hearings

There were four Panel Hearings in November 2017 into allegations that licensees had failed to meet their responsibilities to comply with the *Pharmacy Regulation Act 2010* (the Act) and/or good pharmacy practice at registered premises.

Case 1

The licensee had failed to make adequate arrangements to ensure returned medicines were not re-used, and was not storing and disposing of them in a secure manner. The re-use of dispensed medicines that have left the pharmacy is prohibited under the Act.

There were numerous discrepancies in both the storage of Schedule 8 poisons and the recording of them. Movement detector sensors did not provide adequate coverage of the pharmacy.

Records containing confidential information were not disposed of properly; refrigerator temperatures were not monitored; current works of reference were not held; barcode scanning was inadequate and there were deficiencies in the recording of medicines used in dose administration containers.

The licensee was reprimanded, and the pharmacy is to be re-inspected at the licensee's cost.

Case 2

Discrepancies between stocks of Schedule 8 poisons and the electronic register; unsatisfactory disposal of printed confidential information and incorrect storage of Schedule 8 poisons formed part of the charges. Overall management of the pharmacotherapy service was deficient in that the methadone stock bottle was not clearly labelled, photographs of some patients were absent and accounting for the use of methadone and buprenorphine was unsatisfactory.

The licensee was reprimanded, and a condition inserted in the licence that requires the licensee to carry out quarterly audits, reviewable at 12 months. Each completed audit is to be accompanied by a statutory declaration attesting to the veracity of the audit. The pharmacy will be re-inspected at the licensee's cost.

Case 3

Discrepancies in accounting for Schedule 8 poisons was one of the charges in this hearing. Keys to the Schedule 8 safe were not secured; barcode scanning was not undertaken routinely and there was no temperature data logger in the refrigerator.

The Panel found that the dispensary and its surrounds did not prevent clients from approaching and standing directly in front of the dispensary in order to minimise interruptions and distractions to the dispensing process and to prevent the disclosure of documents and the identity of patients' medicines.

The dispensing balance was to be repaired and certified or replaced and the range of dispensing measures increased. The name of the proprietor was to be displayed at all public entrances.

The licensee was cautioned.

Case 4

The Panel found that the control of keys to the pharmacy premises was not restricted to registered pharmacists; there were discrepancies in the Schedule 8 register; the part of the premise where dose administration containers were assembled was not maintained in a hygienic manner; and there was inadequate security of perimeter doors. Temperature control, signs and equipping were also found to be unsatisfactory.

The licensee was cautioned.

Why are some licensees reprimanded and others cautioned?

The extent and range of matters that form the charges and past history are factors that affect the finding. During the hearing, the Panel notes what steps the licensee has already taken to rectify the deficiencies listed in the inspection report.

Section 61 of the *Pharmacy Regulation Act 2010* states: "If it considers appropriate to do so, the Authority may caution or reprimand a licensee or holder of registration instead of revoking the licence or registration".

Sections 55 to 61 set out the grounds for revocation, the convening and procedure of a panel and its decisions. The decision of the panel is the decision of the Authority. Applications to the Victorian Civil and Administrative Tribunal for a review is limited to cases of refusal to grant licences or registration, the imposition of conditions and revocation of a licence or a registration.

Lessons to be learned

- The Act prohibits the re-use of medicines after dispensing and after they have left a pharmacy or pharmacy department. Dispensed medicines that have left the premises cannot be re-used.
- The Act requires the control of keys or other entry devices (to a pharmacy or pharmacy department) to be restricted to registered pharmacists. Keys cannot be given to any other person, including the police.
- Pharmacy dispensaries must be set up in a way that prevents clients from approaching and standing directly in front of the dispensary to avoid distractions and breaches of privacy.
- The Authority continues to convene Panel Hearings to hear allegations into failures of good pharmacy practice relating to the storage and recording of Schedule 8 poisons.

Christmas - New Year office hours

The Victorian Pharmacy Authority's office will be closed from 12 noon on Friday, 22 December 2017 to Tuesday, 2 January 2018 at 9.00 am. I wish you a happy and safe festive season.

Toni Riley
Chair