Communiqué

No. 1 - 8 February 2018

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

Review of licence application processes – implementation plan

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 assess if these processes were adequate to determine compliance with the *Pharmacy Regulation Act 2010* (the Act).

A copy of the Final Report of the review, published on 31 August 2017, is available on the Authority's website here.

The Authority supports the recommendations of the review and the outcomes the recommendations seek to achieve.

An internal committee was established to consider options for change in detail and the Authority has engaged extensively with its external lawyers, accountants and auditors in planning implementation of actions in response to the review.

A summary of the implementation plan, including actions already implemented, is included below:

Application processes

On 1 January 2018, the Authority introduced revised licence application forms which incorporate a new schedule of required documents. The new forms and revised assessment processes:

- increase scrutiny of pharmacy business commercial arrangements;
- include questions with dichotomous (yes/no) answers;
- streamline the application process by clarifying details of documents required; and
- allow low-risk applications to be processed without delay.

The new application processes represent a significant change and were developed following extensive consultation with the Authority's external lawyers and accountants/auditors.

Applications will be assessed by Authority staff on a case by case basis. Applications initially assessed as high-risk will be referred to a monthly meeting of the Authority for further consideration. They will include but not be limited to:

- those involving complex and technical commercial arrangements;
- those for which there is any indication there may be undisclosed proprietary interests or undue influence; or
- apparent gaps in the documentation supplied by the applicant.

The Authority may then decide to refer these applications to external lawyers, accountants or auditors. An internal Immediate Action Committee of the Authority has been established to facilitate this process and avoid delays.

The Authority may refuse to approve or grant a licence if it is not satisfied that the application complies with the Act.

New processes may result in increased costs to licensees as the Act requires the Authority to be self-funding. Applicants may also experience extended processing times due to the additional application documents requiring assessment.

Guidelines on pharmacy business commercial arrangements are currently being developed to assist applicants and stakeholders to understand the requirements of the Act and facilitate the possible future introduction of certification requirements. Publication of these is expected to commence in February 2018.

Amended penalty descriptions were incorporated into application forms in 2017. A 100-point identification check was introduced on 1 January 2018. The Authority will continue to publish information aimed at educating stakeholders about compliance and penalties for non-compliance.

The inclusion of improved clarity in declarations in application forms (checklists with dichotomous answers), and declarations by other professionals, will be progressed further after development of commercial arrangement guidelines.

The Authority will continue to assess franchise agreements for compliance with the ownership and undue influence provisions of the Act progressively on a risk basis.

Renewal processes

The Authority intends to impose a general notification condition on all pharmacy business licences from 1 July 2018 (on renewal) requiring licensees to notify the Authority of any changes to pharmacy business commercial arrangements (e.g. trusts, partnership agreements, franchise agreements, licence agreements, service agreements and leases).

A declaration by licensees that they have complied with the notification condition will be required commencing with 2019 licence renewals. A trial declaration of compliance with legislation will apply on renewal in 2018. Explicit descriptions of penalties and checklists with dichotomous answers will be included as appropriate.

It is expected that licensee declarations will be used to help risk-stratify pharmacy businesses for audit.

Audit program

The Authority is committed to introducing an audit program of pharmacy business commercial arrangements during 2018. The focus of the audit program will be on undeclared and unlawful interests in pharmacy businesses.

Extensive work has been undertaken towards development of the audit program and this work is continuing.

It is likely that the audit program will include ownership audit and financial audit components. The audit program will be risk-based but there will also be a random component. The selection process will be under the Authority's control.

Other actions

The Authority has and will continue to consult with its interstate counterparts to explore their experience and share information on detecting and dealing with undeclared ownership.

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 October 2017 to 31 December 2017 is now available on the VPA website here.

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

- Adequacy of references
- Reconciliation of S8 stocks and records
- Routine barcode scanning
- Adequacy of arrangements for privacy throughout the pharmacy
- Appropriate storage and display of pseudoephedrine products (out of public view)
- All codeine products stored in the dispensary or lockable storage facility

Risk-based assessment of sterile facilities

The Authority has implemented a risk-based program of targeted inspections to evaluate facilities where pharmacists undertake sterile compounding, including those in hospitals and pharmacies. The program aims to ensure provision of safe and suitably controlled working environments with respect to product and patient safety. In cases where inspections identify non-compliance or concerns, licensees may be required to undertake risk assessments to identify potential risks and suitable mitigations.

Panel Hearings

The Authority held no panel hearings during December and January 2018.

Quarterly circular

The Authority's recent January circular, emailed to all licensees, registered premises, and to other pharmacists on request, includes important information for pharmacists and is available on the Authority's website here.

Toni Riley
Chair