**PHARMACY REGISTRATION BOARD OF WESTERN AUSTRALIA (the Board)**

[ABN 75 635 660 854]

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## 2023 REGISTRATION RENEWAL APPLICATION

**Premises Number -** <**Registration Number**>

**Pharmacy -** <**Pharmacy Name**>

**Pharmacist with overall responsibility -** <**Responsible Pharmacist**>

[Refer Pharmacy Regulations 2010, Regulation 6 – Renewal of registration]

## APPLICANT

**I am** <**RESPONSIBLE PHARMACIST**>.

Yes ☐

**I hold GENERAL REGISTRATION with the Pharmacy Board of Australia.**

Yes ☐

My Registration is free of conditions

Yes ☐

I undertake to report any changes to my Registration to the Board's Registrar within seven (7) days of the change.

Yes ☐

[Refer Pharmacy Act 2010, Section 56 – Pharmacist to have overall responsibility for pharmacy business]

## THE PREMISES AND THE PHARMACY

**The Premises is NOT:**

1. located wholly or partly within a supermarket.
2. capable of being entered from a supermarket.
3. capable of being used to gain entry to a supermarket.

[Refer Pharmacy Act 2010, Section 43 - Grounds for refusal]

**Tobacco products:**

1. are NOT sold or supplied at the Pharmacy.

[Refer Pharmacy Regulations 2010, Regulation 12 - Tobacco products not to be sold or supplied at pharmacies]

**Significant alteration:**

1. I am familiar with the Board's definition of a significant alteration.
2. I have NOT made any significant alteration to the Pharmacy without prior written approval of the Board.

[Refer Pharmacy Regulations 2010, Regulation 14 - Significant alteration to a pharmacy
The Board's Guidelines, Guideline 2.1.1 - Definition of significant alteration]

**The Pharmacy:**

1. is well lit, adequately ventilated and is air conditioned.
2. has fixtures and fittings that are maintained in a safe, clean and hygienic condition and in good repair.

[Refer Pharmacy Regulations 2010, Regulation 15 - Pharmacy to be well lit, air conditioned and kept clean and in good repair]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## SCHEDULE 1 – THE MINIMUM STANDARDS

**Minimum Standards:**

1. The Premises has at least one door allowing direct access to members of the public (the Public) from a street or thoroughfare.

2. The Premises does NOT have direct access to any adjoining premises.

3. The Premises and all fixtures and fittings at the premises are in a safe, clean and hygienic condition and in good repair.

4. Devices and systems are provided and maintained in good working order as is necessary to ensure the Premises is reasonably secure against burglary, robbery, theft and unexplained loss.

5. The Premises is equipped with all prescribed items of equipment, and all are in a safe, clean and hygienic condition and in good repair.

6. The Premises has a copy of, or immediate electronic access to the LATEST edition, and all published amendments or supplements to those editions, of –
   - **A.** the Australian Medicines Handbook (AMH 2023)
   - **B.** the Australian Pharmaceutical Formulary and Handbook (APF25)
   - **C.** the eMIMS or AusDI or MIMS Online or MIMS Integrated or MIMS Annual
   - **D.** the Therapeutic Guidelines
   - **E.** the Pharmacy Act 2010 (WA)
   - **F.** the Pharmacy Regulations 2010 (WA)
   - **G.** the Medicines and Poisons Act 2014 (WA)
   - **H.** the Medicines and Poisons Regulations 2016 (WA)

7. The Premises has a safe and secure location for the keeping of prescription records.

**Background to Statements 8, 9, 10 & 11 below**

If before 18 October 2010:

1. the floor area of the Dispensary was ≥8.3m$^2$ and <10m$^2$,
   and/or
2. the Premises did not have an area in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not a party to the consultation,
   and
3. significant alterations have not been made after 18 October 2010,

then

4. the Premises is exempt from the above requirement(s) until the Board approves an application for significant alterations as complete.

[Refer Pharmacy Regulations 2010, Regulation 13 - Minimum standards of fitness for the competent and safe practice of pharmacy – Schedule 1]

**8.** The Premises has an area for the dispensing of medicines or drugs that has a floor area ≥10m$^2$ (the Dispensary).
If Yes, go to 10
If No, go to 9

**9.** The Dispensary has a floor area ≥8.3m$^2$ and <10m$^2$.

**10.** The Premises has an area in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not a party to the consultation.
If Yes, go to 12
If No, go 11

**11.** The Premises does NOT have an area in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not a party to the consultation.

**12.** The Dispensary has a suitable sink that has hot and cold running water connected.

**13. I understand**:

- **A.** It is my responsibility to ensure the Premises complies with all the applicable requirements of the Minimum Standards.
- **B.** It is my responsibility to ensure procedures, policies and/or protocols are in place to make sure the Premises maintains compliance with all the applicable requirements of the Minimum Standards in a timely manner at all times.
- **C.** **If the Premises is found NOT to comply with the Minimum Standards, the Board may cancel the registration.**

[Refer Pharmacy Regulations 2010, Schedule 1 - Minimum standards of fitness for the competent and safe practice of pharmacy, also known as the Minimum Standards]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## PRESCRIPTION RECORDS

**1.** A record is made of all prescriptions dispensed at, or from, the Premises.

**2.** All prescription records -

- **A.** are dealt with in a confidential manner and kept in a safe and secure manner.
- **B.** for prescription only medicines, are retained for at least 24 months.
- **C.** for controlled prescription drugs, are retained for at least 5 years.

**3.** I am familiar with the Board's Guidelines for Record Keeping, which detail the expectations in relation to storing electronic prescription records, including at off-site premises.

[Refer Pharmacy Regulations 2010, Regulation 16 - Record keeping]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## SUPERVISION

The Pharmacy Business:

1. is carried on under the personal supervision of a pharmacist at all times.

[Refer Pharmacy Act 2010, Section 57 - Supervision of pharmacy business by pharmacist]

**I DECLARE THE ABOVE STATEMENT IS TRUE AND CORRECT** ☐

## OWNERSHIP

1. **If ownership includes a Pharmacist Controlled Company or Companies, I understand:**
   - **A.** the Director(s) and/or Shareholder(s) have NOT changed in the last 12 months, or
   - **B.** changes were made only after an application was APPROVED by the Board.

2. **If ownership includes a Trust or Trusts, I understand:**
   - **A.** the Beneficiaries have NOT changed in the last 12 months, or
   - **B.** changes were made only after an application was APPROVED by the Board.

3. **There has been no breach of the ownership or proprietary interest provisions of Section 55 of the Pharmacy Act 2010 at any time.**

[Refer Pharmacy Act 2010, Section 54 - Ownership of, and interests in, pharmacy business
Pharmacy Act 2010, Section 55 – Limit on ownership of, and interests in, pharmacy businesses]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## OTHER BUSINESS OR BUSINESSES

**Non-pharmacy business:**

1. There is no non-pharmacy business (if any) carried on at the Premises other than that in accordance with Section 59.

[Refer Pharmacy Act 2010, Section 59 - Who may carry on a business that is not a pharmacy business at a registered pharmacy]

**I DECLARE THE ABOVE STATEMENT IS TRUE AND CORRECT** ☐

## PHARMACY PRACTICE

**The Board's Guidelines for the Safe Storage of Medicines in Pharmacies**

1. I am familiar with the Guidelines, which provide the Board's view of the responsibilities of proprietors, proprietary interest pharmacists and pharmacists with overall responsibility in relation to the safe storage of medicines in pharmacies.

2. Procedures, policies and/or protocols are in place to promote the safe storage of medicines at all times.

**The Pharmacy Board of Australia (the PBA) Guidelines for Proprietor Pharmacists**

1. I am familiar with the Guidelines, which focus on the professional responsibilities of proprietary interest pharmacists that impact on the safe, effective delivery of services to the Public.

2. I am aware the responsibilities of proprietary interest pharmacists include ensuring:
   - **A.** employed pharmacists have ready access to the list of essential references specified in Guideline 1 of the PBA Guidelines on practice-specific issues.
   - **B.** ensuring confidential patient information is appropriately stored and accessed.

**The PBA Guidelines for Dispensing of Medicines**

1. I am familiar with the Guidelines, which focus on safe dispensing and labelling of medicines, and providing a good pharmacy service.

2. I understand why and how barcode scanners should be used as part of the dispensing process.
   [Refer Guideline 10.1, Scanners]

**The PBA Code of Conduct**

1. I am familiar with the Code, which sets out the standards of professional conduct expected by the PBA and understand, if a concern is raised about a pharmacist, the Code is used to evaluate the conduct in question.

2. I acknowledge good practice includes providing surroundings that enable private and confidential consultations and discussions, particularly when working with multiple people at the same time, or in a shared space.
   [Refer Code 3.3, Confidentiality and privacy]

**National Immunisation Program National vaccine storage guidelines - Strive for 5**

1. I am familiar with the Guidelines, which provide information and advice for managing vaccine storage.

2. Procedures, policies and/or protocols are in place to ensure people requiring and receiving care receive effective health products, including vaccines that have not been adversely affected by heat or cold.

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## PROFESSIONAL SERVICES

**Do services include the provision of dose administration aids?**

If Yes:

1. I am familiar with Guideline 1.1 of the PBA Guidelines on Dose Administration Aids and Staged Supply of Dispensed Medicines, which detail the requirement for a clean, tidy and orderly packing space of sufficient size with good lighting that is not accessible to the Public.

**Do services include the provision of complex compounding?**

If Yes:

1. I am familiar with:
    - **A.** Guideline 8.1 of the PBA Guidelines on Compounding of Medicines, which detail expectations relating to facilities, working environments, equipment, and safety precautions.
    - **B.** the answers to the questions on the PBA Frequently Asked Questions for pharmacists on the compounding of medicines.
    - **C.** the Extemporaneous Dispensing section of the APF25.

**Do services include approval to dispense methadone and buprenorphine for the treatment of opioid dependence as part of the Community Program for Opioid Pharmacotherapy (CPOP)?**

If Yes:

1. I am familiar with Section 5.3.1 of the latest edition of the Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence, which detail the dosing area requirements.

**Do services include the administration of influenza vaccines by a pharmacist?**

If Yes:

1. I am familiar with Appendix 2 to the Administration of Influenza Vaccines by Pharmacists Structured Administration and Supply Arrangement (SASA), which details the approved **setting** requirements.

**Do services include the administration of other vaccines (not including COVID-19) by a pharmacist?**

If Yes:

1. I am familiar with Appendix 2 to the Administration of Vaccines by Pharmacists SASA, which details the approved **setting** requirements.

**Do services include the administration of vaccines by a medical practitioner or nurse practitioner?**

If Yes:

1. I am familiar with the Pharmaceutical Society of Australia Practice Guidelines for pharmacists providing immunisation services.

**Do services include the administration of COVID-19 vaccines by a pharmacist or a nurse employee?**

If Yes:

1. I am familiar with:
    A. Appendix 2 to the Administration of COVID-19 Vaccines in Pharmacies SASA, which details the approved **setting** requirements.
    B. the **physical environment** requirements, as detailed in the Australian Technical Advisory Group on Immunisation (ATAGI) site requirements for COVID-19 vaccination in community pharmacies.

**Are COVID-19 vaccines stored OUTSIDE of the dispensary?**

If Yes:

1. I am familiar with requirements for the storage of COVID-19 vaccines OUTSIDE of the dispensary detailed in the Western Australian Department of Health and Board Guidelines for the Storage of COVID-19 vaccines in pharmacies.

2. A Premises Plan that meets the Board's Guidelines for Plans of Registered Premises and shows the location of the COVID-19 vaccine refrigerator located OUTSIDE of the dispensary has been provided to the Board.

**Does the pharmacy participate in the Return of Unwanted Medicines Program (the RUM Project)?**

If Yes:

1. Procedures, policies and/or protocols are in place to ensure compliance with all the requirements detailed in the Collection Protocol for Western Australia.

**Does the pharmacy participate in the Western Australian Department of Health Needle and Syringe Program?**

If Yes:

1. Only approved products are supplied.

[Fitpack®, Fitpack® Plus, Fitstick® Plus Pack 3, Fitstick® 5 Plus, Sterafit™ and/or Sterafit™ Plus]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## SIGNAGE

**Display of names**:

1. I am familiar with the Board's Guidelines on the Display of names.

2. The name of the proprietor(s) is(are) displayed on a sign at all entries accessed by the Public so as to be clearly visible.

3. The name of the pharmacist who is regularly and usually in charge of the pharmacy business and the name(s) of other pharmacist(s) on duty are visibly displayed in the professional services area or the place where medicines are usually collected by the Public.

[Refer Guideline 4.1.4 - Display of names]

**Is the Pharmacy approved to claim Australian Government subsidies for Pharmaceutical Benefits Scheme and Repatriation Benefits Scheme prescription medicines?**

If No:

1. I am familiar with the Board's Guidelines on the Unapproved pharmacy notice.

2. The Unapproved Pharmacy Notice is displayed in accordance with the Guidelines.

[Refer Guideline 4.1.6 – Unapproved pharmacy notice]

**I DECLARE THE ABOVE STATEMENTS ARE TRUE AND CORRECT** ☐

## FINAL DECLARATION

**I**, <**Responsible Pharmacist**>, the pharmacist with overall responsibility at <Pharmacy Name>, the pharmacy business carried on at Premises Number <Registration Number>, **do solemnly and sincerely declare**:

1. **I completed this application.**

   Yes ☐

2. **My responses are current, true and correct to the best of my knowledge and belief.**

   Yes ☐

3. **If required, I will provide documentation to support my declarations.**

   Yes ☐

I make my declaration knowing, under Section 64 of the Pharmacy Act 2010, it is an offence to –

- make a statement or provide information,

- to the Board or the Registrar in relation to the compliance, or purported compliance, with any requirement of the Pharmacy Act 2010 knowing that it is false or misleading –

- in a material particular or in a material particular, with reckless disregard as to whether the information is false or misleading in a material particular.

**Yes ☐**

<**Responsible Pharmacist**>

<Pharmacy Name>

[Refer Pharmacy Act 2010, Section 64 – False and misleading information]