NEWS FROM THE TASMANIAN PHARMACY AUTHORITY

On the whole, the cyclical inspections are intended to be informative and educative, rather than punitive, to aid in the early identification and rectification of matters of concern.

INTRODUCTION

The Tasmanian Pharmacy Authority is responsible under the Pharmacy Control Act 2001 (the Act) for administering the registration of pharmacy business premises and approving the ownership of and interests in pharmacy businesses. In undertaking its role, inspections of pharmacy businesses can occur at any time, by persons the Authority has authorised to act as Inspectors.

SCOPE

The Authority inspectors are authorised to inspect pharmacies to ascertain whether provisions of relevant legislation are being met. They are required to gather information with reference to the Act, the Guidelines and other relevant legislation and standards in order for the Authority to be satisfied that premises comply with good pharmacy practice. Relevant legislation includes:

- The Pharmacy Control Act 2001
- The Poisons Act 1971
- The Poisons Regulations 2008

The Authority also recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board of Australia. The Authority has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia.

TYPES OF INSPECTION

Inspections are required to be undertaken when a new or relocated pharmacy business premises, or alterations to a pharmacy business premises, are complete and the pharmacy is ready to operate. Such inspections are triggered by the submission of the AC Form (Advice of Completion) by the owners or managers of the premises; and a satisfactory report results in the premises being formally registered under the Act. Contact is made with the site approximately a day prior to the inspection.

In addition, inspections may occur in response to concerns that a pharmacy premises might be operating in breach of the Act or from unsuitable premises. These inspections are not notified in advance.

The third type of inspection may occur as part of a cyclical inspection process. This activity is an expansion of the Authority Inspection practices, and is being put in place during 2013-14, with the aim of inspecting each pharmacy premises every three years.

On the whole, the cyclical inspections are intended to be informative and educative, rather than punitive, to aid in the early identification and rectification of matters of concern.

Inspectors examine security, privacy, references, dispensary design and equipment (including the computerised dispensing system), fittings, compliance with legislation and pharmacy practice standards, and pay particular attention to storage and management of scheduled substances. The inspectors may gather evidence during inspections, for example by taking photographs.

FREQUENCY

The Authority intends that inspections will be carried out on a cyclical basis at least every three years. As indicated above, inspections may also be triggered by notification of an Advice of Completion, a complaint, or a follow up inspection after deficiencies were identified at a previous inspection.

OUTCOMES OF INSPECTIONS

If the inspection identifies any issues or shortfalls, the owner may be required to respond to the Authority detailing steps taken to rectify the deficiencies. Applications for Registration of the pharmacy business premises might be delayed until all remedial action is taken, or conditional registration might be given.

Should an inspection identify major and serious problems, the Authority has the power to require that the pharmacy premises be closed and no trade to be undertaken from that premises until all work or actions have been carried out; should the work not be carried out, the Authority may cancel the premises registration.

This has serious ramifications for the owners and may impact on a pharmacist's approval to supply PBS subsidised medicine in accordance with section 90 of the National Health Act 1953, as it is a requirement that the pharmacy premises are registered with the relevant authority, in this case the Tasmanian Pharmacy Authority.

If a pharmacy premises registration is cancelled, any attempt to re-register the premises is treated as a new pharmacy application.

Common items requiring responses after Inspections:

- Incomplete or out of date references
- S2 medications greater than 4 metres from dispensary and/or not in line of sight
- Quantities of narcotics in safe not consistent with entry in narcotics register
- No system for identification and removal of Out of Date medication and Out of Date medication found on dispensary shelves

A Self Inspection Form is available on the Tasmanian Pharmacy Authority website. This covers the areas that will be inspected. Pharmacies are encouraged to use this form on a regular basis to help identify any deficiencies that may require correction.

To download the self inspection form
go to http://goo.gl/EpJhr8
or scan the QR

TASMANIAN PHARMACY AUTHORITY

Margie Cole, Registrar

0417 752 348

registrar@pharmacyauthority.tas.gov.au

www.pharmacyauthority.tas.gov.au

PO Box 1082 Sandy Bay TAS 7005