Communiqué

26 September 2017

The Victorian Pharmacy Authority (the "Authority") met on 12 September 2017 at the Authority offices.

Revised Victorian Pharmacy Authority Guidelines

At its September 2017 meeting, the Authority considered proposed amendments to its guidelines after having received comment from stakeholders. The amended guidelines are now available on the Authority's website and take effect from 1 October 2017.

The revised guidelines incorporate amendments in the following areas:

- 4.3.3.4.1 *General dispensary requirements* – addition regarding forward dispensing
- 4.3.13 *Facilities for immunisation services* – clarification regarding "first aid couch or similar" (see below)
- 4.6.1 – *Compounding pharmacies – Premises and equipment* – addition regarding floor coverings and surfaces

Vaccination services

First aid couches

The Authority's current and revised guidelines specify that a "first aid couch or similar" is to be in the room where vaccinations are carried out. The purpose of providing this is for clients who are uneasy about injections in general and are inclined to feel faint, nervous or unsteady.

People who have experienced problems of this kind may then recline or lie down during the procedure.

The Authority does not specify any make, model or design. The requirement may be met by a foldable bed or reclining chair with footrest.

The first aid couch is not intended to be used for CPR.

Privacy

The Authority has become aware that some pharmacies may not be ensuring adequate privacy when administering vaccines. The private consultation area or room used to administer vaccinations must be set up so that the procedure cannot be seen or overheard by other persons in the pharmacy. This does not preclude the use of temporary structures with adequate screening but privacy must be assured.

Raw materials in compounding pharmacies

It is the pharmacist's responsibility to ensure that raw materials meet suitable quality standards and are suitable for compounding. Raw materials - both actives and excipients - should always be obtained from a reputable source. In most cases, the supplier will be an Australian-licensed manufacturer. In other cases, the supplier will be an Australian wholesaler who obtains materials in their original unopened containers from a country where the licensing and other standards are comparable with those observed in this country. The latter include most European countries, Canada, New Zealand, the United States and Singapore. Beyond these, pharmacists should obtain not only a specification and a certificate of analysis from the supplier but also a certificate from an appropriately accredited NATA laboratory attesting that the material conforms to a BP, USP or PhEur standard.

Commercially manufactured products and compounded medicines

When a commercially manufactured product is specified by brand name on a prescription, it should be supplied in preference to a compounded version. This is in accordance with the *Pharmacy Regulation Act 2010*, the Pharmacy Board of Australia's guidelines and in the case of S4 and S8 poisons, the Drugs, Poisons and Controlled Substances Regulations 2017. Similarly, when a medicine is prescribed under its generic name, the commercial product should be supplied if available. If, however, the prescription calls for the medicine to be made up extemporaneously or prescribed in, for example, a base that differs from the commercial version, the prescription should be dispensed in its own terms, subject to the safety of the patient.

Readers may have read a recent case where a commercial manufacturer launched proceedings against a Victorian compounding pharmacy where the manufacturer's product was replaced by one that was compounded. There was a substantial out-of-court settlement before trial in favour of the manufacturer.

Panel hearings

There were four Panel Hearings held in August 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

The allegations were:

- Numerous and significant discrepancies in accounting for transactions of S8 poisons; and
- Failure to store expired S8 poisons securely

The Panel found the allegations proven and the licensee was cautioned.

Case 2

The allegations were:

- Numerous discrepancies in accounting for transactions of S8 poisons;
- Schedule 3 poisons containing codeine were displayed contrary to the Victorian Pharmacy Authority's Guidelines;
- Current editions of mandatory works of references were not kept;
- There was no procedure in place to identify breaches of the cold chain;
- Schedule 2 poisons were stocked outside of the professional service area; and
- Omission to place a dispensing label on each pack of medicine when multiple packs were supplied.

The Panel found the allegations proven and the licensees were cautioned.

Case 3

The allegation was that an applicant for a licence to carry on a pharmacy business had submitted false information within an application to the Victorian Pharmacy Authority. The applicant company had failed to disclose the existence of a trust.

The Panel was satisfied the omission was due to an unintended administrative error. The Panel found the allegation proven and cautioned the licensee.

Note: It is an offence under the *Pharmacy Regulation Act 2010* to include false or misleading information in an application and a person who makes a false declaration may be liable to the penalties of perjury.

Case 4

The allegations were:

- Numerous and significant discrepancies in accounting for transactions of S8 poisons;
- Failure to record in the S8 register the total quantities of methadone and buprenorphine;
- The S8 register did not show the "balance on hand" daily for methadone and buprenorphine;
- Stock of methadone and buprenorphine were not reconciled with actual stock;
- Invoices showing receipt of methadone and buprenorphine were not recorded in the register;

- Schedule 3 poisons were displayed with promotional “shelf talkers”;
- Schedule 3 poisons containing codeine were displayed in a manner contrary to the Victorian Pharmacy Authority’s Guidelines;
- Packing dates and pharmacists’ signatures had not been shown on records relating to dose administration containers for 60 patients for about eight months;
- Barcode scanning was not routinely undertaken;
- Incident records for three years in a dedicated file were not kept;
- The confidentiality of dispensed medicines was known to other persons;
- There was no procedure to ensure maintenance of the cold chain;
- Schedule 2 poisons were stored outside of the professional service area;
- Dose administration aids (DAAs) were not suitably labelled or accompanied by another method of providing cautionary and advisory information;
- Pharmacist Certification for opioid pharmacotherapy had not been completed;
- Take-away doses for pharmacotherapy were not labelled adequately; and
- Non-current prescriptions for pharmacotherapy prescriptions were not segregated from current prescriptions.

The Panel found all the allegations proven, issued a caution, and inserted a condition in the licence requiring the licensee to carry out a quarterly audit and send a copy of the completed audit with a statutory declaration to the Authority at prescribed quarterly intervals.

The Panel referred the matter back to the Authority to determine whether the pharmacy should be re-inspected at the licensee’s cost.

Instances of alleged contravention of the Drugs, Poisons and Controlled Substances Regulations are routinely forwarded to the Department of Health and Human Services.

Toni Riley
Chair