

NEWSLETTER – October 2024

In this issue:

- Expressions of interest for appointment as a Pharmacist Member of the Authority
- Inspection report additions and updates
- Scale Calibration
- Owners' responsibilities
- Maintenance of vaccine storage refrigerators and equipment
- Approval requirements for premises works/alterations
- Authority Activities April 2024 to September 2024

Expressions of interest for appointment as a Pharmacist Member of the Authority

The Authority is seeking expressions of interest (EOI) from suitably qualified and experienced pharmacists for appointment as a Pharmacist Member of the Authority commencing from May 2024. Please submit your application on the <u>EOI form</u> along with all required supporting documentation to registrar@pharmacyauthority.tas.gov.au. EOIs close on 15 November 2024.

Inspection report additions and updates

Addition:

Security access register

The pharmacy shall maintain a **security access register** which includes details of who has access to the keys and/or codes to the pharmacy and safes at any given time. An upcoming QC2020 update will include a requirement for pharmacies to keep a register of persons who hold keys/codes.

Reference: QC2020 AS 85000:2024

Updates:

Complex compounding third party referrals procedure requirements:

There should be **a written agreement** between the referring pharmacy and the compounding pharmacy (third party supplier) which outlines the responsibilities of each party.

Reference: QC2020 AS 85000:2024 - 5.3.1

Please be reminded of the following important points:

- Referring pharmacy must not: re-label or re-dispense the compounding prescription
 - take payment for the compounded medicine
 - add a "handling fee" for the patient to pay for transferring the prescription to the compounding pharmacy
- Compounding pharmacy: Payment should be taken at time of initial consultation/risk assessment call
 - Should provide follow-up contact with the patient, including instructions, storage information, how to use and follow-up.

registrar@pharmacyauthority.tas.gov.au

Ph: 0417 752 348

Scale Calibration

Professional calibration of weighing and measuring equipment should now be undertaken **annually** where previously the minimum standard was every two years. Scale calibration certificates from a qualified technician are acceptable as evidence of compliance.

Owners' responsibilities

The Members remind all owners, **regardless of their location with respect to their pharmacy**, of their continuing obligation to be compliant with all required pharmacy legislation, codes, standards, and guidelines. It is recommended the <u>Self Inspection Form</u> is completed annually as means of monitoring compliance to the above requirements.

Maintenance of vaccine storage refrigerators and equipment

The Authority works collaboratively with Department of Health, Communicable Disease Prevention Unit (CDPU) to provide direction to pharmacy owners on the compliance requirements for the provision of pharmacy vaccination services. CDPU have reported to the Authority a number of providers (pharmacy and non-pharmacy) where temperature recording has not been completed appropriately and in some cases, the lack of available and reliable data has resulted in patients requiring re-vaccination.

As a result, the Authority has now aligned the Inspection report template and Self-Inspection template with CDPU with regard to the issues below:

- 1. Manual temperature recording of vaccine storage refrigerators
 - All immunisation providers delivering/maintaining National Immunisation Program/State/Commonwealth funded vaccines must have at least two (2) devices for monitoring vaccine refrigerator temperatures, and one of these must be a data logger. The frequency for reviewing data logger records is a minimum of once a week, however, providers may choose to do this more frequently. More frequent review of the data logger temperature records does not remove the need to have a secondary source for monitoring refrigerator temperatures.
 - The secondary temperature monitoring device must have a visual display (either in-built or external to the fridge) which can display the minimum, maximum and current temperatures. The visual display must be used to record the minimum, maximum and current temperatures on a 'Minimum/maximum vaccine refrigerator temperature chart' (or equivalent) twice daily, before being reset and signed off by the operator.
- 2. Manual Fridge temperature monitors which only provide WHOLE number readings.

Whole number readings will not allow you to monitor for temperatures between 8 and 9 degrees. The recommendation is to record twice daily data logger temperatures in place of the manual fridge temperature readings. A second temperature monitoring device is still required to provide instant visual inspection of the fridge temperature at time of dispensing and the device must be reset daily.

- 3. Pharmacy vaccine storage refrigerators must be serviced ANNUALLY **and** have current QC2020 cold chain certification or equivalent to be compliant.
- 4. Contingency equipment (ice/blocks, cooler/eski and a maximum/minimum thermometer/ uninterruptable power supply for the refrigerator) must be available for vaccine storage in the event of power outage or refrigeration equipment failure.

CDPU have developed temperature monitoring chart template and cold chain breach flowchart as an alternative to the ones available from National Vaccine Storage Guidelines 3rd edition, Strive for 5 appendices. These are available for download from the external links section of the <u>Authority website</u>.

registrar@pharmacyauthority.tas.gov.au

Ph: 0417 752 348

Approval requirements for premises works/alterations

If you are considering ALTERATIONS to your pharmacy, RELOCATION of your pharmacy, or setting up a NEW pharmacy, you <u>must</u> complete and submit to The Authority ONE of the below forms:

- PA Application for Alterations to a Pharmacy Premises
- PNR- Application New or Relocation of Pharmacy Premises

You <u>must not</u> commence any works on the pharmacy premises, externally or internally, until in-principle approval has been provided in writing to you by the Authority. Failure to comply with this requirement may attract fines of up to \$3900.

Authority Activities April 2024 to September 2024

The Tasmanian Pharmacy Authority has conducted **58** inspections and evaluated **14** applications for either alterations, assessment of a vaccination area or new/relocating pharmacy premises. Several inspection reports have been forwarded to relevant authorities for their assessment.

The Chair and Professional Officer attended the Pharmacy Premises Registering Authorities of Australia (PPRAA) meeting in May 2024. The Professional Officer attended a two-day Pharmacy Compounding Chemist of Australia workshop to better understand the requirements of complex compounding and as result what is required in an inspection.

The 2024-25 renewals cycle has been completed with the issue of:

- 118 body corporate eligibility certificates
- 115 individual eligibility certificates
- 165 premises registration certificates
- 17 late fees

The <u>2023-24 Annual Report</u> and audited financial statements were completed and submitted to the Department of Health in accordance with legislative requirements.

The Authority continue to work closely with personnel from Pharmaceutical Services Branch (PSB) to ensure the smooth transition of operational Authority functions to be provided by PSB. This transition will occur progressively from 1 November 2024.

registrar@pharmacyauthority.tas.gov.au

Dating 1450mmH.a. 1100mmW.a.440mm D. dug safe balled to concrete floor.



Ph: 0417 752 348