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ACT COMMUNITY PHARMACY INSPECTION GUIDE

A risk-based approach to community pharmacy inspections in the ACT

2023

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Introduction

The Health Protection Service (HPS) monitors the use of medicines, poisons and therapeutic goods in the ACT community to ensure public safety. Inspectors from the HPS conduct a range of regulatory activities to ensure that medicines and poisons are prescribed, stored and supplied in accordance with relevant legislation.

Purpose

This Community Pharmacy Inspection Guide (Guide) has been developed to ensure a consistent, risk based and transparent approach to community pharmacy inspections. The Guide is designed to assist both inspectors and pharmacists on community pharmacy inspection processes, criteria and enforcement actions. The Guide should be read in conjunction with the *Public Health Act 1997* (PH Act) , the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act) and the Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation).

Community Pharmacy Legislation

In the ACT, a community pharmacy must be licensed according to the PH Act and must comply with the requirements of the Public Health (Community Pharmacy) Code of Practice 2016.

In addition, the MPTG Act and MPTG Regulation, including legislative instruments such as the Medicines, Poisons and Therapeutic Goods (Guidelines for Treatment of Opioid Dependency) Approval 2018 (No 1) and Medicines, Poisons and Therapeutic Goods (Vaccinations by Pharmacists) Direction 2022 (No 1), establish authorisations and requirements to deal with medicines and poisons.

To ensure that community pharmacies comply with their ACT legal requirements, the HPS performs routine pharmacy inspections. Inspections can occur at any reasonable time and without prior notice.

Compliance assessment

During community pharmacy inspections, Medicines and Poisons Inspectors use the Pharmacy Premises Inspection Form and Opioid Dependency Treatment (ODT) Inspection Form (for ODT licensed pharmacies only) (Appendix A and Appendix B). These forms contain inspection criteria that relate to the legislative requirements under the PH Act and MPTG Act.

Medicines and Poisons Inspectors use a risk-based approach to assessing pharmacy compliance against each of the inspection criteria. A Consequence Table and Risk Matrix has been developed at Appendix C to define a level of risk that may be applied to instances of non-compliance during an inspection. Risk levels correlate with the potential risk to public health arising from the non-compliance, as summarised in table 1.

Table 1: Non-compliance risk level correlation to public health risk.

Level of Risk	Description
Low Risk	Does not pose an imminent risk of harm to public health.
Medium Risk	Does not pose an imminent public health risk but does require correction (may become an imminent public health risk if not corrected within specified timeframes).
High Risk	May cause harm to public health and requires immediate rectification.
Extreme Risk	Poses an imminent, serious public health risk that requires immediate rectification and may require immediate enforcement action.

Scoring system

During an inspection, a pharmacy can be deemed compliant, non-compliant, critically non-compliant or not applicable against each of the criterion on the Pharmacy Premises and/or ODT Inspection Forms. If a pharmacy is deemed non-compliant against a criterion, then a level of risk is determined for the non-compliant issue using the Community Pharmacy Risk Assessment Tool at Appendix D.

Each risk level is then given a score of non-compliance as below:

Level of Risk	Score	Level of Risk	Score
Low Risk	1	High Risk	6
Medium Risk	2	Extreme Risk	18

At the end of the inspection, the Total Non-compliance Score (TNS) is calculated by adding the total scores for all non-compliant issues identified against the criteria on the Pharmacy Premises Inspection Form and/or ODT Inspection Form.

Total non-compliance score	Overall Inspection Result
5 or less	Compliant
Between 6 and 17	Non-compliant
18 or greater	Critically Non-compliant

If the TNS is five or less, the pharmacy will be given an Overall Inspection Result as Compliant on the inspection form. Any minor issues that require attention will be recorded by the Inspector on the form for the pharmacy's action. For example, if a pharmacy has two low risk non-compliances the TNS for the pharmacy would be 2 and the pharmacy will be deemed overall Compliant, with minor issues recorded on the form. A follow up inspection is not required in these circumstances. The pharmacy will be provided with a copy of the inspection form.

If the TNS is between 6 and 17, the pharmacy will be deemed non-compliant and, in most cases, served an Improvement Notice. For example, if a pharmacy has two medium risk and two low risk non-compliances, the TNS for the pharmacy would be 6 and the pharmacy will be deemed overall Non-Compliant. The Inspector will serve an Improvement Notice on the pharmacy that outlines areas of non-compliance to rectify within a specified timeframe, with a copy of the inspection form.

An Improvement Notice is an enforcement tool issued under the PH Act that directs a pharmacy to undertake a corrective action in relation to a breach of their legislative requirements. For example, if one of the factors contributing to a high TNS is that the name of the Pharmacist in Charge in the premises was not displayed, an Improvement Notice may be issued to direct the pharmacy to display the name of the Pharmacist in Charge and all persons practicing as a pharmacist by a specific date.

An Improvement Notice is not a punitive measure, however there are potential consequences for a pharmacy not following up with actions required of the Notice.

A follow up inspection will be conducted around the due date of the Notice to determine compliance. The inspector will issue a Revocation Notice[1] if they are satisfied that the Improvement Notice has been complied with in full. If the pharmacy has not complied with the Improvement Notice, the inspector will refer the matter to senior staff within the HPS who will consider further actions.

If the TNS is 18 or above the pharmacy will be deemed Critically Non-Compliant and the matter will be referred to senior staff within the HPS to consider further enforcement options or measures to mitigate harm to public health. For example, if a pharmacy has one extreme risk non-compliance, the TNS for the pharmacy would be 18 and the pharmacy will be deemed Critically Non-Compliant. As a result, the HPS may take enforcement action up to and including closing the pharmacy under a Prohibition Order, varying or suspending the pharmacy's licence, disciplinary actions against a pharmacist, referral to the Australian Health Practitioner Regulation Agency or commencing a prosecution.

ACKNOWLEDGMENT OF COUNTRY

ACT Health acknowledges the Traditional Custodians of the land, the Ngunnawal people. ACT Health respects their continuing culture and connections to the land and the unique contributions they make to the life of this area. ACT Health also acknowledges and welcomes Aboriginal and Torres Strait Islander peoples who are part of the community we serve.

ACCESSIBILITY

If you have difficulty reading a standard printed document and would like an alternative format, please phone 13 22 81.

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[1] A Revocation Notice is legal document that means that the original Improvement Notice has been revoked.

Appendix A – Community Pharmacy Inspection Form

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Community Pharmacy Premises Inspection Form

Health Protection Service
25 Mulley Street Holder ACT 2611
P: 6205 1700 F:6205 1705
Locked Bag 5005 Weston Creek ACT 2611
hps@act.gov.au

Premises Details		
Trading Name:	Date: / /	Start Time: am/pm
Premises Address:		File No:
Proprietor/Licensee:		
Licence/Registration Number:	Licence/Registration Expiry Date:	
Inspection conducted with: Position: Proprietor ☐ Manager ☐ Person in Charge ☐ Other ☐:		
Inspection Type: Scheduled ☐ Follow Up ☐ Complaint ☐ New Licence/Registration ☐ Refurbishment ☐ Other ☐		

The following items are used to determine the compliance with the *Public Health Act 1997* and the *Medicines, Poisons and Therapeutic Goods Act 2008*.

✓ – Compliant L – Low Risk Non-compliance (NC) M – Medium Risk NC H – High Risk NC E – Extreme Risk NC N/A - Not Applicable

	Pharmacy Premises	
1	Enclosed area with direct public access	
2	Dispensary size is at least eight square metres	
3	Adequate free working space in dispensary	
4	Pharmacy appropriately ventilated and hygienic	
5	Adequate lighting	
6	Pharmacist able to supervise shop adequately	
7	Appropriate equipment for extemporaneous preparation	
8	Appropriate counselling facilities	
9	Dedicated fax for urgent communications	
	Conduct of Business	
10	Pharmacy constantly under the control of pharmacist while open for business	
11	Prominent display of all practising pharmacists	
12	Prominent display of Pharmacist-In-Charge	
	Legislation and Reference Works	
13	Current version of the APF	
	Current version of the AMH	
	Current version of the TG or e-TG	
	Current version of AMH Children's Companion	
	Current version of PI or CMI	
	Current version of a drug interaction reference	
	Current Version of Don't Rush to Crush Handbook	
14	Current version of a complementary/alternate medicine reference	
	Current version of a scheduling guide	
	Access to legislation controlling pharmacy practice	
	Storage of Scheduled Medicines	
15	Appropriately stores 'Pharmacy Only' medicines	
16	Appropriately stores 'Pharmacist Only' medicines	
17	Appropriately stores 'Prescription Only' medicines	

	Storage of Controlled Medicines	
18	Appropriately stores controlled medicines	
19	Compliant controlled medicine storage receptacle	
20	Storage receptacle locked on inspection	
21	Storage receptacle key/combination appropriately controlled	
22	Controlled medicine register stored on premises	
23	Controlled medicine register entries up-to-date	
24	Controlled medicine balances correct (see attached Controlled Medicines Report)	
25	Controlled Medicinces stock adjustments/losses explained	
	Storage of Medicines requiring Refrigeration	
26	Dedicated refrigerator for storing cold chain medicines	
27	Appropriate monitoring of temperature	
	Dispensing of Medicines	
28	Appropriate labelling of prescription medicines	
29	Appropriate recording of dispensed medicines	
30	Telephone/Faxed prescription followed up adequately	
31	Emergency prescriptions recorded appropriately	
32	Dispensed prescriptions appropriately endorsed	
33	Appropriately stores dispensed prescriptions in premises	
	Vaccination Standards(if applicable)	
34	Pharmacist(s) undergone accredited training course	
35	Pharmacist(s) hold ASCIA(1 yr) CPR(1 yr) First Aid(3 yr) Cert	
36	Adequate vaccine storage and temperature monitoring	
37	Designated professional services area and waste disposal	
38	In date and complete anaphylaxis response kit	
39	An emergency response protocol on display	
40	Adequate hand washing or hand sanitisation facilities	
41	Adequate patient monitoring area	
42	Adequate record keeping	
	Compliance with Special Conditions	
43	Appropriately complies with special conditions	

Risk Level	Score for Each Risk Level	Total Number of Non-Compliance	Total Score for Each Risk Level
Low Risk	1		
Medium Risk	2		
High Risk	5		
Extreme Risk	15		
Total Non-compliance Score for the Pharmacy			

If Total Non-compliance Score for pharmacy is ≤ 5 the pharmacy will be considered compliant or compliant with minor issues.

If Total Non-compliance Score for pharmacy is between 5 and 15 the pharmacy will be considered non – compliant

If Total Non-compliance Score for pharmacy is ≥ 15 the pharmacy will be considered critically non- compliant.

Overall Inspection Result: ☐ Compliant ☐ Non Compliant ☐ Critically Non Compliant Follow Up Date: ...../...../.....

Inspector's Name:	Inspector's Signature:	Finish Time: am/pm
Received By:	Signature:	Date & Time:

NOTE: Failure to attend to the items in this report within the times specified may render you liable to legal action under the *Public Health Act 1997* and the *Medicines, Poisons and Therapeutic Goods Act 2008*.

Appendix B – Opioid Dependency Treatment Centre Inspection Form

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Opioid Dependency Treatment Centre Inspection Form

Health Protection Service
25 Mulley Street Holder ACT 2611
P: 02 5124 9700 F:02 5124 5554
Locked Bag 5005 Weston Creek ACT 2611
hps@act.gov.au

Premises Details		
Trading Name:	Date: / /	Start Time: am/pm
Premises Address:		File No:
Proprietor/Licensee:		
ODT Licence Number:	Licence Expiry Date:	
Inspection conducted with: Position: Proprietor ☐ Manager ☐ Person in Charge ☐ Other ☐:		
Inspection Type: Scheduled ☐ Follow Up ☐ Complaint ☐ New Licence ☐ Refurbishment ☐ Other ☐		

The following items are used to assess compliance with the *Public Health Act 1997* and the *Medicines, Poisons and Therapeutic Goods Act 2008.*

✓ – Compliant L – Low Risk Non-compliance (NC) M – Medium Risk NC H – High Risk NC E – Extreme Risk NC N/A - Not Applicable

Storage of Opioid Dependency Medicines		
1	Compliant opioid dependency treatment medicine storage receptacle	
2	Appropriately stores opioid dependency treatment medicines.	
3	Storage receptacle locked on inspection	
4	Storage receptacle key/combination appropriately controlled	
5	Controlled medicines register for opioid dependency treatment is stored on premises	
6	Controlled medicine balance correct	

Opioid Dependency Treatment Licence Inspection		
7	Appropriate counselling/ dosing facilities	
8	Current Opioid Dependency Treatment Centre Licence	
9	All prescriptions for clients current	
10	Controlled medicines register entries for opioid dependency treatment are up to date	
11	All dispensing pharmacist(s) have undergone training	

Medicine, Form and Strength	Safe	Reg.	Diff.
BUPRENORPHINE			
Subutex s/l tab 0.4mg			
Subutex s/l tab 2mg			
Subutex s/l tab 8mg			
BUPRENORPHINE/NALOXONE			
Suboxone s/l filmtab 2mg/0.5mg			
Suboxone s/l filmtab 8mg/2mg			
METHADONE			
Biodone Forte syrup 25mg/5ml			
Methadone Syrup 25mg/5ml			

Item Nos.	Items Requiring Action	Due Date

Risk Level	Score for Each Risk Level	Total Number of Non-Compliance	Total Score for Each Risk Level
Low Risk	1		
Medium Risk	2		
High Risk	6		
Extreme Risk	18		
Total Non-compliance Score for the Pharmacy			

If Total Non-compliance Score for pharmacy is ≤ 5 the pharmacy will be considered compliant or compliant with minor issues*.

If Total Non-compliance Score for pharmacy is between 5 and 18 the pharmacy will be considered non – compliant.

If Total Non-compliance Score for pharmacy is ≥ 18 the pharmacy will be considered critically non- compliant.

Overall Inspection Result: ☐ Compliant ☐ Non-compliant ☐ Critically Non-compliant Rectification Date: ...../...../.....

**Unless otherwise stated, pharmacies deemed to be compliant with minor items of non-compliance must be rectified within 4 weeks of the inspection.*

Inspector's Name:	Inspector's Signature:	Finish Time: am/pm

Received By:	Signature:	Date & Time:

NOTE: Failure to attend to the items in this report within the times specified may render you liable to legal action under the *Public Health Act 1997* and the *Medicines, Poisons and Therapeutic Goods Act 2008.*

Appendix C – Consequence Table and Risk Matrix

The Consequence table assigns a level of severity against a range of harms as they are defined in the PH Act and MPTG Act.

Consequence table ***Section 6(1)* MPTG Act**				
Harms	**Minor**	**Moderate**	**Major**	**Catastrophic**
Accidental or deliberate poisonings	Ingestion of a poison or medicine with some adverse effects. Some first aid treatment required.	Poisoning or overdose requiring medical treatment.	Serious poisoning or overdose requiring hospital admission or ongoing medical treatment.	Death or near death due to poisoning or overdose.
Medicinal misadventure	Some adverse effects experienced due to misadventure (mishap) with a medicine. Includes dispensing error for schedule 4 or 8 medicine which may lead to the above.	Overdose or adverse effects of a medicine requiring medical treatment. Includes dispensing error for schedule 4 or 8 medicine which may lead to the above.	Serious overdose or adverse effects of a medicine requiring hospital admission or ongoing medical treatment. Includes dispensing error for schedule 4 or 8 medicine which may lead to the above.	Death or near death due to overdose or adverse effects of a medicine. Includes dispensing error for schedule 4 or 8 medicine which may lead to the above.
Diversion of regulated substance for abuse	Theft or diversion of a schedule 3 medicine for own use or supply to others.	Theft or diversion of schedule 4 medicines for own use or supply to others.	Theft or diversion of schedule 8 medicines for own use or supply to others. Includes the theft or diversion of lower scheduled substances (eg. S3) for illicit manufacture of schedule 8 or 9 substances.	Theft or diversion of large quantities of schedule 4 or 8 medicines for supply to others.
Manufacture of regulated substances that are subject to abuse			Limited illicit manufacture of a schedule 8 or 9 substance.	Organised, broad scale illicit manufacture of a schedule 8 or 9 substance.
Other harm from regulated therapeutic goods	Some adverse effects experienced. Some first aid treatment required.	Medical treatment required.	Hospital admission or ongoing medical treatment required.	Death or near death.

The Risk Matrix is used to determine the level of risk by comparing the consequence of a harm against the likelihood of it occurring.

Risk Matrix ***Section 4(a)* PH Act**					
Harm from facilities, equipment, products and activities		Some adverse effects experienced. Some first aid treatment required.	Medical treatment required.	Hospital admission or ongoing medical treatment required.	Death or near death.
Historical Likelihood	**Likelihood**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Is expected to occur in most circumstances	**Almost Certain**	**H**	**H**	**E**	**E**
Will probably occur	**Likely**	**M**	**H**	**H**	**E**
Might occur at some time in the future	**Possible**	**L**	**M**	**H**	**E**
Could occur but doubtful	**Unlikely**	**L**	**L**	**M**	**H**
May occur but only in exceptional circumstances	**Rare**	**L**	**L**	**L**	**H**

The consequence table and risk matrix has been developed by the HPS based on a subjective assessment of the likelihood and consequences of each potential event as they relate to the regulation of community pharmacies in the ACT.

Note: Not all inspection criteria have a full range of risk levels assigned to them. Some criteria may have a limited range, such as only Low or Medium Risk, or only Extreme Risk.

Appendix D – Community Pharmacy Risk Assessment Tool

Pharmacy Premises *Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (3)*	**Low risk**	**Medium risk**	**High risk**	**Extreme risk**
Does the community pharmacy consist of an enclosed area with direct access to a public place?			• The pharmacy is not operating in an enclosed area • The public does not have direct access to the pharmacy	
Does the community pharmacy contain an area set aside for the dispensing of items on prescription that is not less than 8 square metres? (dispensary)		There is an area set aside for dispensing, but the dispensary size is less than 8 square metres.	There is no specific area set aside for dispensary.	
Does the community pharmacy have at least 1 square metre of free working space, which is not less than 40cm wide for the dispensing of prescriptions?			The free working space is less than the requirement.	
Is the community pharmacy appropriately ventilated and hygienic?	• Some Ventilation • Some Hygiene E.g. Dust around air conditioning vents in the ceilings. Small accumulation of waste, dirt or other matter on floor or walls that can be easily cleaned.	• Poor Ventilation • Poor Hygiene E.g. Hazardous spill left on the floor without cleaning at the time of inspection.	• No adequate ventilation present in the pharmacy • Very poor hygiene E.g. Accumulation of waste, dirt or other matters on floors, walls or ceilings that is consistent with weeks to months' worth of build-up.	
Is there adequate lighting in the pharmacy?		Poor lighting in the pharmacy or dispensary.	No lighting in pharmacy or dispensary.	
Is the pharmacy constructed in a manner where the pharmacist can supervise the shop adequately?	Pharmacist is unable to supervise the supply of Schedule 2 medication.			
Does the pharmacy contain appropriate equipment for compounding of extemporaneous preparations?			The pharmacy does not contain appropriate equipment for compounding of extemporaneous preparations within their scope of practice.	
Is there an appropriate counselling facility available in the pharmacy?	Limited or no space available for confidential counselling of patients.			
Does the pharmacy have a dedicated fax machine for urgent communications?	• The pharmacy does not have a dedicated fax machine • The fax machine is not working			

Conduct of Business ***Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (5)***	**Low risk**	**Medium risk**	**High risk**	**Extreme risk**
Is the pharmacy premise constantly under the control of a pharmacist while open for business?				There is no pharmacist controlling the pharmacy.
Is there prominent display of the name of the pharmacist in charge followed by the words 'Pharmacist in Charge'	• There is no display of the name of pharmacist in charge. • The name of 'Pharmacist in Charge' is not correct.			
Is the name of all persons practicing in the community pharmacy as a pharmacist displayed in a public place in a clearly legible notice in the premises?	• The name of pharmacist(s) practicing in the pharmacy is not displayed in a clearly legible notice in the premises. • The name of pharmacist(s) displayed is not correct.			
Legislation and Reference Works ***Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (2)***	**Low risk**	**Medium risk**	**High risk**	**Extreme risk**
Does the pharmacy have current edition of • **the APF** • **the AMH** • **the TG or e-TG** • **the AMH Children's Companion** • **current version of PI or CMI** • **drug interaction reference** • **SHPA Don't Rush to Crush Book**	The pharmacy does not have current versions of some of the prescribed references.	The pharmacy does not have current version of more than 3 of the prescribed references.	The pharmacy does not have current versions of any of the prescribed references.	
Does the pharmacy have access to • **A complementary or alternate medicine reference** • **current scheduling guide** • **access to legislation controlling pharmacy practice**	The pharmacy does not have access to a complementary/alternate medicine reference. Pharmacy does not have access to current scheduling guide and legislation controlling pharmacy practice.			

Storage of Medicines	Low risk	Medium risk	High risk	Extreme risk
Are 'Pharmacy only' medicines stored appropriately in the pharmacy? **Section 520(1), MPTG Regulation 2008**	The 'pharmacy only' medicine is not stored within 4m of, or in sight of the dispensary and pharmacist is unable to supervise sale.			
Are 'Pharmacist only' medicines stored appropriately in the pharmacy? **Section 520(2), MPTG Regulation 2008**			The 'pharmacist only' medicines are kept in a part of the premises where the public have direct access.	
Are 'Prescription Only' medicines stored appropriately in the pharmacy? **Section 520(2), MPTG Regulation 2008**			The 'prescription only' medicines are kept in a part of the premises where the public have direct access.	
Are controlled medicines stored appropriately in the pharmacy? **Section 533(3)(a), MPTG Regulation 2008**			Controlled medicines are stored outside the safe. But there is no direct public access to the storage area.	The controlled medicines are kept outside the safe in a part of the premises where the public has direct access.
Does the pharmacy have a compliant safe? **Schedule 5 of MPTG Regulation 2008**		Controlled medicines are stored in a safe which meets body, door and lock requirements as per schedule 5, but the safe does not meet moulding requirements. E.g. The safe is fixed to the floor with only 3 expanding bolts.	Controlled medicines are stored in a safe which does not meet the body, door or lock requirements. E.g. Controlled medicine is stored on the shelf or in a wooden safe.	
Is the safe kept locked all the time when not in immediate use?		The safe is not in immediate use but kept open at the time of inspection.		

Section 533(3)(b), MPTG Regulation 2008				
Is the safe key/ combination appropriately controlled? Section 533(3)(c) or (d), MPTG Regulation 2008	The safe key is not in the possession of pharmacist at the time of inspection. Non-pharmacist staff have knowledge of the combination to the safe and can access it.			
Are the controlled medicines register(s) stored on premises? Section 540(4), MPTG Regulation 2008	The most recent controlled medicine register is stored on the premises. The previous registers (within the last two years) are stored offsite.	The most recent of controlled medicine register is stored on the premises. The previous registers (within the last two years) are missing or have been thrown out.		There is no controlled medicines register.
Are the entries in the controlled medicines register up to date? Section 51(1), *MPTG Act 2008*		A number of controlled medicine dealings have not been written into the register more than 24 hours after the dealings occurred.	Frequent repeated incomplete or missing register entries into the controlled medicines register.	
Are the controlled medicine balances correct? Section 51(1), 58(3), 58(4) MPTG Act 2008	The controlled medicine register balance of up to 5% of product line stored in the pharmacy did not match with the actual stock on hand during inspection AND were resolved at the time of inspection.	The controlled medicine register balance of 5-10% of product line stored in the pharmacy did not match with the actual stock on hand during inspection AND was resolved at the time of inspection. OR The controlled medicine register balance of up to 5% of product line stored in the pharmacy did not match with the actual stock on hand during inspection AND was NOT resolved at the time of inspection. OR Unexplained loss at the time of inspection or unexplained stock adjustment of controlled medicines (up to 10 tablets/capsules/films etc of solid form products and up to 10mL of liquid products). OR	The controlled medicine register balance of 10-20% of product line stored in the pharmacy did not match with the actual stock on hand during inspection. OR The controlled medicine register balance of 5% to 10% of product line stored in the pharmacy did not match with the actual stock on hand during inspection AND was NOT resolved at the time of inspection. OR Unexplained loss at the time of inspection or unexplained stock adjustment of controlled medicines (up to 100 tablets/capsules/films etc of solid dosage form products and up to 100mL of liquid products). OR 3-5 entries made in drug register within the last 12 months as suspected loss/theft of controlled medicines without notifying the Pharmaceutical Services Section.	The controlled medicine register balance of more than 20% of product line stored in the pharmacy did not match with the actual stock on hand during inspection. OR Unexplained loss at the time of inspection or unexplained stock adjustment of controlled medicines (More than 100 tablets/capsules/films etc of solid dosage form products and more than 100mL of liquid products). OR More than 5 entries made in the drug register within the last 12 months as suspected loss/theft of controlled medicines without notifying the Pharmaceutical Services Section. OR Suspected diversion of controlled medicines.

		Up to 2 entries made in the drug register within the last 12 months as suspected loss/theft of controlled medicines without notifying the Pharmaceutical Services Section.		
Is there a dedicated refrigerator available in the pharmacy for storing cold chain medicines? Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (3)(a)vi			There is no dedicated refrigerator for storing cold chain medicines.	
Does the refrigerator have appropriate temperature monitor control?		The refrigerator does not have temperature control.		

Dispensing of Medicines MPTG Regulation 2008	Low risk	Medium risk	High risk	Extreme risk
Is there appropriate labelling of dispensed medicines? **Section 123, MPTG Regulation 2008**	Some dispensed medications listed in Appendix K of SUSMP does not have sedation warning.	Other labelling requirements of dispensed medicine is not consistent with MPTG Regulation. OR Most dispensed medications listed in Appendix K of SUSMP does not have sedation warning.		There is no dispensing label on dispensed medicines.
Is there appropriate recording of dispensed medicines? **Section 125, MPTG Regulation 2008**		The recording of dispensed medicine is not consistent with MPTG Regulation.		Pharmacy is not recording of the supply of medicine.
Are telephone/faxed prescriptions followed up adequately? **Section 120(1)(g), MPTG Regulation 2008**	Pharmacy has some S8 oral/faxed prescriptions which are not adequately followed up. OR Pharmacy has up to 25 S4 oral/faxed prescriptions which are not adequately followed up	Pharmacy has more than 5 S8 oral/faxed prescriptions which are not adequately followed up. OR Pharmacy has more than 25 S4 oral/faxed prescriptions which are not adequately followed up.	Pharmacy has more than 10 S8 oral/faxed prescriptions which are not adequately followed up. OR Pharmacy has more than 100 S4 oral/faxed prescriptions which are not adequately followed up.	Pharmacy supplies medication to patients without supply authority from a medical practitioner.
Are emergency supply recorded appropriately? **Section 254, MPTG Regulation 2008**		The recording of dispensed medicine is not consistent with MPTG Regulation.		Pharmacy is not recording of the supply of medicine.
Are dispensed prescriptions properly endorsed? **Section 124, MPTG Regulation 2008**	Prescriptions for schedule 4 medications are not endorsed with the word 'cancelled'.	Prescriptions for schedule 8 medications are not endorsed with the word 'cancelled'.		
Are dispensed prescriptions stored appropriately in the pharmacy/ CHO approved location? **Section 120, MPTG Regulation 2008**	Dispensed prescriptions are stored in a secured area outside the pharmacy premises where only the pharmacist has access to without obtaining approval from the Chief Health Officer.		Dispensed prescriptions are stored in a place where public has direct access to the storage.	Dispensed prescriptions are not stored by the pharmacy for at least 2 years.

Vaccination Standard (applicable for pharmacies providing vaccination service)				
Vaccination Standards Public Health (Community Pharmacy) Code of Practice 2016 (No 1) Schedule 1 (4)	**Low risk**	**Medium risk**	**High risk**	**Extreme risk**
Has pharmacist(s) administering vaccines undergone accredited training course?			The pharmacist or intern pharmacist administering vaccine has not done accredited training course.	
Does the pharmacist hold current ASCIA, CPR and First Aid Certificates?			Pharmacist does not have current ASCIA, CPR and First Aid certificates.	
Does the pharmacy have an adequate vaccine storage and temperature monitoring?		There is poor temperature monitoring of vaccine storage fridge.	There is no dedicated fridge for adequate storage of vaccines. OR Faulty fridge OR There is no temperature monitoring.	
Is there a compliant designated professional services area and adequate waste disposal?		The designated professional service area is not compliant according to the Vaccination Standards	There is no designated professional service area. OR There is no adequate waste disposal.	
Is there an in date and complete anaphylaxis response kit?				Pharmacy has no access to an anaphylaxis response kit.
Is there an emergency response protocol and consumer information about a consumer's right to make a complaint on display?	Pharmacy does not have display of 'consumer information about a consumer's right to make a complaint.	There is an emergency response protocol but is not displayed.	There is no emergency response protocol in place.	
Is there adequate hand washing or hand sanitisation facilities?			There is no adequate hand washing or hand sanitisation facilities.	
Is there a designated patient monitoring area?		There is a designated patient monitoring area but the pharmacist who has completed the training is not able to easily monitor the patient.	There is no designated patient monitoring area.	
Is there adequate record keeping of vaccinations?			• There is no written procedure in place for the vaccination process, dealing with adverse events, obtaining and recording patient consent and sending vaccination records back to the patient's nominated GP. OR • The patient records does not contain all the relevant information as per the vaccination standard.	There is no record keeping of vaccinations conducted.