victorian pharmacy authority

15 July 2015

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

Dear Minister

STATEMENT OF EXPECTATIONS FOR VICTORIAN PHARMACY AUTHORITY

Thank you for your letter dated 30 May 2015.

The Victorian Pharmacy Authority (the Authority) is pleased to provide this response to the Statement of Expectations including activities planned and currently being undertaken.

IMPROVEMENTS AND TARGETS

Stakeholder consultation and engagement

Revising the stakeholder communication plan

In early 2015 the Authority conducted a strategic review which guided its work plan for 2015. This included a revised communication plan which incorporates a new communiqué now published monthly following each Authority meeting. The Authority is currently investigating methods to evaluate its communications in accordance with the communication plan (to be implemented by December 2015).

Establishing written protocols

The Authority has established written protocols to facilitate interaction with the Drugs and Poisons Regulation Group within the Department of Health and Human Services and the Pharmacy Board of Australia. This will improve coordination of investigation and disciplinary processes and mutually benefit regulators and stakeholders.

Increased accountability and transparency

Reviewing the performance measurement systems put in place by equivalent interstate pharmacy regulators

The Authority has commenced a review of the performance measurement systems put in place by equivalent pharmacy regulators operating interstate with a view to benchmarking its performance and performance measurement systems. This includes sharing of inspection protocols, the development of common inspection protocols and also conducting site visits with interstate inspectors with the aim of achieving a degree of national consistency.

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Establishing service standards

The Authority processes applications in a timely manner but has not previously stated service standards.

The Authority aims to carry out an initial assessment within five working days of receipt of a complete application. For low risk applications (within delegation of Authority officers), processing should be completed within a further three working days. Authority officers will continue to rely on self-certification by pharmacists to expedite licensing and registration to enable trading to commence without delay.

For high risk applications (outside delegation) processing should be completed within three working days following a decision at the next monthly meeting of Authority members, or within three working days of receipt of further information (including consultant advice). The Authority will report on these service standards in its 2016 Annual Report.

Developing standard processes, streamlining reporting and establishing baseline data

The Authority will continue to audit its activities and standardise processes to improve reporting. Investigation reporting, panel hearing notifications and associated documentation are currently being standardised to streamline reporting and aid compilation of statistics on the Authority's enforcement actions. This data will then be communicated back to licensees in the form of circulars or communiqués on the Authority website and via annual reporting (to be implemented by December 2015).

A report on panel hearings held over the previous financial year was recently compiled. These reports aid identification of patterns of non-compliance and also highlight opportunities for cooperation with other regulatory bodies. For example, over 90% of panel hearings in 2013-14 considered, among other deficiencies, breaches of drugs and poisons legislation. Investigations involving such breaches are now routinely referred to Drugs and Poisons Regulation, Department of Health and Human Services. Referral of investigations is also undertaken to prevent regulatory overlap and reduce the regulatory burden on licensees.

Regular provision of information to licensees

The Authority will increase accountability and transparency by informing licensees and other stakeholders of its regulatory activities and enforcement actions.

To this end, the Authority is committed to publishing circulars and communiqués to keep licensees informed about Authority activities, their legislative obligations and highlight common deficiencies observed during inspections. The Authority published its third circular in May 2015 and the frequency of circular publication on the Authority website has now been increased to four times a year.

Circulars and monthly communiqués will include a summary of matters considered at panel hearings and resulting enforcement actions. This information also appears in the Annual Report. Circulars are also used to inform stakeholders about current issues and priorities for the Authority, especially areas representing the greatest risk to the Authority's regulatory outcomes.

Clearer and more consistent regulation

Developing further information about the Authority's regulatory approach

Information regarding registration and license applications, approvals and notifications is available on the Authority website. The Authority will now also include the following information on its regulatory approach to further assist stakeholders:

- A guide to licensing, registration and approval processes on the website to improve understanding of application processes and requirements.
- A summary of the Authority's risk-based approach to regulation.

Reducing the regulatory burden on licensees

Licensees currently have the option of completing paper based registration and licence renewals or renewing online. The Authority aims to reduce the regulatory burden on licensees by increasing the proportion of licensees renewing online by end of 2015 – 2016 (80% of licenses were renewed online in 2014 but only 20% of registrations).

The Authority analysed why there is a low rate of registration renewals completed online and put in place a strategy to increase the percentage of online registrations by licensees by 50% (a BPAY payment option was added for the first time for 2015-2016 renewals).

Conduct periodic liaison

The Authority will undertake periodic liaison with the Pharmacy Board of Australia and both the Drugs and Poisons Regulation Group and Radiation Safety section within the Department of Health and Human Services to determine ways to reduce the burden for regulated entities within the sector.

Risk-based strategies

Review of inspection protocols

The Authority responds to developments in the profession and changing community needs by reviewing its inspection protocols and guidelines annually. For example, a new inspection protocol for non-sterile compounding pharmacies has been developed and most compounding pharmacies in Victoria have now been inspected. In collaboration with the Department of Health and Human Services, Radiation Safety section, the Authority is currently in the process of developing and implementing a new inspection protocol for facilities in which pharmacists prepare radiopharmaceuticals. A future priority will be to review inspection protocols and Authority guidelines for facilities at which pharmacists compound sterile pharmaceuticals.

Enhancing the risk database

The Authority has a risk management policy in place and maintains a risk database. Although specific regulatory risks related to premises are regularly reviewed and used to structure the Authority's inspection program, these risks were not previously captured in the risk database. The Authority will enhance its risk-based approach to regulation by applying a more structured approach to managing and prioritising regulatory risks.

This is being achieved by:

- Reviewing regulatory risks and incorporating these into the risk database (June 2015);
- Assessing regulatory risks (June 2015); and
- Utilising regulatory risk assessments to inform prioritisation of Authority activities (to be implemented by December 2015).

Using statistics from inspection reports to guide education

The Authority aims to inspect every pharmacy in Victoria (currently 1331 pharmacy businesses and 76 pharmacy departments) at least every three years. A second tier of targeted inspections is conducted on a risk basis as follows. The Authority aims to conduct inspections of new or altered pharmacies or following a change of ownership within three months, and reviews based on high risk deficiencies identified in a prior inspection within twelve months of the previous inspection.

Statistics obtained from inspection reports will be used to guide the inspection program and education towards areas of significant non-compliance and high-risk deficiencies.

Compliance related assistance and advice

Encouraging self-auditing

Authority officers will continue to reinforce the contents of the Guidelines and encourage licensees to self-audit their premises to track their compliance with guidelines and legislation. The Authority has made changes to its website to make the self-auditing tool more readily accessible and self-auditing will be encouraged in regular circulars and in letters sent to licensees following inspections.

Providing advice and assistance in a timely manner

The Authority will continue to ensure that at least one pharmacist is available during office hours to provide assistance and advice to applicants, licensees, pharmacists and the general public by telephone or email in a timely manner. The Authority aims to respond to verbal requests for assistance and advice by the next working day, or within three working days in the case of written requests.

REPORTING AND CONSULTATION

In implementing these measures, the Authority with consult with stakeholders, including the community, as appropriate.

The Authority will report on progress to achieve these SOE standards within the 2015 and 2016 Annual Reports to the Health Minister.

The Authority will also continue to further review and streamline regulatory processes.

Yours sincerely

Michael Scavone
Chair