Communiqué

12 December 2017

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

Annual Report

The Authority's 2016-17 Annual Report was tabled in Parliament on 19 October 2017. The Authority's Annual Report can be accessed on its website here.

Improving Authority performance based on stakeholder feedback

In December 2016, the Authority commissioned *PharmConsult* to conduct an external review of its licence application and renewal processes. The review included two phases of stakeholder consultation.

The Final Report of the *PharmConsult* review was published on the Authority's website. The Authority established an internal committee to consider the recommendations of the Final Report in detail. It is expected that this process will result in improvements to allow the Authority to ensure that the complex commercial arrangements common in the contemporary pharmacy ownership environment comply with the ownership restrictions of the Act.

In May and June 2017, the Authority also surveyed recent licence and registration applicants regarding its application processes, and other stakeholders on the effectiveness of its communications. The purpose was to identify process improvements and reduce regulatory burden.

Application processes

Feedback on ease of use and access to application forms was positive. However, less than 50% of applicants were aware that there is a guide to application processes resource available on the Authority's website. The guide takes the form of flowcharts and frequently asked questions. The existence of this resource will be highlighted to applicants and stakeholders in future communications. It can be accessed on the Authority's website here.

Feedback on the Authority's application service standards and communication with applicants was also positive.

Communications

Up to 40% of pharmacists and 50% of stakeholders surveyed were unaware of the Self-Audit form available on the Authority's website. The self-audit form is a useful tool for pharmacists and owners to monitor their compliance with pharmacy legislation and guidelines. The Authority will highlight the utility of the self-audit form in future communications and inspectors will continue to promote its use to pharmacists during inspections. The self-audit form can be accessed here.

Less than 50% of respondents were aware that the Authority endeavours to have at least one pharmacist in the office to respond to enquiries on working days. Pharmacists and stakeholders may call to speak to a pharmacist with any questions about pharmacy legislation and guidelines or the Authority's activities. If an Authority pharmacist is unable to respond to an enquiry they are usually able to refer the enquirer to the correct agency.

Based on feedback from respondents, future quarterly circulars will include an area of special focus and a “did you know” topic to highlight important topics and to remind pharmacists of ongoing requirements. The VPA website will also include links to pharmacist immunisation and opioid replacement requirements on the website of the Department of Health and Human Services.

Owners and pharmacists in charge are reminded to ensure email addresses for all registered premises are notified to the Authority as email is the Authority’s main form of communication. Monthly Circulars and licence/registration renewal invoices are sent to the premises email address notified to the Authority (owners also have the option of nominating an email address for billing purposes). Non-owner pharmacists may request to be included on the mailing list for circulars.

Revised licence application forms

The Authority is revising its licence application forms. New forms will include requirements for additional documents relating to commercial arrangements and 100 points of identification. These will be available on the Authority’s website shortly and old forms lodged after 31 December 2017 will not be accepted.

Storage of Schedule 8 poisons

Illegal and insecure storage of Schedule 8 poisons often accounts for licensees attending Panel Hearings due to the significant risks to public safety. Examples may include storage of excess stock in cabinets, drawers or cupboards because the capacity of the safe is inadequate; returned, unwanted or expired stock is sometimes seen on top of RUM bins. The potential for diversion of these drugs by staff is possible and detection would prove difficult. Inspection reports also continue to note cases of keys to the S8 safe being stored in drawers.

The Drugs, Poisons and Controlled Substances Regulations 2017 (regulations 74 and 75) set out the specification for the “storage facility” required for S8 and S9 poisons and create the offences for contravention. The penalty is up to 100 penalty units. In substance, these regulations have been unchanged for decades.

Assays of compounded medicines

Pharmacists who describe themselves as ‘compounding pharmacists’ are reminded that at least one sample of a commonly prepared medicine is to be sent to an independent laboratory once a year for assay and a copy of the assay certificate forwarded to the Authority on request.

Panel hearings

There were two Panel Hearings held in October 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.

Case 1

A pharmacist was reprimanded after an inspection found that a number of matters previously identified at earlier inspections remained outstanding despite the licensee having certified that the deficiencies had been rectified. These were:

- The S8 safe was used to store other things and was not kept locked
- The storage of methadone concentrate intended for use was unsatisfactory
- The absence of a temperature data logger
- Schedule 3 poisons were displayed contrary to the Drugs, Poisons and Controlled Substances Regulations 2017

A condition was inserted into the licence requiring the licensee to carry out quarterly self-audits of the pharmacy (to be reviewed after 12 months). The Panel also directed that (i) photographic evidence be supplied to demonstrate that the professional service area was arranged in accordance with the Authority’s guidelines; and (ii) that written procedures be supplied for temperature monitoring.

Case 2

A caution was recorded in the case of a licensee following an inspection where:

- Returned S8 poisons were not stored in accordance with the regulations and inadequate records kept
- Unwanted and out-of-date medicines had not been disposed of
- The frequency of barcode scanning was low
- Mandatory references were out of date
- S3 poisons (including codeine) were displayed contrary to the regulations and guidelines
- Absence of a temperature data logger
- Duty pharmacists had not been supplied with the necessary passwords
- A refrigerator containing S4 poisons was not secured

The Panel also directed the licensee to submit written procedures to deal with the management of returned and unwanted medicines.

Toni Riley
Chair