Communiqué

Number 6, 2019

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

Authority member appointments

Esther Alter retired from her membership of the Authority on 30 June 2019. Esther was a member of the Authority since its inception in August 2010, and also served as a member of the former Pharmacy Board of Victoria. Authority members and staff sincerely thank Esther for her long-standing service and dedication as a lawyer member.

Following the expiration of Mrs Alter's term, the Governor in Council appointed Elizabeth Kennedy as a lawyer member for a three-year term until 30 June 2022.

Elizabeth is currently General Counsel and Corporate Secretary of Peter MacCallum Cancer Centre. She has previously been Corporate Counsel at Epworth HealthCare Group, other hospitals, and corporate solicitor to the Australian Medical Association (Victoria). Elizabeth specialises in health and medical law. She has written many legal articles, and presented on many varied health and medical topics. She is Chair of the Appeals Committees of The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australasian College of Surgeons, and the Australasian College for Emergency Medicine. She has sat as the community member on disciplinary panels for AHPRA.

Elizabeth is Adjunct Professor in the Department of Epidemiology and Preventive Medicine at Monash University. Until the end of 2016, she was a Senior Lecturer in the Department, and taught health professionals undertaking post graduate studies about law for health systems. She is a currently a Director of Eastern Melbourne Health Care Network Ltd.

Complex compounding

In February 2019, the Authority alerted licensees about recent inspections that have identified pharmacies carrying out complex compounding in breach of guidelines and/or legislative requirements.

Some of these matters have been the subject of recent panel hearings and include:

- Complex compounding being undertaken in pharmacy premises that do not meet the requirements of VPA Guidelines.
- Compounding and supply arrangements not in accordance with the relevant exemptions in the Therapeutic Goods Regulations.

The Authority has continued to identify cases where complex compounding is undertaken in inappropriate circumstances and reiterates its alert to licensees to:

- Review all extemporaneous compounding undertaken to determine if it includes ***complex compounding*** as defined in the Pharmacy Board of Australia Guidelines on compounding of medicines [Note: this includes *compounding that requires or involves special competencies, equipment, processes or facilities* – examples include preparations containing hazardous ingredients (such as hormones or antibiotics) and micro-dose single-unit dosage forms. The Authority considers that in most cases the preparation of capsules will constitute complex compounding.
- If undertaking complex compounding, ensure that the premises meet the requirements of the VPA Guidelines (a suitably equipped and enclosed laboratory is required) and that compounding is undertaken in accordance with the Pharmacy Board of Australia Guidelines on compounding of medicines.
- Ensure supply arrangements are in accordance with the Pharmacy Board of Australia Guidelines on compounding of medicines and therapeutic goods legislation, e.g. medicines compounded at a pharmacy cannot be supplied to another pharmacy for dispensing and on-supply, medicines cannot be compounded and supplied for general sale in the pharmacy.

Some licensees have been approached by pharmacists trained in compounding and agreed to hand over responsibility to them for establishing a compounding service within the pharmacy. The Authority reminds all licensees that they are ultimately responsible for ensuring that a pharmacy is carried on in accordance with the law and good pharmacy practice.

All pharmacists undertaking or considering undertaking complex compounding should thoroughly research relevant guidelines and legislation and undertake appropriate risk assessments. The Authority may refer pharmacists who breach guidelines and legislation to the Pharmacy Board of Australia.

Quarterly performance report

The Authority's performance measurement framework provides information on its activities and intended outcomes.

The quarterly performance report for the period 1 April 2019 to 30 June 2019 is now available on the VPA website.

Based on statistics from inspections carried out during the period, inspectors will focus on the following areas in coming months:

- Adequacy of reference library
- Timely and accurate recording of transactions in Schedule 8 Poisons
- Regular reconciliation of Schedule 8 medicine stocks & records
- Appropriate storage of all Schedule 8 poisons
- Barcode scanning undertaken routinely during dispensing
- Dispensary maintained as a private area dedicated to dispensing
- Appropriate storage and display of Schedule 3 medicines including pseudoephedrine

Recent panel hearings

In May 2019 there were five panel hearings into allegations that licensees had failed to meet their responsibilities to comply with the Act and/or good pharmacy practice at registered premises. A summary of a selection of the hearings follows.

Case 1

The licensee failed to maintain true and accurate balances of Schedule 8 poisons in their possession. Some S8 poisons were not stored in a drug safe.

The identity of dispensed medicines was not kept private in that open baskets were used for transfer between the dispensary and cash and wrap counter, the matter having been raised in a previous inspection. Barcode scanning was not routinely undertaken during dispensing in accordance with Pharmacy Board of Australia Guidelines.

The licensee was cautioned and required to develop and submit a procedure to assure the privacy of dispensed medicines in the pharmacy on an ongoing basis.

Case 2

The licensee altered the registered premises prior to seeking Authority approval.

The alterations were being undertaken at the time an officer of the Authority inspected the pharmacy. The licensee failed to restrict access to some S8 poisons and maintain the dispensary as a private area dedicated to dispensing. S4 poisons were stored outside the dispensary and not in a lockable facility.

There were deficiencies in required references and a procedure had not been implemented for temperature monitoring of the drug refrigerator.

The licensee was cautioned.

Case 3

Complex compounding, including compounding involving the handling of hazardous substances, was undertaken at the pharmacy premises contrary to the requirements of VPA Guidelines. There was no dedicated compounding laboratory, no powder containment cabinet for operator and environment protection and a lack of suitable protective clothing.

The panel accepted the director of the corporate licensee's explanation that the compounding had been undertaken by an employee pharmacist without his knowledge, including after business hours.

The licensee was cautioned.

Case 4

Complex compounding, including compounding involving the handling of hazardous substances, was undertaken at the pharmacy premises without a dedicated compounding laboratory contrary to the requirements of VPA Guidelines.

Expiry dates for compounded medicines were not assigned in accordance with good pharmacy practice in that creams and ointments were labelled to be discarded a number of days after opening.

The premises were not maintained in a clean and hygienic manner with respect to the compounding activities. There was inadequate barcode scanning, no procedure for temperature monitoring of the drug refrigerator using a temperature data logger and deficiencies in required references.

Some S8 poisons were not stored in a drug safe. These included a raw material for compounding, the matter having also been noted at a previous inspection.

The licensee was reprimanded and a condition imposed on the premises registration that complex compounding is not to be undertaken at the registered premises.

Privacy reminder

Case 1 above refers to the transfer of dispensed medicines throughout a pharmacy in open baskets.

The *Pharmacy Regulation Act 2010* includes a requirement [Clause 9(h) of the Schedule to the Act] for the purposes of the licence to carry on the pharmacy business and the registration of the premises which states:

> *Adequate arrangements are in place to ensure that the identity of a medicine being supplied or dispensed to a client of the pharmacy or pharmacy department cannot be known by another person present in the pharmacy or pharmacy department who is not a person carrying on the pharmacy business or pharmacy department or a member of the staff of the business or department.*

Pharmacists may be aware of recent media coverage about a consumer being robbed at knifepoint after leaving a pharmacy in Western Australia. The consumer had just had a prescription for alprazolam tablets filled, and these were demanded by the attacker along with the consumer's wallet.

It is not clear whether or not the dispensed medicines were identified by the attacker in the pharmacy.

However, when informing staff and consumers about the legislative requirement to maintain the privacy of dispensed medicines in the pharmacy, licensees are also encouraged to highlight the potential public safety risks that could result from consumers' medicines being identifiable after dispensing.

David McConville
Chair
19 July 2019