victorian pharmacy authority

2 March 2018

Hon. Jill Hennessy MP
Minister for Health
GPO Box 4057
MELBOURNE VIC 3001

Dear Minister

MINISTERIAL STATEMENT OF EXPECTATIONS - VICTORIAN PHARMACY AUTHORITY

The Victorian Pharmacy Authority (the Authority) is pleased to report on improvements implemented in response to your Statement of Expectations for the period 1 July 2016 to 30 June 2017, which was subsequently extended until 31 December 2017.

Improvements

Consulting stakeholders - principally pharmacists - during 2016-17 to identify further opportunities to reduce the regulatory burden on small business and improve the performance of the Authority.

The Authority's stakeholder engagement plan was updated to include seeking and evaluating feedback from licensees and stakeholders. This included feedback on the Authority's application processes and the effectiveness of the Authority's communications.

In December 2016, the Authority commissioned *PharmConsult* to conduct an external review of its licence application and renewal processes. Pharmacists and other pharmacy stakeholders were consulted during the review. The Final Report of the *PharmConsult* review was published on the Authority's website, and an internal committee of the Authority established in August 2017 to consider the recommendations of the Final Report in detail. The Authority supports the recommendations of the review and has commenced implementation of the recommendations. The review will result in improvements to help the Authority ensure that the complex commercial arrangements common in the contemporary pharmacy ownership environment comply with the ownership restrictions of the *Pharmacy Regulation Act 2010* (the Act).

In May and June 2017, the Authority surveyed recent licence and registration applicants to obtain their feedback on its application processes. It also surveyed pharmacists and other stakeholders on the effectiveness of its communications, with a view to identifying process improvements and reduce regulatory burden.

Improvements implemented as a result of stakeholder feedback have and will continue to be communicated back to stakeholders via regular communiqués and circulars.

Prioritising regulatory activities based on an established risk framework. This will include for example prioritising inspections of pharmacy premises on the basis of a risk assessment.

The Authority has made further improvements to its established risk framework. Statistics obtained from inspection reports are now used to focus the inspection program, and its education component, towards areas of significant non-compliance and risk.

Commencing in November 2016, quarterly meetings of inspectors now take place to discuss areas of significant non-compliance and risk based on statistics obtained from recent inspection reports.

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In December 2016 inspectors began focusing on these areas during inspections and the Authority began routinely publishing current areas of focus in its quarterly Circular from April 2017. This information will be reinforced by inspectors during inspections of registered premises.

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.

Designing and implementing a publicly available performance measurement framework that provides information on the Authority's activities and intended outcomes.

The Authority published its performance measurement framework and commenced publication of a quarterly performance report in July 2017. The framework provides information on the Authority's activities and intended outcomes including applications, service standards, approvals, inspections, risk-based focus of future inspections, investigations and panel hearings. The Authority's work in this area is shared with other pharmacy premises regulators through the Pharmacy Premises Registering Authorities of Australia (PPRAA) group.

The Authority has and will continue to share information on its inspection protocols and reporting and collaborate with other state/territory pharmacy premises regulators where possible with the aim of achieving national consistency.

Developing a systematic approach to collaborating and sharing information with other regulators, including with the Department's Drugs and Poisons Regulation business unit and the Australian Health Practitioner Regulation Agency.

The Authority developed revised protocols for collaboration with other regulators in consultation with the Department of Health and Human Services Drugs and Poisons Regulation branch, the Australian Health Practitioner Regulation Agency and the Pharmacy Board of Australia in June 2017. Collaboration with other regulators is further supported by the Authority's Stakeholder Engagement Plan, revised extensively in consultation with the Department of Health and Human Services during 2016-17. The revised protocols include new procedures for the assessment and tracking of complaints about licensees and registered premises. The Authority is confident that these initiatives will improve collaboration with other regulators and achieve more consistent regulatory approaches. Joint inspections with departmental radiation safety officers have also continued during 2016-17.

The Authority will publish this report on its website and in its 2018 Annual Report.

The Authority is committed to identifying opportunities to improve its regulatory performance and will continue to review and streamline its processes.

Yours sincerely

Toni Riley
Chair