



NEWSLETTER – September 2023

Authority Activities June – August 2023.

The Tasmanian Pharmacy Authority has conducted 25 inspections and evaluated 15 applications for either alterations, assessment of a vaccination area and new or relocating pharmacies.

**Changing your safe? Developing a vaccination space? Changing the dispensary?
Changing the location or storage of scheduled medicines?
Relocating your pharmacy? Planning to include another business within
the pharmacy business premises?**

Section 71KB(1) of the *Pharmacy Authority Act 2001* (Act) stipulates:

“The Owner/s of a pharmacy business **must not** cause or allow an alteration to be made to the relevant pharmacy business premises unless the alteration has been approved by the Authority. Penalty: fine not exceeding 20 penalty units” (\$3,900.00)

Section 71KA of the Act defines alterations as any alteration, whether permanent or temporary that is likely to affect or interfere with –

- (a) the dispensing of medicines or drugs on the premises; or
- (b) the storage of medicines or drugs on the premises; or
- (c) access to the premises; or
- (d) the security arrangements for the premises or any part thereof; or
- (e) the professional activities of the pharmacist.

You will find the appropriate form at [Tasmanian Pharmacy Authority - forms](#)
However, if you are uncertain, please contact the Registrar.

Annual declaration forms for trusts and exempt body corporates

Annual declarations are required for all owners who hold their interest in a pharmacy business either:

- as a trustee for a trust; or
- via a body corporate trustee of a trust which is a unit holder in a unit trust.

Details of these corporate structures are not captured during the annual renewal process, thus the annual declaration is required to ensure that the entities are compliant with the eligibility requirements of the Act.

Declaration forms will be sent out in late September and must be returned by 31 October 2023.

Annual renewal for 2023.

Thank you for returning your annual renewal application in the allocated time of just one month!

Renewals were delayed because as at 30 June 2023, the new fees regulations had not proceeded through Government. Currently, it is unknown when, and in what form, the new fee structure will take effect.

Advice will be provided to all Owners as soon as practicable once the outcome is clear.

Common issues identified during an inspection that require remedial actions.

1. Compliance with National Vaccination Storage Guidelines “Strive for Five”, 3rd edition.
2. Maintaining an up-to-date reference library as required by the Pharmacy Board of Australia.
3. Issues with non-compliance with Section 71E(3) of the *Pharmacy Control Act 2001* that the Authority may have regard to such as:
 - the standard or proposed standard of presentation of the premises, including the external appearance and internal fittings; and
 - the physical condition of the premises, and the condition of associated amenities such as lighting, ventilation, and sanitation; and
 - the security of the premises and in particular the security of dispensing and storage areas; and
 - key professional requirements such as the need for –
 - professional supervision of the sale and supply of medicines and drugs
 - customer privacy and counselling
 - sufficient storage for medicines and drugs
 - whether there is or will be reasonable public access to the premises, and in particular, access for disabled persons; and
 - any issues of compliance regarding State or council legislative requirements on matters such as fire safety and occupational health and safety; and
 - in the case of leased premises, the terms of the lease.

A friendly reminder.

Pursuant to Section 9(a) of the *Pharmacy Control Act 2001* the Authority has the power to share information with pharmacists' registration authorities and other relevant bodies.

For example, a referral may be made to the Pharmaceutical Services Branch if at an inspection, the inspector notes issues of non-compliance with the *Poisons Act 1971*. Other bodies to which a referral may be made include Ahpra, Therapeutic Goods Administration and Communicable Diseases Prevention Unit.

Refrigerator temperature monitoring requirements.

The requirements for twice daily recording of refrigerator temperatures where vaccines are stored have been amended.

Compliance with the requirements of 'the National Vaccination Storage Guidelines - Strive for 5, 3rd edition' can be demonstrated by:

- presentation of a written record, preferably on Strive for 5 vaccine fridge temperature chart; or
- record of the downloaded twice daily data records from the data logger along with the person who downloaded the data and the time it was downloaded.

A minimum/maximum thermometer must also be available in case of power failure.

Twice daily recording allows timely alerts of breaches in the cold chain, and is particularly important if there is equipment failure, battery failure or power outages.

Amendments to the Tasmanian Pharmacy Authority Guidelines.

Section 8.1:

Pharmacy keys and alarm codes must only be held by a pharmacist, and no person is to be allowed to enter or remain on the approved a pharmacy business premises unless a pharmacist is present at all times.

- the only exception is that a key may be held by the Tasmanian Fire Service (TFS) for use only by TFS personnel in an emergency and these keys are held in accordance with the TFS key management system.

PO Box 1082
Sandy Bay TAS 7006

registrar@pharmacyauthority.tas.gov.au

Ph: 0417 752 348

Painting 1450mm x
1100mm W x 440mm
D. drug safe bolted
to concrete floor.