



SELF-INSPECTION FORM NEW PHARMACY BUSINESS PREMISES OR FOR USE FOR REGULAR CHECKS OF PHARMACY PREMISES

Pursuant to Part 4 of the Pharmacy Control Act 2001

Use this form after the development of new pharmacy premises have been completed, to determine whether the premises meet the requirements of the Pharmacy Control Act 2001 and are therefore ready for registration and inspection by the Authority. This form can also be used when pharmacists wish to ensure premises are meeting the requirements of the Act and Guidelines.

This Form must be submitted together with Form DOC (Declaration of Completion of New Pharmacy Premises and Intention to Commence Trading Advice) PRIOR TO the commencement of trading of new or relocated pharmacies.

PHARMACY NAME: _____

PHARMACY ADDRESS: _____

Self-Inspection Date:/...../.....

- 1 If the Pharmacy is transferring from another site, has all the pharmacy **signage** been removed from the old site?
YES / NO / NOT APPLICABLE
- 2 If the pharmacy is transferring from another site, have all **internet references** to that old site been amended/deleted/updated?
YES / NO / NOT APPLICABLE
- 3 Are there any **other businesses** in the Pharmacy? (eg: lotto agency, ATM, newsagent)
YES / NO
If **YES**: Has the Authority been made aware of those businesses?
YES / NO
- 4 Does anyone concerning those activities have access to the pharmacy **out of hours** (eg: the bank to refill the ATM)?
YES / NO
- 5 If the premises are **leased**, has the lease been approved by the Authority?
YES / NO

- 6 Is there **direct access** to or from any adjoining premises? (eg: Doctor's Surgery)
YES / NO
 If **YES**: Has the Authority been made aware of those businesses?
YES / NO
- 7 Can anyone from any adjoining premises access the pharmacy out of pharmacy hours?
YES / NO
- 8 Does the pharmacy carry on a depot?
YES / NO
 If **yes**:
 Address of Depot:.....
- 9 Does the pharmacy have any off-site storage or warehouse for stock, bulk goods or records?
YES / NO
 If **yes**: are any scheduled items stored there?
YES / NO
 If **YES**: are any records there stored in a secure way to restrict access, in accordance with privacy principles?
YES / NO
- 10 Have the premises been developed and fitted out in accordance with plans approved-in-principle by the Authority?
YES / NO
- 11 Has there been any changes to the plans originally lodged with the Authority? If yes, please contact the Authority and advise accordingly and provide an updated copy of the plans.
YES / NO

A. PHARMACY DESIGN & PRACTICE (TPA Guidelines & Pharmacy Control Act Sections 71A – 71J)

A1 Do the premises comply with the Building Code and other State or council legislative requirements on matters such as fire safety and occupational health and safety?	YES / NO
A2 Is the pharmacy constructed to be secure from unauthorised access through doors, windows, walls and ceilings?	YES / NO
A3 Has the pharmacy got an alarm system fitted with a siren, and which is monitored by a central monitoring station on a 24-hour basis?	YES / NO
A4 Has the alarm system got a back-up and monitoring system, such that any attempt to disable or isolate the alarm system, or line failure, will result in a response?	YES / NO
A5 Has the pharmacy got an area for the unpacking and storage of goods which is not in the professional service area, which is a workable size commensurate with the size of the pharmacy and denies access to any member of the public?	YES / NO

A6 Is there an area for the provision of counselling about dispensed or other medicines, so that the privacy of the person receiving the counselling can be assured?	YES / NO
A7 Does the pharmacy have access for disabled persons?	YES / NO
A8 Is access for the public provided by direct access from a street or public walkway?	YES / NO
A9 Does the pharmacy complies with supermarket access rules? ie: <ul style="list-style-type: none"> • The pharmacy is not located wholly or partly within a supermarket; or • The pharmacy is not capable of being entered from within a supermarket; or • The pharmacy is not capable of being used to gain entry to a supermarket. 	YES / NO
A10 Is access to any other premises shown on the plans approved by the Authority and consistent with those plans? (especially for new or relocating premises)	YES / NO / NA
A11 Are tobacco products or alcoholic beverages are sold in the premises?	YES / NO
A12 Are any animals present on the premises (Guide dogs & support animals exempt)?	YES / NO

B. DISPENSARY & EQUIPMENT (Tasmanian Pharmacy Authority Guidelines):

B1 Is the Dispensary of an adequate size to allow for the free and clear movement of the pharmacist when dispensing?	YES / NO
B2 Is there adequate lighting and ventilation?	YES / NO
B3 Is there is a sink of stainless steel or other material approved by the Authority with an impervious surround, and supplied with hot and cold running water?	YES / NO
B4 Is the dispensing bench covered with an impervious covering which is not less than 40 centimetres wide?	YES / NO
B5 Is there not less than 1.0 square metres of free working space per dispensary station?	YES / NO
B6 Are conditions of temperature and humidity suitable for the storage of all drugs and medicines kept in the dispensary, and are those conditions maintainable?	YES / NO
B7 Is public access to the dispensary restricted and controlled?	YES / NO
B8 Can the pharmacist-on-duty effectively supervise the pharmacy premises where medicines are kept, sold or supplied, and supervise the staff?	YES / NO
B9 Are medicines stored in a manner that will not promote the sale of a product or draw undue attention to a product?	YES / NO
B10 Is packing of dose administration containers (such as Webster packs) carried out in a dedicated area where distractions are minimised, and which complies with PSA standards and with adequate lighting and ventilation? Is this done offsite? If so, the Authority will need to know where and whether you use a contracted company for this activity. Provide address of offsite packing of DAAs:	YES / NO / NA

C. EQUIPMENT (Pharmacy Control Act, QCPP Guidelines and Tasmanian Pharmacy Authority Guidelines)

C1 A means of refrigeration complying with the “Cold Chain Management Standard” of the Quality Care Pharmacy program (QCPP) or equivalent minimum standards	YES / NO
C2 The min/max daily refrigerator temperatures are monitored and recorded C2a If the pharmacy is vaccinating are the refrigerator temperatures recorded twice daily?	YES / NO YES / NO/ NA
C3 Please confirm that all refrigerated medications are stored separately from all food stuffs.	YES / NO
C4 Does the pharmacy provide facilities for vaccination/immunisation services?	YES / NO
C5 Does the pharmacy use a dispensing robot? If YES, please provide the make and model:	YES/NO/NA

D. COMPOUNDING & EQUIPMENT (Pharmacy Control Act and Tasmanian Pharmacy Authority Guidelines)

D1 Does the pharmacy undertake complex compounding? Complex compounding means the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves specific competencies, equipment, processes, or facilities. (e.g. hormone, cytotoxic or IV preparations)	YES / NO
D2 Does this pharmacy undertake simple compounding? IF YES: GO TO D3 – D7 (inclusive) IF NO: GO TO D8	YES / NO
D3 Does the pharmacy have adequate calibrated metric weighing and measuring equipment possessing capacities and precision suitable for the compounding, dispensing and sale of drugs and medicines; (+/- .01 g on electronic scales)?	YES / NO
D4 When were the scales AND weights last professionally calibrated (the accepted standard is every two years) Weights Date: Scales date:	
D5 Does the pharmacy have adequate compounding and blending equipment for simple compounding?	YES / NO
D6 Does the pharmacy have adequate vessels suitable for storage and supply of all commonly used pharmaceutical preparations?	YES / NO
D7 Are there adequate facilities for heating required for dispensing and compounding drugs and medicines?	YES / NO
D8 If the pharmacy does not undertake any compounding, you must provide an appropriate written procedure to deal with prescriptions of medications that require compounding?	

E. REQUIRED REFERENCES (PBA Pharmacy Guidelines on Practice-Specific Issues - List of References as at 2020)

MUST HAVE	Version	Available
E1 Australian Pharmaceutical Formulary and Handbook (APF) APF24 (online or hard copy)	24 th ed	Y / N / OUT OF DATE
E2 Australian Medicines Handbook (AMH) AMH 20	2020	Y / N / OUT OF DATE
E3 Therapeutic Guidelines Series eTG (online version ONLY)		Y / N / OUT OF DATE
E4 A source of current Australian Product Information and Consumer Medicine Information		Y / N / OUT OF DATE
<input type="checkbox"/> MIMS Annual with MIMS Abbreviated; or		
<input type="checkbox"/> eMIMS; or		
<input type="checkbox"/> MIMS Online; or		
<input type="checkbox"/> AusDI Advanced/AusDI		
E5 A Drug Interaction reference		Y / N / OUT OF DATE
<input type="checkbox"/> AusDI Advanced/AusDI; or		
<input type="checkbox"/> Drug Interaction Facts – Facts and Comparisons; or		
<input type="checkbox"/> eMIMS; or		
<input type="checkbox"/> MIMS Online; or		
<input type="checkbox"/> Micromedex; or		
<input type="checkbox"/> Stockley’s Drug Interactions Online; or		
<input type="checkbox"/> Lexicomp Interactions		
E6 AMH Children’s Dosing Companion	2020	Y / N / OUT OF DATE
E7 Australian Don’t Rush to Crush Handbook in HARD COPY or as part of an optional extra subscription with MIMS Online	3rd edition	Y / N / OUT OF DATE Y/N

F. ONLINE REFERENCES (REQUIRED) (Pharmacy Control Act s71 and Guidelines Part B 7; PBA Guideline 1)

The following can be accessed electronically via bookmarked websites or more easily by use of the following single link: http://www.pharmacyauthority.tas.gov.au/about/links/	
F1 Copies of the legislation controlling the practice of pharmacy:	
Health Practitioner Regulation National Law Act (the National Law) as in force in each state and territory	YES / NO
Pharmacy Control Act 2001 (as amended)	YES / NO
Poisons Act 1971 (and amendments)	YES / NO
Poisons Regulations 2008 (and amendments)	YES / NO
Relevant Therapeutic Good Administration Guidelines e.g. the Advertising Code and the Price Code	YES / NO
The Tasmanian Pharmacy Authority Guidelines – current version	YES / NO
Information in relation to the Privacy Act 1988 (and amendments)	YES / NO
The Poisons List or the Standard for the Uniform Schedule for Drugs and Poisons (SUSDP)	YES / NO
F2 Australian Immunisation Handbook	YES / NO
F3 The Pharmacy Board of Australia (PBA) Guidelines	YES / NO
F4 Professional practice standards and guidelines published by the PSA and SHPA	YES / NO
F4 The Merck Manual of Diagnosis and Therapy (Merck Sharp and Dohme)	YES / NO
F5 A Medical Dictionary	YES / NO
F6 An evidence-based reference work on complementary and alternative medicines - e.g. Medline Plus	YES / NO

G. CONDUCT OF PHARMACIST & ASSISTANTS: (Tasmanian Pharmacy Authority Guidelines and Pharmacy Control Act)

G1 Is the surface of the dispensing bench kept clean, sanitary, and in good repair?	YES / NO
G2 Is the working area and clothing of any persons working in the dispensary kept clean and free from any contaminants?	YES / NO
G3 Is the equipment maintained in good working order?	YES / NO
G4 Is smoking of tobacco or any other substances prohibited in the pharmacy?	YES / NO
G5 Is the consumption of alcohol or recreational drugs prohibited in the pharmacy?	YES / NO
G6 Are the standards of personal hygiene, dress, and appearance of all staff in the pharmacy appropriate for a health care setting?	YES / NO
G7 Does the Pharmacist in Charge state that any person assisting in the dispensing process is appropriately trained for the tasks being undertaken?	YES / NO

H. DISPENSING

(PSA Professional Practice Standards, PBA, Pharmacy Control Act and Tasmanian Pharmacy Authority Guides, Poisons Regulations 2018)

H1 Does the Pharmacy have a documented and appropriate procedure for dispensing which is available in the area where the dispensing takes place e.g. PDL Guide for Good Dispensing?	YES / NO
H2 Is dispensing done in accordance with the procedure?	YES / NO
H3 Is there a documented process for managing and following up Owing Scripts?	YES / NO

I. THE DISPENSARY COMPUTER SYSTEM (Pharmacy Control Act s71E and Guidelines Part B 10)

I1 Dispensary Software: FRED / LOTS / MINFOS / AQUARIUS / Z Dispense / _____	
I2 The Pharmacist in Charge states that regular computer backups occur: Frequency: Daily / Other _____	YES / NO
I3 Are computer backups fully automated (i.e. no human intervention required)? If NO : Are detailed written procedures of the back-up of the computer system available	YES / NO YES / NO
I4 Does the Pharmacist in Charge state that backups are stored off-site and retained in accordance with statutory requirements?	YES / NO
I5 Barcode scanners and dispensing software are present at every dispensing station and are always used as part of the dispensing procedure?	YES / NO

J. DISPOSAL & DESTRUCTION (Pharmacy Control Act s71E, Guidelines Part B 10)

J1 Does the Pharmacy have a documented procedure for the checking, removal, and disposal of expired stock from the pharmacy shelves which is available in the area where stock is held?	YES / NO
J2 Is the stock on the pharmacy shelves within expiry dates?	YES / NO
J3 Is all out-of-date stock awaiting disposal marked as such and stored away from other stock?	YES / NO
J4 Is a RUM Bin available within the dispensary area and is it being used?	YES / NO
J5 Does the pharmacist state that records containing personal information (such as patient records, prescription labels, rubbish which includes personal details etc) are destroyed or permanently de-identified when no longer needed for any purpose?	YES / NO

K. STORAGE OF SCHEDULED SUBSTANCES (Pharmacy Control Act s71E, Guidelines Part B 11 and Poisons Regulations 2018)

<p>K1 Narcotic substances Are all Schedule 8 items stored apart from other substances in an enclosure that is constructed and secured in a manner approved by the Secretary? (A level 4 safe which is securely locked and is either a torch and drill resistant in-floor safe; or a free-standing safe of at least 500kg which is bolted and glued to the floor).</p>	YES / NO
<p>K2 Narcotic substances - If a dispensing robot is used, does it contain narcotics?</p>	YES / NO / NA
<p>K3 Are all DAA packs containing narcotics kept (along with their stock boxes) in a locked day safe/approved narcotic safe during the day and an approved locked narcotic safe over night?</p>	YES / NO / NA
<p>K4 Is a day safe or day storage drawer used? If yes:</p>	YES / NO / NA
<p>K4a Is it kept locked when not in use and is the key held by the pharmacist or in an inaccessible place?</p>	YES / NO / NA
<p>K4b Are all narcotics placed in the night safe whenever the pharmacy is closed?</p>	YES / NO / NA
<p>K4c Are all dispensed narcotics awaiting collection, including DAA packs and staged supply, stored in the day or night safe during the day, and in the night safe when the pharmacy is closed?</p>	YES / NO / NA
<p>K5 Does the Pharmacist in Charge state that the key or code or details of the safe combination for the Narcotics Safe is kept either on the pharmacist's person or in a place not readily accessible to other persons?</p>	YES / NO
<p>K6 Does the Pharmacist in Charge state that the key or code or details of the safe combination are NOT left on the pharmacy premises while the pharmacy is closed?</p>	YES / NO
<p>K7 Are any substance specified in Schedule 3 or 4 to the Poisons List kept in either a storeroom and/or in the dispensary so that the public does not have access to the substance?</p>	YES / NO
<p>K8 Is any substance specified in Schedule 2 of the Poisons List – (a) kept in the dispensary or in a secure storeroom so as to ensure that it is not readily accessible to the public; or (b) is on a horizontal shelf that is – (i) affixed to, or placed immediately against, an internal wall or partition separating the dispensary from the remainder of the premises; or (ii) not more than 4 metres from, and in clear line of sight of, the dispensary</p>	YES / NO
<p>K9 Is Pseudoephedrine Storage appropriate?</p>	YES / NO
<p>K9a Are all S3 pseudoephedrine products are stored in the dispensary or pharmacy storeroom?</p>	YES / NO
<p>K9b Are pseudoephedrine product stock levels minimal?</p>	YES / NO
<p>K9c Are products (where possible) are kept out of sight of public, particularly high-risk products such as single active and antihistamine combinations?</p>	YES / NO
<p>K9d Recording of the supply of products should occur where the purchaser is not a customer who is known to the pharmacist as a person of good character (bona fide regular local, account or prescription customer)?</p>	YES / NO

L. REGISTER OF DRUGS OF DEPENDENCE (Pharmacy Control Act s71E, Guidelines Part B 11 and Poisons Regulations 2018)

L1 A DD Register is maintained in accordance with the requirements of Regulation 13 of the Poisons Regulations 2008?	YES / NO
L1a Is the stock regularly reconciled against the register?	YES / NO
L1b Are entries made within 48 hours of dispensing?	YES / NO

M. LABELLING OF DISPENSED MEDICINES (Pharmacy Control Act s71E, Guidelines Pt B10)

<p>M1 All dispensed containers are labelled with –</p> <p>(a) the words "Keep out of reach of children" in red on a white background; and</p> <p>(b) the name of the patient (or in the case of an animal the name of the owner of the animal); and</p> <p>(c) the name, address, and phone number of the pharmacy; and</p> <p>(d) cautionary labels; and</p> <p>(e) particulars set out in the prescription; and</p> <p>(f) the initials of the dispensing pharmacist</p> <p>Numbers or letters on a label are –</p> <p>(a) at least 1.5 mm high; and</p> <p>(b) in clear and distinct contrast to the background</p>	YES / NO
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N. PRESCRIPTIONS (Pharmacy Control Act s71E, Guidelines Part B 11 and Poisons Regs 2018)

N1 The Pharmacist in Charge states that Prescriptions are recorded in the approved system and produced on request and states that hard copies of all cancelled prescriptions are retained for 2 years.	YES / NO
N2 Retaining Schedule 8 Prescriptions:	
N2a The Pharmacist in Charge has stated that when repeats are authorised, prescriptions are retained at pharmacy	YES / NO
N2b Transfers of repeats are done only after authorisation from Pharmaceutical Services Branch and in a secure manner	YES / NO
N3 Dispensing of Narcotic Prescriptions Does the pharmacist, when dispensing any prescription for a narcotic substance, if not familiar with the handwriting/signature of the prescriber, verify the authenticity of the script with the prescriber before dispensing?	YES / NO
N4 Marking of Narcotic prescriptions Prescriptions are marked with the following details by the dispensing pharmacist:	
<ul style="list-style-type: none"> • dated and personally signed* on duplicate at each supply. • address of pharmacy and name of proprietor, identification code/prescription number matching label are marked. • at last supply, prescription is cancelled. • cancelled scripts are retained and stored securely in accordance with Privacy Principles 	YES / NO
N5 Narcotic repeat intervals: Are repeat intervals endorsed on the script in handwritten ink as required on S4D and S8 prescriptions (NB – there is only a 4-day leeway over the life of the script)?	YES / NO
N6 Does the Pharmacist(s) use DORA?	YES / NO / SOMETIMES

**THIS SECTION MUST BE COMPLETED FOR NEW/RELOCATING
PHARMACIES**

DECLARATION:

I, _____ AHPRA No: _____
Clearly PRINT the name of the Registered Pharmacist making this declaration

POSITION _____
EITHER an owner of this pharmacy, OR the Pharmacist appointed by the owner(s) to be regularly and usually in charge

declare that:

- a. the answers to questions are true and correct to the best of my knowledge and belief
- b. I am aware that a person found guilty of making a false or misleading statement is guilty of an offence and is liable to a penalty of up to 100 penalty units under Section 68, *Pharmacy Control Act 2001*.
- c. I am authorised to make this declaration.

I make this solemn declaration under the *Oaths Act 2001*

Declared at: _____ **On:** _____
Place Date

Signature

Before me: _____
Signature of Justice, Commissioner for Declarations or authorised person

**IF YOUR PHARMACY IS NEW OR RELOCATING,
PLEASE EMAIL YOUR COMPLETED FORM TOGETHER WITH FORM "DOC" TO**

registrar@pharmacyauthority.tas.gov.au