

## Community Pharmacy Premises Inspections

A community pharmacy must comply with the *Medicines, Poisons and Therapeutic Goods Act 2008* and *Public Health Act 1997* which establish authorisations and criteria to deal with medicines and poisons, and operate a community pharmacy.

Medicines and Poisons Inspectors from the Health Protection Service use a Community Pharmacy Inspection Form and Opioid Dependency Treatment Centre (where relevant) Inspection Form to assess pharmacy compliance during an inspection. The following table links criteria from the forms with the legislative requirements.

This guide is intended to assist community pharmacy owners and staff to meet their requirements and prepare for a future potential inspection.

Criteria and Legislative Requirements	
<b>Pharmacy Premises</b>	
The pharmacy consist of an enclosed area with direct access to a public place.	<a href="#"><u>Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1</u></a> (3)
The pharmacy contains an area set aside for dispensing of items on prescription that is not less than 8 square metres (dispensary).	
The community pharmacy has at least 1 square metre of free working space, which is not less than 40cm wide for the dispensing of prescriptions.	
The pharmacy is appropriately ventilated and hygienic.	
There adequate lighting in the pharmacy.	
The pharmacy is constructed in a manner as to allow the pharmacist to supervise the sale of scheduled medicines.	
The pharmacy contains appropriate equipment for compounding of extemporaneous preparations.	
There is an appropriate counselling facility available in the pharmacy.	
The pharmacy has a dedicated fax machine for urgent communications.	
<b>Conduct of Business</b>	
The pharmacy is constantly under the control of a pharmacist while open for business.	<a href="#"><u>Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1</u></a> (5)
The name of the pharmacist in charge followed by the words 'Pharmacist in Charge' is displayed prominently.	
The name of all pharmacists practicing in the pharmacy is displayed in a public place.	

<b>Legislation and Reference Works</b>	
<p>The pharmacy has a current version of:</p> <ul style="list-style-type: none"> <li>• the APF</li> <li>• the AMH</li> <li>• the TG or e-TG</li> <li>• the AMH Children’s Companion</li> <li>• current version of PI or CMI</li> <li>• drug interaction reference</li> <li>• SHPA Don’t Rush to Crush Book</li> </ul>	<p><a href="#"><i>Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (2)</i></a></p>
<p>The pharmacy has access to:</p> <ul style="list-style-type: none"> <li>• A complementary or alternate medicine reference</li> <li>• current scheduling guide</li> <li>• access to legislation controlling pharmacy practice</li> </ul>	
<b>Storage of Medicines</b>	
‘Pharmacy only’ medicines are stored appropriately in the pharmacy.	<a href="#"><i>Section 520(1), MPTG Regulation 2008</i></a>
‘Prescription Only’ medicines are stored appropriately in the pharmacy.	<a href="#"><i>Section 520(2), MPTG Regulation 2008</i></a>
Controlled medicines are stored appropriately in the pharmacy.	<a href="#"><i>Section 533(3)(a), MPTG Regulation 2008</i></a>
The pharmacy has a compliant safe.	<a href="#"><i>Schedule 5 of MPTG Regulation 2008</i></a>
The safe is kept locked at all time when not in immediate use.	<a href="#"><i>Section 533(3)(b), MPTG Regulation 2008</i></a>
The safe key/combination is appropriately controlled.	<a href="#"><i>Section 533(3)(c) or (d), MPTG Regulation 2008</i></a>
The controlled medicines register(s) is stored on the premises.	<a href="#"><i>Section 540(4), MPTG Regulation 2008</i></a>
The entries in the controlled medicines register are up to date.	<a href="#"><i>Section 51(1), MPTG Act 2008</i></a>
The controlled medicine balance is correct.	
There is a dedicated refrigerator available in the pharmacy for storing cold chain medicines.	<p><a href="#"><i>Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (3)(a)vi</i></a></p>
The refrigerator has an appropriate temperature monitor control.	
<b>Dispensing of Medicines</b>	
Dispensed medicines are appropriately labelled.	<a href="#"><i>Section 123, MPTG Regulation 2008</i></a>
There is appropriate recording of dispensed medicines.	<a href="#"><i>Section 125, MPTG Regulation 2008</i></a>
Telephone or faxed prescriptions are followed up adequately.	<a href="#"><i>Section 120(1)(g), MPTG Regulation 2008</i></a>
Emergency supply is recorded appropriately.	<a href="#"><i>Section 254, MPTG Regulation 2008</i></a>
Dispensed prescriptions are properly endorsed.	<a href="#"><i>Section 124, MPTG Regulation 2008</i></a>

Dispensed prescriptions are stored appropriately in the pharmacy/ CHO approved location.	<a href="#">Section 120, MPTG Regulation 2008</a>
<b>Vaccination Standards (if applicable)</b>	
The pharmacist(s) administering vaccines have undergone an accredited training course.	<a href="#">Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2019 (No 1)</a>
The pharmacist(s) hold current ASCIA, CPR and First Aid Certificates.	
The pharmacy has an adequate vaccine storage and temperature monitoring.	
There is a designated professional services area and adequate waste disposal.	
There is an in-date and complete anaphylaxis response kit.	
There is an emergency response protocol and consumer information about a consumer's right to make a complaint on display.	
There are adequate hand washing or hand sanitisation facilities.	
There are designated patient monitoring area.	
There are adequate record of vaccinations.	
<b>Opioid Dependency Treatment Licence</b>	
Controlled medicines for opioid dependency treatment are stored appropriately.	<a href="#">Section 533(3)(a), MPTG Regulation 2008</a>
The pharmacy has a compliant opioid dependency treatment medicine storage safe.	<a href="#">Schedule 5 of MPTG Regulation 2008</a>
The safe is kept locked at all times when not in immediate use.	<a href="#">Section 533(3)(b), MPTG Regulation 2008</a>
The safe key/combination is appropriately controlled.	<a href="#">Section 533(3)(c) or (d), MPTG Regulation 2008</a>
The opioid dependency treatment medicine register is stored on premises.	<a href="#">Section 540(4), MPTG Regulation 2008</a>
There are appropriate counselling/dosing facilities or facilities available in the pharmacy.	
The pharmacy has a current Opioid Dependency treatment Licence.	
All prescriptions for Opioid Dependency Treatment patients are current.	<a href="#">Section 120(1)(g), MPTG Regulation 2008</a>
Entries in the opioid dependency treatment medicine register are up-to-date.	<a href="#">Section 51(1), MPTG Act 2008</a>
The controlled medicine balance is correct.	
All opioid dependency treatment dispensing pharmacist(s) have undergone training.	