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TASMANIAN PHARMACY AUTHORITY

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SELF-INSPECTION FORM
NEW PHARMACY BUSINESS PREMISES
and REGULAR COMPLIANCE CHECKS OF PHARMACY PREMISES

Pursuant to Part 4 of the Pharmacy Control Act 2001

Use this form to determine whether the new or relocated pharmacy premises meet the requirements of the *Pharmacy Control Act 2001*(*the Act*) and is therefore ready for registration and inspection by the Tasmanian Pharmacy Authority (TPA).

AND regularly, to ensure the pharmacy premises continues to meet the requirements of *the Act* and the TPA 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's full name: .....

Pharmacy's physical address: .....

Phone: ..... **Fax**.....

Email address:.....

Owner(s):
.....

FOR NEW PREMISES ONLY:

1. Have the premises been developed and fitted out in accordance with plans approved-in-principle by the Authority? YES / NO

IF NO, PLEASE CONTACT THE REGISTRAR TO ADVISE ACCORDINGLY AND PROVIDE AN UPDATED COPY OF THE PLANS

A. PHARMACY DESIGN

A1 Is the pharmacy relocating from another site? **IF YES, (i)** has all the pharmacy signage been removed from the old site? (ii) Are all internet references amended to reflect the new address TPA Guidelines v6.3 s7	**YES /** NO / **NA** **YES /** NO **YES/**NO
A3 Does the pharmacy have a s90 Medicare License to be an Approved PBS Supplier?	YES / NO
A4 If the pharmacy DOES NOT have a s90 Medicare Licence, is the Limited Supply Notice prominently displayed? TPA Guidelines v6.3 s6	**YES /** NO **/ NA**
A5 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? *Pharmacy Control Act 2001* s71E(3)(g), TPA Guidelines v6.3 s8	**YES /** NO
A6 Is the pharmacy constructed to be secure from unauthorised access through doors, windows, walls, and ceilings? *Pharmacy Control Act 2001* s71E(3)(c) and TPA Guidelines v6.3 s8	**YES /** NO
A7 Does the pharmacy have an alarm system fitted with a siren which is monitored by a central monitoring station on a 24-hour basis?	**YES/** NO
A7a How are the premises locked/unlocked Key? Swipe card? Press Button? Other? Please specify……	 YES / NO YES / NO YES / NO YES / NO
A7b How is the alarm activated/de-activated? Numerical keypad? Press button fob? Swipe card?	**YES** / NO YES / **NO** YES / **NO**
A7c Does the process of secure access to the premises comply with the Tasmanian Pharmacy Authority Guidelines, i.e., require a two-phase ACCESS system?	**YES** / NO
A7d Does the pharmacy have a register of holders for all keys, access devices and security codes for the pharmacy?	**YES** / NO
A7e Does anyone other than a pharmacist have the ability to unlock the pharmacy?	YES/NO
Are keys held by the Tasmanian Fire Service? (a key may be held by the Tasmanian Fire Service (TFS) for use only by TFS personnel in an emergency)	YES/NO

A7f Are non-pharmacists (excepting for TFS personal attending in an emergency) allowed in the pharmacy without the direct supervision of a pharmacist? *Pharmacy Control Act 2001* s71E(3)(c) and TPA Guidelines v6.3 s8 and s8.1	YES / **NO**
A8 Does the pharmacy alarm system have a back-up and monitoring system, such that any attempt to disable or isolate the alarm system, or linefailure, will still result in a response? *Pharmacy Control Act 2001* s71E(3)(c) and TPA Guidelines v6.3 s8	**YES /** NO
A9 Does the pharmacy have 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? *Pharmacy Control Act 2001* s71E(3)(d) and TPA Guidelines v6.3s8	**YES /** NO
A10 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? *Pharmacy Control Act 2001* s71E(3)(d)(ii) and TPA Guidelines v6.3 s8	**YES /** NO
A11 Does the pharmacy have access for persons with a disability or mobility concerns? I.e.: Ramp access or similar. Could someone in a wheelchair open and fit through the doors? **A11a** If **not** how does the pharmacy deal with issues of access for such persons? …… …… …… *Pharmacy Control Act 2001* s71E(3)(e) and TPA Guidelines v6.3 s8	**YES /** NO
A12 Is there direct access for the public provided by a street or public walkway (i.e.: not through a separate business)? *Pharmacy Control Act 2001* s71E(3)(e) and TPA Guidelines v6.3 s8	**YES /** NO
A13 Does the pharmacy comply with supermarket access rules as follows: • 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. *Pharmacy Control Act 2001* s71E(2)(c) and TPA Guidelines v6.3 s8	**YES /** NO
A14 If the pharmacy premises are new, relocating or have undergone approved alterations, is access to any other premises shown on the plans approved by the Authority and consistent with those plans? *Pharmacy Control Act 2001* s71E(3)(f) and TPA Guidelines v6.3 s7	**YES /** NO **/ NA**

A15 If the pharmacy has any adjoining premises, is the access controlled so that only the registered pharmacist has access to the pharmacy premises after hours. …… …… *Pharmacy Control Act 2001* s71E(3)(f) and TPA Guidelines v6.3 s8	**YES** / NO/NA
A16 Are there any other businesses operating **within** the pharmacy? Lotto agency, newsagency, insurance agency, ATM machine **IF YES** – please provide details of that business below: …… …… **A16a** If there are other businesses, please provide below details of after-hours access by those above listed businesses: …… …… *Pharmacy Control Act 2001* s71E(3)(f); and TPA Guidelines v6.3 s8	YES / NO
A17 Are tobacco products or alcoholic beverages sold on the premises? A17a Does the pharmacy dispense nicotine e-cigarettes and/or nicotine vaping products? A17a(i)If YES, does the pharmacy hold a current smoking product license issued under the Public Health Act 1997? *Pharmacy Control Act 2001* s71E, PharmBA Guidelines on Practice-Specific Issues Guideline 9, TPA Guidelines v6.3 s18 and *Public Health Act 1997*	YES **/ NO** YES/NO YES/NO/NA
A18 Are any animals present on the premises? (Guide dogs and accredited assistance dogs are exempt) *Pharmacy Control Act 2001* s71E, *Dog Control Act 2000* and TPA Guidelines v6.3 s18	YES **/ NO**
A19 Are the premises leased? **IF YES,** does the Authority have a copy of the lease? (If no, please provide a copy) *Pharmacy Control Act 2001* s71E(3)(h); and TPA Guidelines v6.3 s7	YES / NO YES / NO
A20 Are all the working areas of the pharmacy clean, sanitary and in good repair? *Pharmacy Control Act 2001* s71E(3) and TPA Guidelines V6.3 s18	YES/NO

B. DISPENSARY

B1 Is the surface of the dispensing bench clean, sanitary, and in good repair? **B1a Does** the dispensing bench have an impervious covering with not less than one (1) square metre of free working space per dispensary station? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s8.2	**YES /** NO **YES/**NO
B2 Is the Dispensary of adequate size to allow free and clear movement of the pharmacist(s) while dispensing? *Pharmacy Control Act 2001* s71E and TPA Guidelinesv6.3 s8.2	**YES /** NO
B3 Is there adequate lighting and ventilation? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 v8.2	**YES /** NO
B4 Is the equipment maintained and in good working order? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s9	**YES /** NO
B5 Is there a sink of stainless steel or other material (approved by the Authority) with an impervious surround, and supplied with hot **and** cold running water? *Pharmacy Control Act 2001* s71E, TPA Guidelines v6.3 s8.2	**YES /** NO
B8 Are the conditions of temperature and humidity suitable and stable for the storage of drugsand medicines kept in the dispensary? e.g.: an air conditioner; if there is no air conditioning, there needs to be some proof that the temperature is consistently appropriate, a log of daily temperatures which provides evidence of that. *Pharmacy Control Act 2001* s71E(3)(b), TPA Guidelines v6.3 s8.2	**YES /** NO
B9 Is public access to the dispensary restricted and controlled? *Pharmacy Control Act 2001* s71E(3)(b), TPA Guidelines v6.3 s8.2	**YES /** NO
B10 Is the pharmacist on duty able to effectively supervise the pharmacy premises where all scheduled medicines are kept, sold, or supplied and the persons employed therein? *Poisons Regulations 2018* Part B 43(3), *Pharmacy Control Act 2001* s71E(3)(d)(i), TPA Guidelines v6.3 s8.2	**YES /** NO
B11 Does the pharmacy use a dispensing robot? Make and model of the robot:.....	YES/ NO

C. REFRIGERATION

C1 Does the means of refrigeration comply with the "Strive for Five" of the National Vaccine Storage Guidelines OR Equivalent to minimum standards? a) proof of purchase within the last 12 months OR b) proof of annual preventive maintenance or according to manufacturer's specification; and c) evidence of QC2020 cold chain certification or equivalent within the last 24 months. *Pharmacy Control Act 2001* s71E(3)(d)(iii), TPA Guidelines v6.3 s9, National Vaccine Storage Guidelines – Strive for 5, 3rd edition, QC2020 (Please ensure there is evidence of this available during an inspection)	**YES /** NO
C2 Is there a refrigerator(s) used for scheduled medicines outside the boundary of the dispensary (e.g., within a consult room)? **IF YES:** Is this refrigerator then kept locked when **not** under direct supervision of the pharmacist and that key kept under supervision of the pharmacist **or** the room containing the refrigerator kept locked, and that key kept under supervision of the pharmacist when not in use? *Poisons Regulations 2018* Part B 43(3), *Pharmacy Control Act 2001* s71E(3)(d)(iii), TPA Guidelines v6.3 s13	YES / NO **YES** / NO/ NA
C4a Are there at least two devices for monitoring dispensary refrigerator(s) temperatures? **Visual display monitor (built-in or external) .....** **Data logger .....** **(Dispensary refrigerator refers to any medical grade refrigerator that stores medicines including vaccines)** **C4ai** Are the refrigerator(s) temperatures **manually checked and recorded twice daily and include current temperature reading with** entries signed or initialled? Compliance can be demonstrated by presentation of written record, preferably on the Strive for 5 vaccine fridge temperature chart. (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). **C4bi Do the temperature records demonstrate that refrigerator temperatures are maintained in the range 2-8°C?** **C4bii** If the pharmacy manually records temperature of its dispensary fridge is it recorded to one decimal place (#.# or whole numbers (#)?(answer in space pls) **C4biii Is there a written procedure outlining actions to be taken on identification of a temperature breach, and evidence that it is followed?** Inspectors should review the temperature records and associated cold-chain documentation **C4biv Is contingency equipment available for the storage of vaccines/medications in the event of a cold chain breach? (ice blocks, cooler/eski and a maximum/minimum thermometer or UPS(uninterruptible power supply) for refrigerator power supply?** **C4c** Is the data logger checked **weekly** as a minimum standard? *Pharmacy Control Act 2001* s71E(3)(d)(iii), TPA Guidelines v6.3 s8.2 and s13, National Vaccine Storage Guidelines– Strive for 5, 3rd edition, QC2020 (Please ensure there is evidence of the above available during an inspection)	**YES /** NO **YES/**NO YES/NO **YES/**NO **YES/** NO --------- **YES/**NO **YES/**NO **YES /** NO
C5 Are all refrigerated medications stored separately from food stuffs? *Poison Regulations 2018* Part B 43(4),*Pharmacy Control Act 2001* s71E(3)(d)(iii), TPA Guidelines v6.3 s9	**YES /** NO

D. COMPOUNDING & EQUIPMENT

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, sterile preparations, cytotoxic or IV preparations)**	YES / NO
D2 Does this pharmacy undertake **simple** compounding? **IF YES: ANSWER D3 – D8a (incl)** **IF NO: COMPLETE D8b and D9 (incl)**	YES / NO
D3 Does the pharmacy have adequate calibrated metric weighing and measuring equipment possessing capacities and precision suitable for simple compounding? (+/- .01 g on electronic scales) *Pharmacy Control Act 2001* s71E and TPA Guidelines v6 .3 s12	**YES** / NO DIGITAL / ANALOGUE SCALES
D4 WHEN were the scales **AND** weights last professionally calibrated? **(The accepted standard is annually)** **SCALES date** **WEIGHTS date** **(Weights only if scales are analogue)**	 **…./……/……** **…./……/……** NA
D5 Does the pharmacy have adequate compounding and blending equipment for simple compounding? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s12	**YES** / NO
D6 Does the pharmacy have adequate vessels suitable for storage and supply of all commonly compounded pharmaceutical preparations? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s12	**YES** / NO
D7 Does the pharmacy have adequate facilities for heating if it is required for simplecompounding? HOTPLATE / OTHER: _____ **OR** Does the pharmacy have a compounding policy which states that compounding requiring the application of heat will not be performed? *Pharmacy Control Act 2001* s71E, APF 25 and TPA Guidelines v6.3 s12	**YES** / NO **YES**/NO
D8a If the pharmacy is using only digital scales and, if there are any other scales present, have these scales been **removed or decommissioned** to disallow their use? **D8b** If the pharmacy is **not undertaking any compounding**, then have **all SCALES** on the premises been either **removed or decommissioned** to disallow their use? *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s12	**YES** / NO / NA **YES** / NO / NA
D9 If the pharmacy **does not** undertake any compounding, do they have **an appropriate written procedure** to deal with prescriptions of medications that require compounding? (Please ensure there is evidence of this available during an inspection)	**YES/NO/NA**

E. PHARMACY SERVICES

E1 Does the pharmacy have a consultation room(s)? **E1a** How many consultation rooms does the pharmacy have? **E1b** Are the consultation rooms clean and appropriate for use? *Pharmacy Control Act 2001* s71E(3)(b) and TPA Guidelines v6.3 s8	YES / NO Number:…… YES / NO
E2 Is the packing of **dose administration aids** a service provided by this pharmacy? If yes please complete the following, tick **all** that apply: **[ ] In this pharmacy** **[ ] By this pharmacy at a remote/offsite location: **Provide address details below** **[ ] By a contracted company: **Provide address details below** **[ ] Other: **Provide address details below** Name & address of contracted company, address of offsite packing, other details etc: **……** **……** *Pharmacy Control Act 2001* s71E and TPA Guidelines v6.3 s8.2	YES / NO
E3 Complete this section **if any packing of dose administration aids is done** on this premises: **E3a** Is the packing area in a clearly defined and secure area where distractions are minimised (i.e., PSA compliant)? **E3b If the packing is done in a separate room is this room kept locked while not in use (if the DAA medications and completed packs are stored in this room)?……** **E3c** Is there adequate lighting and ventilation for appropriate drug storage?…… **E3c** Does each patient have a **current** drug chart?…… **E3d** Does each patient have an appropriate audit trail of any changes or issues?…… **E3f** If a patient has a **S8** packed, where is the stock stored before and after being packed and when the pack is completed? (Please complete below) **……** *Poisons Regulations 2018 Part 3 7 (29), Pharmacy Control Act 2001* s71E, PSA DAA Guidelines and TPA Guidelines v6.3 s8.2	**YES /** NO **YES /** NO **YES /** NO / **NA** **YES /** NO **YES /** NO **YES /** NO **YES /** NO
E4 Does the pharmacy provide **vaccination/immunisation services**? This service may be infrequent (e.g.: short timeframe for flu vaccinations) or permanent; and the service may be provided by a suitably qualified pharmacist, nurse immuniser, doctor, or other qualified health professional. Regardless, the premises must be suitable. **IF YES, complete E4 and E5:**	YES / NO
E4a Is there a private room or consultation area for this activity?	**YES /** NO
E4b Is the area private in terms of (i) visibility? And (ii) sound (i.e. full height walls)?	**YES /** NO **YES /** NO
E4c Is there CCTV that can see within the private consult area?	YES **/ NO**
E4d Is the floor area sufficient and clear of equipment and furniture, to accommodate a client,a carer, and the immuniser, and all the equipment necessary to store and administer the vaccines? (minimum 4m^2 AND minimum width of 2000mm at any point)?	**YES /** NO

E4e Is there an impervious bench or desk ?	**YES /** NO
E4f Are there sufficient chairs to accommodate the immuniser, patient, and carer within the room?	**YES /** NO
E4g Is the area in the room sufficient to allow administration of first aid (both sitting andlying)? (minimum 4m^2 AND minimum width of 2000mm at any point)?	**YES /** NO
E4h Is there a secure sharps disposal bin, **kept at least 1.3 metres** above the floor?	**YES /** NO
E4i Is there adequate hand washing or hand sanitation facilities?	**YES /** NO
E4j Is there adequate seating nearby for a client to be observed by a pharmacist (orimmuniser or suitably qualified person) following vaccination?	**YES /** NO
E4k Is there an **anaphylaxis response kit** available that contains: 1. At least three ampoules of adrenaline 1:1000 (please check it is in date) 2. At least three 1ml syringes (please check it is in date) 3. At least three 22-25 gauge, 25mm long needles (for IM injection) (please check it is in date) 4. At least three drawing up needles (19 or 21 gauge) (please check it is in date) 5. Cotton swabs 6. Pen and paper to record any event. 7. A laminated copy of 'Doses of intramuscular 1:1000 adrenaline for anaphylaxis' 8. A laminated copy of 'Recognition and treatment of anaphylaxis' *Pharmacy Control Act 2001* s71E, TPA Guidelines v6.3 s13, B 10A, Australian Immunisation Handbook	**YES/**NO **YES/NO** **YES /** NO **YES /** NO **YES /** NO **YES /** NO **YES /** NO **YES /** NO
E5 Does the pharmacy have approval from the following bodies and respective documentation as evidence of compliance. 1. Tasmanian Pharmacy Authority (must have an approved consult room) 2. Immunisation Program Approval from Department of Health 3. Authorised Immuniser Approval certification for all pharmacist immunisers *Poisons Regulation 2018* Part 4 82(d), *Pharmacy Control Act 2001* s71E, TPA Guidelines v6.3 s13, B 10A, Tasmanian Immunisation Program Guidelines (Please ensure there is evidence of the above available during an inspection)	**YES /** NO **YES /** NO **YES / NO**

E6 Does the pharmacy carry on **depot-Like activities**? A depot is where the pharmacy has an alternative location such as a corner store or Post Office that a patient can drop prescriptions and collect medication from. If yes, please answer the following: **E6a** Address of Depot/s: ……. **E6b** What scheduled medicines are provided via depot arrangements? (circle all that apply) **E6c** Is there a written procedure for the provision of medicines via depot arrangements? **E6d**How are prescriptions transmitted and received? …… …… **E6e** How is patient counselling provided to patients obtaining medicines via the depot? …… …… **E6f** How are products stored at the depot with regard to security, confidentiality and medication integrity? …… …… **E6g** Who is the person in charge of the depot? …… **E6h** How often does the pharmacist visit the depot to ensure that all procedures and storage requirements are being adhered to? …… **E6i** What records are kept of products provided via depot arrangements: i. Items departing the pharmacy ii. Signature of driver receiving items for transport iii. Signature of depot operator on receipt of items iv. Signature of consumer on receipt of items …… ……	YES / NO S2 S3 S4 S4D S8 YES/NO
E7 Does the pharmacy provide **opioid replacement therapy (ORT)**? ORT involves the supply of methadone/biodone liquid, or buprenorphine tablets or injections or buprenorphine/naloxone films to clients enrolled in the Tasmanian Pharmacotherapy program. If Yes **E7a** Is there a private room or consultation area for this activity? **E7b** Do all employed pharmacists have **Tasmanian** accreditation to provide the forms of ORT supplied or administered ? (accreditation email/certificates- can be provided by Department of Health, Alcohol and Drug Services adspharmacy@ths.tas.gov.au) Pharmacy Board of Australia (PBA) Code of Conduct and PBA Guidelines (DAA and staged supply); Pharmaceutical Society of Australia-Professional Practice Standards V5; Tasmanian Opioid Pharmacotherapy Policy and Program Clinical Practice Standards Opioid Dependence Treatment (ODT) Community Pharmacy Program - Pharmacy Programs Administrator (ppaonline.com.au) (Please ensure there is evidence of this available during an inspection)	**YES /** NO **YES /** NO **YES /** NO

F. REQUIRED REFERENCES

F1 Does the pharmacy have access to **current versions** of all references required by the Pharmacy Board of Australia, as listed at https://www.pharmacyauthority.tas.gov.au/wp-content/uploads/2021/03/Pharmacy-Board-Guidelines-Guidelines-on-the-practice-specific-issues-Guidline-1-5.pdf TPA Guidelines v6.3 s10, PharmBA Guidelines – Practice Specific Issues Guideline1	**YES /** NO
F2 The Pharmacy Board of Australia require the following access to online references via bookmarks on the dispense computer. The Authority provides a direct link to these via a links page on our website**.** Is the **TPA link used** and bookmarked on the dispense computer? **(https://www.pharmacyauthority.tas.gov.au/about/links/)** TPA Guidelines v6.3 s10, PharmBA Guidelines – Practice Specific Issues Guideline1	**YES /** NO

H. CONDUCT OF PHARMACISTS & ASSISTANTS:

H1 Are the working areas and attire of any persons working in the dispensary clean and free from any contaminants? *Pharmacy Control Act 2001* s8 (c), TPA Guidelines v6.3s18	**YES /** NO
H2 Is smoking of tobacco or any other substances permitted in the pharmacy? *Pharmacy Control Act 2001* s8 (c), TPA Guidelines v6.3 s18	YES **/ NO**
H3 Is the consumption of alcohol or use of illicit drugs permitted in the pharmacy? *Pharmacy Control Act 2001* s8(c), TPA Guidelines v6.3 s18	YES **/ NO**
H4 Are the standards of personal hygiene, dress, and appearance of all staff in the pharmacy appropriate for a health care setting? *Pharmacy Control Act 2001* s8 (c), TPA Guidelines v6.3 s18	**YES /** NO
H5 Have all pharmacists and pharmacy assistants been appropriately trained for the tasks being undertaken, especially where assisting in the dispensing process? *Pharmacy Control Act 2001* s8(c), PharmBA Guidelines for Proprietor Pharmacists Guideline 3, TPA Guidelines v6.3 s18	**YES /** NO

I. DISPENSING

I1 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? *Pharmacy Control Act 2001* s8(c), PharmBA Guidelines for Proprietor Pharmacists Guideline 3, TPA Guidelines v6.3 s8.2 (Please ensure there is evidence of this available during an inspection)	**YES /** NO
I2 Is dispensing done in accordance with the procedure? *Pharmacy Control 2001* Act s8(c), PharmBA Guidelines for Proprietor Pharmacists Guideline 3, TPA Guidelines v6.3 s8.2	**YES /** NO

J. THE DISPENSARY COMPUTER SYSTEM

J1 Dispensary Software: FRED / LOTS / MINFOS / AQUARIUS / Z Dispense /_ _ _ _ _ _ _ _ _ _ _ _ _ _ _	
J2 Do regular computer backups occur: **Frequency**: Daily / Other_ _	**YES /** NO
J3 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? *Pharmacy Control 2001* Act s8c, PharmBA Guidelines for Proprietor Pharmacists Guideline 3, TPA Guidelines v6.3 s8.2	**YES /** NO **YES /** NO /NA
J4 Are backups are stored off-site and retained inaccordance with statutory requirements? *Pharmacy Control Act 2001* s8c, PharmBA Guidelines for Proprietor Pharmacists Guideline 3, , TPA Guidelines v6.3 s8.2	**YES /** NO
J5 Are barcode scanners installed at every dispensing station? (This must also include forward dispensing stations) *Pharmacy Control Act 2001* s8, PharmBA Guidelines for Dispensing of Medicines 10.1, PDL Guide to Good Dispensing, , TPA Guidelines v6.3 s8.2	**YES /** NO
J6 Generate a scan report for a 1-month period (consider the previous calendar month). Does the scan report indicate that **every** pharmacist is using barcode scanner as part of the dispensing procedure at all times? *Pharmacy Control Act 2001* s8, PharmBA Guidelines for Dispensing of Medicines 10.1, PDL Guide to Good Dispensing, , TPA Guidelines v6.3 s8.2	**YES /** NO

K. DISPOSAL & DESTRUCTION

K1 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? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2 (Please ensure there is evidence of this available during an inspection)	**YES /** NO
K2 Is the stock on the pharmacy shelves within their expiry dates? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2	**YES /** NO
K3 Are there broken packs on the shelf without both the expiry dates **and/or** the batch numbers present? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2	YES / **NO**
K4 Is all out-of-date stock awaiting disposal marked as such and stored away from other stock? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2	**YES /** NO
K5 Is a Return of Unwanted Medicines (RUM) Bin available within the dispensary area and is it being used? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2	**YES /** NO
K6 Is there a shredder or other means of destroying or permanently de-identifying records containing personal information? *Pharmacy Control Act 2001* s8, TPA Guidelines v6.3 s8.2	**YES /** NO

L. STORAGE OF SCHEDULED SUBSTANCES

L10 Are schedule 3 and 4 medicines stored in the dispensary in a manner that will not promote the sale of a product or draw undue attention to a product? *Poisons Regulations 2018* Part4 43(2), *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s11	**YES /** NO
L11 Does the pharmacy have any offsite storage or a warehouse for stock, bulk goods, prescriptions, or confidential records? **L11a If YES** does this offsite storage include any scheduledmedicines? And - please provide address below: **.....** **L11b If YES** Is this storage site accessible only by or in the presence of a pharmacist? *Pharmacy Control Act 2001* s71E(3)(d), TPA Guidelines v6.3 s8.2 and s18	YES / NO YES / NO /NA **YES**/NO

N. LABELLING OF DISPENSED MEDICINES

N1 Are all dispensed containers are labelled with – (a) the words "Keep out of reach of children" **unobscured** in red on a white background; and (b) the name of the patient (or in the case of an animal, the name of the owner of the animal); and (c) the name, address, and phone number of the pharmacy; and (d) cautionary labels; and (e) particulars set out in the prescription; and (f) the initials of the dispensing pharmacist Numbers or letters on a label are – (a) at least 1·5 mm high; and (b) in clear and distinct contrast to the background *Pharmacy Control 2001* Act s8(c) *Therapeutic Goods Act 1989*- Guidelines for the labelling of medicines(tga.gov.au) Pharm BA Guidelines for dispensing medicines (2018) 7.2	**YES /** NO

Documents used to formulate this form include.

1. *Pharmacy Control Act 2001*
2. *Poisons Regulations 2018*
3. *Public Health Act 1997*
4. *Dog Control Act 2000*
5. *Therapeutic Goods Act 1989*
6. Tasmanian Pharmacy Authority (TPA) Guidelines v6.2
7. Pharmacy Board of Australia (PharmBA) Codes and Guidelines
8. Pharmaceutical Society of Australia Standards and Guidelines
9. Australian Immunisation Handbook
10. Tasmanian Immunisation Program Guidelines
11. Tasmanian Opioid Pharmacotherapy Policy and Program Clinical Practice Standards
12. National Vaccine Storage Guidelines – Strive for 5, 3rd edition
13. PDL Guide to Good Dispensing – current edition.

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