



SELF INSPECTION FORM – PHARMACY PREMISES

Pursuant to Part 4 of the Pharmacy Control Act 2001

Use this form at any time for your own self-assessment, to determine whether the premises are likely to meet the requirements of the *Pharmacy Control Act 2001*. This SIF Self Inspection Form is for pharmacist's use and **need not be returned to the Authority**.

In order to arrange an Inspection to finalise the approval and registration of altered or new premises, you **MUST** submit to the Authority **Form DOC – Declaration of Completion** and **Form CIF Completion Inspection Form**.

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** 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 and approved those business?

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 and approved those business?

YES / NO

7 Can anyone from any adjoining premises access the pharmacy out of pharmacy hours?

YES / NO

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

A1 Do you believe that 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 so as 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 is 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 Are there adequate facilities for the heating required for dispensing and compounding drugs and medicines?	YES / NO
B4 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
B5 Is the dispensing bench covered with an impervious covering which is not less than 40 centimetres wide?	YES / NO
B6 Is there not less than 1.0 square metres of free working space per dispensary station?	YES / NO

B7 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
B8 Is public access to the dispensary restricted and controlled?	YES / NO
B9 Can the pharmacist on duty effectively supervise the pharmacy premises where medicines are kept, sold or supplied, and supervise the staff?	YES / NO
B10 Are medicines stored in a manner that will not promote the sale of a product or draw undue attention to a product?	YES / NO
B11 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 or not you use a contracted company for this activity.	YES / NO / NA

C. EQUIPMENT (Tasmanian Pharmacy Authority Guidelines):

C1 Does the refrigeration comply with the “Cold Chain Management Standard” of the Quality Care Pharmacy program (QCPP) or equivalent minimum standards, so that temperatures are recorded and monitored at least daily (and twice daily for fridges where vaccinations are stored).	YES / NO
C2 Is the refrigeration of medicines kept separate to any refrigerator used for foodstuffs	YES / NO
C3 Are accurately calibrated metric weighing and measuring equipment possessing capacities and precision suitable for the compounding, dispensing and sale of drugs and medicines available?	YES / NO
C4 Does the dispensary have compounding and blending equipment for powders, liquids and pastes and similar?	YES / NO
C5 Are there vessels suitable for storage and supply of all commonly used pharmaceutical preparations, liquids and powders available?	YES / NO
C6 Is there a range of equipment appropriate to speciality practice needs which would be sufficient to comply with standards relevant to that speciality?	YES / NO / NA
C7 If there is an area for the provision of immunisation/vaccination services, has the Authority approved it and does it comply with <i>either</i> the PSA “Practice guidelines for the provision of immunisation services within pharmacy” <i>or</i> the Pharmacy Guild’s “Guidelines for Conducting Immunisation Services within a Community Pharmacy Environment”.	YES / NO / NA

REFERENCE LIBRARY (Pharmacy Board of Australia – List of References; **updated 14 Feb 2017**):

D. REQUIRED REFERENCES

MUST HAVE	Version	Available
D1 Australian Pharmaceutical Formulary and Handbook (APF) APF23	23 rd ed	Y / N / OUT OF DATE
D2 Australian Medicines Handbook (AMH) AMH 16	2017	Y / N / OUT OF DATE
D3 Therapeutic Guidelines Series (the complete set in hard copy), <i>or</i> eTG	Nov 2015	Y / N / OUT OF DATE

MUST HAVE	Version	Available
D4 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	2017	
<input type="checkbox"/> eMIMS; or		
<input type="checkbox"/> MIMS Online; or		
<input type="checkbox"/> AusDI Advanced/AusDI		
D5 A Drug Interaction reference (updated at least quarterly):		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		
D6 AMH Children’s Dosing Companion	2016/17	Y / N / OUT OF DATE
D6a Australian Don’t Rush to Crush Handbook (Hard copy) OR Is this accessed by MIMS online option?	2 nd edition	Y / N / OUT OF DATE YES / NO
D7 An evidence-based reference work on complementary and alternative medicines:		Y / N / OUT OF DATE
<input type="checkbox"/> Herbs and Natural Supplements: An evidence based guide. Braun and Cohen; or		
<input type="checkbox"/> Herbal Medicines. Barnes, Anderson and Phillipson; or		
<input type="checkbox"/> Herbal Medicines and Dietary Supplements package (which can be accessed through Medicines Complete); or		
<input type="checkbox"/> MedlinePlus: Drugs, Supplements, and Herbal Information; or	online	
<input type="checkbox"/> Natural & Alternative Treatments: EBSCO; or		
<input type="checkbox"/> Natural Medicines (formerly Natural Standard and Natural Medicines Comprehensive Database)		

E. ONLINE REFERENCES (REQUIRED)

The following must be accessed electronically via **bookmarked websites**

NB: If you bookmark the Authority's "LINKS" page, this Section E will be compliant!	LINK AVAILABLE
TPA LINKS page: http://www.pharmacyauthority.tas.gov.au/LINKS.html	
TPA LINK USED - bookmarked on pharmacy computers <i>YES means individual references E1 – E4 below need not be checked further</i>	YES / NO
E1 Copies of the legislation controlling the practice of pharmacy:	
<input type="checkbox"/> Health Practitioner Regulation National Law Act (the National Law) as in force in each state and territory	YES / NO
<input type="checkbox"/> Pharmacy Control Act 2001 (as amended)	YES / NO
<input type="checkbox"/> Poisons Act 1971 (and amendments)	YES / NO
<input type="checkbox"/> Poisons Regulations 2008 (and amendments)	YES / NO
<input type="checkbox"/> Relevant Therapeutic Good Administration Guidelines e.g. the Advertising Code and the Price Code	YES / NO
<input type="checkbox"/> The Tasmanian Pharmacy Authority Guidelines – current version	YES / NO
<input type="checkbox"/> Information in relation to the Privacy Act 1988 (and amendments)	YES / NO
<input type="checkbox"/> The Poisons List or the Standard for the Uniform Schedule for Drugs and Poisons (SUSDP)	YES / NO
E1a Australian Immunisation Handbook	YES / NO
E2 The Pharmacy Board of Australia (PBA) Guidelines	YES / NO
E2a Professional practice standards and guidelines published by the PSA and SHPA	YES / NO
E3 The Merck Manual of Diagnosis and Therapy (Merck Sharp and Dohme)	YES / NO
E4 A Medical Dictionary	YES / NO

F. OPTIONAL REFERENCES:

(Other optional references as **appropriate to the pharmacist's area of practice**)

What are the pharmacy's **area(s) of practice**? _____

What relevant references are therefore available?	Version
F1 A pharmacology reference	
F2 An over the counter reference	
F3 A geriatric reference	
F4 Subscriptions to current pharmacy journals.	
F5 An injectable drugs reference	
F6 A drugs in Pregnancy and breast feeding reference	
F7 References to support speciality practice	
F8 Others: (list)	

G. CONDUCT OF PHARMACISTS and ASSISTANTS: (Tasmanian Pharmacy Authority Guidelines)

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

H. DISPENSING (PSA Professional Practice Standards, Dispensing, Criterion 1)

H1 Does the Pharmacy has a <i>documented</i> 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 all dispensing done in accordance with these procedures?	YES / NO
H3 Does the pharmacy have a <i>documented</i> emergency supply/owing script procedure which includes procedures for managing and following up owing scripts?	YES / NO

I. THE DISPENSARY COMPUTER SYSTEM (Pharmacy Code Section 25)

I1 Dispensary Software: FRED / LOTS / MINFOS / AQUARIUS / Z Dispense _____	
I2 Are audit trails of all amendments to patient details and prescription details maintained?	YES / NO
I3 Is the software regularly backed up? Frequency: Daily / Other _____	YES / NO
I4 Are there <i>written</i> procedures for the back-up of the computer system? OR Is the backup fully automated?	YES / NO OR YES / NO
I5 Are the backups are stored off-site and retained in accordance with statutory requirements?	YES / NO
I6 Are barcode scanners present at each and every dispensing station and <i>always used</i> as part of the dispensing procedure?	YES / NO

J. OUT-OF-DATE MEDICINES (PSA Professional Practice Standards, Dispensing, Criterion 6)

J1 Does the Pharmacy has a <i>documented</i> procedure for the checking, removal and disposal of expired stock from pharmacy shelves which is available in the area where stock is held?	YES / NO
J2 Is stock on the pharmacy shelves all current (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?	YES / NO
J5 Are records containing personal information (such as patient records, prescription labels etc) destroyed or permanently de-identified when no longer needed for any purpose?	YES / NO

K. STORAGE OF SCHEDULED SUBSTANCES (Poisons Regulations 2008)

<p>K1 Narcotic substances– Regulation 25 Are all Schedule 8 items stored apart from other substances in a level 4 compliant safe which is securely locked (a torch and drill resistant in-floor safe <i>or</i> a free standing safe of <i>at least</i> 500kg which is bolted and glued to the floor)?</p>	YES / NO
<p>K2 Is a day safe or storage drawer used? If YES:</p> <ul style="list-style-type: none"> • Is it kept locked when not in use and the key held by the pharmacist in charge? • Are all narcotics including DAA packs placed in the main safe at the end of the day? • Are dispensed narcotics awaiting collection stored in the locked day or night safe during the day and then returned to the night safe for overnight storage? 	YES / NO ↓ YES / NO YES / NO YES / NO
<p>K3 Is the key or code or details of the safe combination for the Narcotics Safe kept either on the pharmacist's person or in a place not readily accessible to other persons?</p>	YES / NO
<p>K4 Is the key or code or details of the safe combination left on the pharmacy premises while the pharmacy is closed?</p>	YES / NO
<p>K5 Are all substance specified in Schedule 3 or 4 to the Poisons List kept in either of the following so that the public does not have access to the substance? (Regulation 39): (a) a storeroom kept secure and under the control of the pharmacists; or (b) the dispensary</p>	YES / NO YES / NO
<p>K6 Are all substance specified in Schedule 2 of the Poisons List – (a) kept in the dispensary or secure storeroom so they are not readily accessible to the public; <i>or</i> (b) 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 YES / NO YES / NO
<p>K7 Is pseudoephedrine storage appropriate? ie:</p> <ul style="list-style-type: none"> • All S3 pseudoephedrine products are stored in the dispensary or pharmacy storeroom • Pseudoephedrine product stock levels are minimal • Products (where possible) are kept out of sight of general public, particularly high risk products such as single active and antihistamine combinations • 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) 	YES / NO YES / NO YES / NO YES / NO

L. REGISTER OF DRUGS OF DEPENDENCE

<p>L1 Is the DD Register maintained in accordance with the requirements of the Regulation 13 of the Poisons Regulations 2008, and is it:</p> <ul style="list-style-type: none"> • Regularly reconciled against stock balances • Entries are made within 48 hours of dispensing 	YES / NO YES / NO
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M. LABELLING OF DISPENSED MEDICINES (Poisons Regulations 2008 Regulations 84 and 46):

<p>M1 Are all dispensed containers labelled with compliant labelling? ie:</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 as required by subregulation (3) of the Poisons Regulation; 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>	<p>YES / NO</p>
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N. PRESCRIPTIONS (Poisons Regulations 2008)

<p>N1 Are all prescriptions recorded in the approved system? (Reg 46(8)(c)) Are hard copies of all cancelled prescriptions retained for 2 years (Reg 46(12)(b))</p>	<p>YES / NO YES / NO</p>
<p>N2 Retaining Schedule 8 Prescriptions (Reg 23(2)) Where repeats are authorised, are prescriptions retained at pharmacy and repeats made from same pharmacy as original dispensing. Are transfers of repeats done only after authorisation from Pharmaceutical Services Branch?</p>	<p>YES / NO</p>
<p>N3 Dispensing of Narcotic Prescriptions Are narcotic prescriptions are dispensed in accordance with Regulation 23? and Prescriptions are verified in accordance with Regulation 24?</p>	<p>YES / NO YES / NO</p>
<p>N4 Marking of Prescriptions (Reg 46) Are all prescriptions marked with the following details?</p> <ul style="list-style-type: none"> • dated and initialled or signed IN PERSON 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 and stored securely in accordance with privacy principle 	<p>YES / NO/ NOT ALWAYS</p>
<p>N5 Repeat intervals (Regs 23(5)–(7) and 44(3)–(5)) Are repeat intervals endorsed as required on S4D and S8 prescriptions?</p>	<p>YES / NO</p>

OFF-SITE STORAGE

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, they must be moved immediately to the pharmacy and stored there in accordance with the Poisons Act and Regulations.*

If YES: are any records which are stored there in a way to restrict access, is secure and is in accordance with privacy principles?

YES / NO