Pharmaceutical Samples Permit Application Form

*Medicines and Poisons Act 2014*

Table of Contents

[INSTRUCTIONS and INFORMATION i](#_Toc98511829)

[PART 1: APPLICATION for a PHARMACEUTICAL SAMPLES PERMIT 1](#_Toc98511830)

[1. Details of applicant (nominated Permit holder) 1](#_Toc98511831)

[2. Pharmaceutical samples stored at the premises 1](#_Toc98511832)

[3. Premises, storage and access 2](#_Toc98511833)

[4. Return of samples at end of day 3](#_Toc98511834)

[5. Orders from clients 3](#_Toc98511835)

[6. Declaration by APPLICANT to obtain a Permit 4](#_Toc98511836)

[PART 2: PERSONAL INFORMATION: APPLICANT 5](#_Toc98511837)

[7. Identification of applicant (nominated Permit holder) 5](#_Toc98511838)

[8. Qualifications and experience of applicant 5](#_Toc98511839)

[9. Prior licences/permits for medicines/poisons held by applicant 5](#_Toc98511840)

[10. Criminal check for applicant 6](#_Toc98511841)

[11. Financial resources of applicant 6](#_Toc98511842)

[12. Declaration by APPLICANT (includes probity check consent) 6](#_Toc98511843)

[PART 3: Payment and Checklist 7](#_Toc98511844)

[13. Payment: 7](#_Toc98511845)

[14. Checklist 8](#_Toc98511846)

[Part 4: Appendix 9](#_Toc98511847)

[Appendix A: Certifying true copies of photographic identification 9](#_Toc98511848)

|  |
| --- |
| INSTRUCTIONS and INFORMATION  |
|  | This application form is for a new **Pharmaceutical Samples Permit** for representatives of pharmaceutical companies to store and carry samples to supply to authorised persons, such as medical practitioners. This form MUST be completed by the applicant (nominated Permit holder) who will be the Permit holder and is suitably qualified and understands the requirements and terminology contained in this application.**All communication will ONLY be with the nominated Permit holder.**To request a change to an existing Permit, please complete an Application to Change a Pharmaceutical Samples Permit, found at: [Application forms for Licences and Permits](https://ww2.health.wa.gov.au/Articles/A_E/Application-forms-for-Licences-and-Permits)There are four parts to this form:Part 1: Application form for a Pharmaceutical Samples PermitPart 2: Personal Information: Identification, Fitness and Probity to be completed by the Permit holder.Part 3: Payment and checklist.Part 4: Appendix  |
|  | **Permit holder, qualifications and /or experience****2.1** **Permits are issued to:*** 1. Individual applicants who must complete Part 2: Personal Information Identification, Fitness and Probity and sign the declaration at Section 12.

The applicant must have qualifications and/or experience related to handling, storage and recording supply of Schedule 2,3 or 4 medicines and be employed (including under a contract) as a pharmaceutical representative by the pharmaceutical company.Applicants should familiarise themselves with the relevant parts of the Medicines and Poisons Regulations 2016 as there are prescribed limits on both the number of samples that can be stored at a premises listed on the Permit and the number of samples that can be carried in vehicles.**2.2 Permit holder responsibilities**If the Permit is issued, it is the responsibility of the applicant (Permit holder) to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and any conditions placed on the Permit.The Permit holder should review standard operating procedures used by the organisation to check they are consistent with the mandatory requirements of the legislation and any conditions placed on the Permit.There are penalties under the Act for providing false or misleading information when applying for a new Permit. |
|  | **Storing samples at self-lock storage facilities** Samples may be stored at self-lock storage facilities. However, at no time can persons other than representatives of the pharmaceutical company take delivery of or be in possession of samples at a self-lock storage facility. This restriction includes staff of the self-lock storage facility. |
|  | **Required documents** The applicant is required to submit copies of certain documents. If documents are not in English, also attach a translation certified as completed by a National Accreditation Authority for Translators and Interpreters (NAATI) accredited translator.Copies of photographic identification documents, such as a drivers licence or passport must be certified as a true copy. A list of people who can certify copies of documents is found in Appendix A. |
|  | **Signatures** All signatures must be signed in ink or via a verifiable electronic signature. An electronic signature is only acceptable if the submitted application allows the Department to verify the signature.A “signature” that is copied and pasted and a “signature” that is the person’s name in a font style resembling handwriting will not be accepted. |
|  | **Issuing a Permit** Applying for a Permit does not guarantee it will be issued. An application must be deemed complete and payment received before the application is sent to the approvals team where a desktop risk assessment is conducted by an authorised officer.The Department assesses each application individually and may decide against issuing a Permit. If the Permit is issued:* it will expire 1 year after the date of issue,
* a renewal application will be mailed to the postal address approximately 2 months prior to expiry.
	+ It is the Permit holder’s responsibility to inform the Department if the postal address changes.

If the Permit is not issued:* the applicant will be provided with details of the reasons in writing,
* the yearly Permit fee will be refunded,
* the application fee is non-refundable.
 |
|  | **Processing applications** Applications will be processed in order of receipt after payment has been processed by Finance, provided the required fee has been paid. To ensure a timely decision about your application, please: * Complete all required Sections of the application,
* **Attach** all requested documentation to the application,
* Ensure the application is accompanied by a completed Personal Information Form for the applicant and any persons nominated to have responsibility for a premises,
* Respond to requests from the Department for additional information as soon as possible,
* Make sure appropriate staff are available if the Department needs to conduct a premises inspection,
* Please submit your application as a Word document and not a photograph.
 |
|  | **Extra information**When applying for a Permit please refer to the: [Guide to applying for a Licence or Permit](https://ww2.health.wa.gov.au/Articles/A_E/Application-forms-for-Licences-and-Permits) |
|  | **Submitting the application** Please email completed form and other requested documentation to: mprb@health.wa.gov.au |
| **Incomplete applications may be delayed or returned to the applicant** |
| **Please keep a copy of the completed application form for reference** |

|  |
| --- |
| PART 1: APPLICATION for a PHARMACEUTICAL SAMPLES PERMIT |

|  |
| --- |
| Details of applicant (nominated Permit holder)  |
| Please refer to instruction number 2, for information on the requirements for being a Permit holder. |
| Title: |       | Forename/s: |       | Surname: |       |  |
| Address: |       | Suburb: |       | Postcode: |       |  |
| Telephone: |       | Fax: |       | Email: |       |  |
| Position in business: |       |  |
| The applicant must complete Part 2, Personal Information: Identification, Fitness and Probity |
| **1.1** | **Business or trading name of pharmaceutical company:** |       |  |
| **1.2** | **Contact details for pharmaceutical company:** |
|  | Postal address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax:  |       | Email:  |       |  |
| **1.3** | **Residential address of applicant: pharmaceutical representative (required):** |
|  | Street address: |       | Suburb: |       | Postcode: |       |  |
| **1.4**  | **Address for correspondence** Contact details for pharmaceutical representative: |
|  | Preferred address for correspondence (renewal reminders will be sent to this address): |
|  | [ ]  Pharmaceutical company address as shown above at 1.2 or  |
|  | [ ]  Residential address of pharmaceutical representative as shown above at 1.3 or  |
|  | [ ]  Other: please complete preferred correspondence address below: |
|  | Postal address: |       | Suburb:  |       | Postcode:  |       |  |
|  |

|  |
| --- |
| Pharmaceutical samples stored at the premises  |
|  |
|

|  |  |  |
| --- | --- | --- |
| **Details of medicine** | **Schedule 2, 3 or 4** | **Approximate number of boxes or bottles required\*** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|  |  |  |

 |
| \*Note: a maximum of 100 samples each, of up to 5 medicines may be stored at a premises. |
| **2.1**  | **Schedule 2,3 and 4 medicines** |
|  | Please describe how the receival and supply of medicines in Schedule 2, 3 and 4 will be recorded: |
|  |       |  |
|  |       |  |
|  |
| **2.2**  | [ ]  Check to confirm records of receival and supply of Schedule 2, 3,4 medicines will be kept for a minimum of 2 years. |

**Part 1: Application for a Pharmaceutical Samples Permit**

|  |
| --- |
| Premises, storage and access |
| Please indicate at which premises pharmaceutical samples will be stored (Check all that apply) |
| [ ]  Pharmaceutical representative’s residence: Complete Section 3.1 and 3.4 |
| [ ]  Self-locked storage unit (optional): Complete Section 3.2 and 3.4 |
| [ ]  Licensed wholesaler located in Western Australia (optional): Complete Section 3.3 and 3.4 |
| **3.1**  | [ ]  **Residential address of pharmaceutical representative as stated at Section 1.3** |
|  | 3.1.1 | Storage of non-refrigerated medicines at the residential premises (Please check which one applies): |
|  |  | [ ]  Locked room  | [ ]  Locked cupboard |
|  | 3.1.2 | Will medicines requiring refrigeration be stored at the premises?  |
|  |  | [ ]  No |
|  |  | [ ]  Yes: please check how the refrigerated medicines will be stored (Please check which one applies) |
|  |  |  | [ ]  Locked room with a refrigerator | [ ]  Locked refrigerator. |
|  |  | Please confirm how the temperature of refrigerated medicines will be monitored: |
|  |  | [ ]  Vaccine refrigerator with an inbuilt thermometer or data logger with downloadable data. |
|  |  | [ ]  Normal refrigerator with temperature data logger with downloadable data. |
|  |  | Manual thermometers are not sufficient for continuous monitoring of refrigerated medicines. The temperature data logger must record multiple data points (not just maximum and minimum temperatures) and must create an alarm if the temperature is outside the designated range. |
|  | 3.1.3 | Access to pharmaceutical samples |
|  |  | **[ ]** Please confirm you will be the only person with access to samples stored at your residential address. |
|  | 3.1.4 | Please describe how unauthorised persons, including other household residents, including children, will be prevented from accessing samples stored at home. |
|  |  |       |  |
|  |  |       |  |
| **3.2** | [ ]  **Self-locked storage unit (optional)** |  |
|  | Name of storage facility: |       |  |
|  | Street address: |       | Suburb: |       | Postcode: |       |  |
|  | Is the storage unit temperature controlled? | **[ ]** Yes | **[ ]** No |
|  | If no, please describe how you will ensure the samples are held at the manufacturer’s recommended temperature? |
|  |       |  |
|  |       |  |
|  | 3.2.1 | Will the self-locked storage unit contain your samples or will samples from other pharmaceutical representatives also be stored at the same unit. (Please check which one applies): |
|  |  | **[ ]** Only my samples | **[ ]** My samples plus those of other representatives: complete a) below: |
|  |  | a) **If** the unit stores samples of other representatives, how will the samples be kept separate? |
|  |  |       |  |
|  |  |       |  |
|  |  | b) Who will sign for deliveries of samples at the storage unit (Please check all that apply): |  |
|  |  | **[ ]**  Self | **[ ]** Other representatives | **[ ]** Other, please specify: |       |  |
|  |  | **[ ]**  Please confirm that no-one, other than yourself and the representatives you share the storage unit with (if applicable), has access to the storage unit. |
|  |  | **[ ]**  Please confirm that the storage facility staff do not have access to the storage unit, unless accompanied by you or another representative with whom you share the storage unit |

**Part 1: Application for a Pharmaceutical Samples Permit**

|  |
| --- |
| **3. (continued) Premises, storage and access** |
| **3.3** | [ ]  **Licensed wholesaler located in Western Australia (optional)** |
|  | Name of licensed wholesaler: |       |  |
|  | Street address: |       | Suburb: |       | Postcode: |       |  |
| **3.4** | **Loss or theft of Schedule 4 medicines** |
|  | [ ]  | Check to confirm any loss or theft of Schedule 4 medicines will be reported to MPRB as soon as reasonably practicable using the form found at: [Reporting loss or theft of medicines and poisons](https://ww2.health.wa.gov.au/Articles/N_R/Reporting-loss-or-theft-of-medicines-and-poisons) |
|  |
| Return of samples at end of day |
| Please check the boxes to confirm the following statements: |
| **[ ]**   | Samples will only be kept in my vehicle whilst it is being used in the course of my business |
| **[ ]**   | At the end of the business day, samples will be removed from my vehicle and returned to the secure storage at the premises address/es I have provided in Section 3 of this form. |

|  |
| --- |
| Orders from clients  |
| Please check the box to confirm the following statement: |
| [ ]  | Samples will only be supplied to authorised health professionals following receipt of a written order signed by the health professional. |
|  |  |

**Part 1: Application for a Pharmaceutical Samples Permit**

|  |
| --- |
| Declaration by APPLICANT to obtain a Permit |
| This declaration relates to the application itself and must be signed by the applicant (nominated Permit holder).Please refer to Instruction 6 for information on acceptable signatures. |
| I (provide full name):  |       |  |
| of (provide full address): |       |  |
| hereby declare:  |
|  | The information contained in this application form is true and correct. |
|  | I am aware that penalties apply under the *Medicines and Poisons Act 2014* for providing false or misleading information in this application. |
| Signature of applicant:  |       | Date:  |       |  |
| **Witnessed by:** |
|  |       |  |       |  |
| (Signature of Witness) | (Name of Witness) |

|  |
| --- |
| PART 2: PERSONAL INFORMATION: APPLICANT  |

|  |
| --- |
| Identification of applicant (nominated Permit holder) |
| **7.1 Personal Details** |
| Title: |     | Forename/s: |       | Surname: |       | Date of birth: |       |  |
| Address: |       | Suburb: |       | Postcode: |      |  |
| Postal address:  |       | Suburb: |       | Postcode: |      |  |
| Mobile number: |       | Email:  |       |  |
| Position in business: |      |  |
| **7.2 Certified true copy of a photographic identification document** |
| **ATTACH** a certified1 copy of a WA State Government or Australian Government issued photographic identification document such as drivers licence or passport. Non-government issued identification documents will not be accepted. |
| 1Copy of photographic identification document must be certified as a true copy by a person authorised to witness statutory declarations (see Appendix A for a list of persons authorised to certify a true copy). |
|  |

|  |
| --- |
| Qualifications and experience of applicant  |
| The applicant must have qualifications and/or experience related to handling, storage and recording supply of Schedule 2, 3 and 4 medicines.Please **attach** copies of a **CV and/or qualifications** which demonstrate your suitability as a Permit holder for a Pharmaceutical Samples Permit. |

|  |
| --- |
| Prior licences/permits for medicines/poisons held by applicant  |
| **9.1**  | Have you (or a company of which you were a corporate officer or a partner) previously held a Licence or Permit, under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory, that was suspended or cancelled? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the Licence or Permit number, the name of the business, when the cancellation or suspension occurred, the reason for the cancellation or suspension and which state or territory the cancellation or suspension occurred in: |
|  |       |  |
|  |       |  |
|  |       |  |
|  |
| **9.2** | Have you (or a company of which you were a corporate officer) ever been refused a Licence or Permit under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory? |
|  | [ ]  No |
|  | [ ]  Yes: please provide details of the name of the business, what type of Licence or Permit you applied for, why your application was refused and which state or territory the refusal occurred in: |
|  |       |  |
|  |       |  |
|  |

**Part 2: Personal information about the applicant (Permit holder)**

|  |
| --- |
| Criminal check for applicant  |
| Have you ever been convicted of, or are there charges pending for an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory  |
| [ ]  No |
| [ ]  Yes: you must **attach** full details in the form of a Statutory Declaration. Your declaration must include the:* Name of the court including state/territory or country, all relevant dates and any sentences received
* The nature of the alleged offence and circumstances surrounding the offences
 |

|  |
| --- |
| Financial resources of applicant  |
| **11.1** | Have you been declared bankrupt or a debtor under any bankruptcy law?  |
|  | [ ]  No |
|  | [ ]  Yes: What date was/will your bankruptcy be discharged? |       |  |
| **11.2** | Have you ever been a corporate officer of a company that was wound up or subject to an application for, or placed in, receivership or liquidation? | [ ]  [ ]  Yes | [ ]  [ ]  No |
|  |

|  |
| --- |
| Declaration by APPLICANT (includes probity check consent)  |
| This declaration relates to the personal information provided by the applicant and includes probity check consent.Please refer to Instruction 6 for information on acceptable signatures. |
|  | In accordance with Section 39 of the *Medicines and Poisons Act 2014*, I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity to hold a Pharmaceutical Samples Permit. These searches may include (without limitation) corporate searches, checks with health professional registration boards (including registration status and release of information on any current or ongoing investigations) and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity. |
|  | I am at least 21 years of age. |
|  | The information contained in this application form is true and correct. |
|  | I am aware there are penalties under the *Medicines and Poisons Act 2014* for providing false or misleading information. |
|  | I am aware of my responsibility for the safe storage and supply of Schedule 2 ,3 or 4 medicines and will ensure compliance with the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016, and compliance with conditions placed on the Permit. |
|  | I will notify the Department of Health if I am no longer employed as a pharmaceutical representative of the pharmaceutical company named in Section 1.1 |
|  Signature: |       | Name: |       | Date: |       |  |
|  |

# PART 3: Payment and Checklist

|  |
| --- |
| Payment |
| **Fee: $212** |
| Comprising a non-refundable application fee of $106 and 1-year Permit fee of $106.Permit fee only will be refunded if the Permit is not issued. |
| * + 1. [ ]  Credit Card – American Express and Diners not accepted
 |
|  | Card type: | [ ]  MasterCard | [ ]  Visa  |
|  | Name on card: |       | Card number:  |        |  |
|  | Expiry date: |       | Amount:  **$212** |
|  | Signature of cardholder: |       | Date:  |       |  |
|  |
| * + 1. [ ]  Direct debit to bank
 |
|  | **Please quote applicant’s name or business name in the reference** |
|  | Bank: Commonwealth Bank: | **BSB**: 066 040  | **Account number:** 13300018 | Amount: **$212** |
|  | Receipt Number: |       | Payment date:  |       |  |
|  |
| * + 1. [ ]  Cheque or money order – made payable to DEPARTMENT OF HEALTH
 |

**PART 3: Payment and Checklist**

|  |
| --- |
| Checklist |
| Please ensure all the appropriate requested documentation is attached for: |
| **Part 1 Application for a Pharmaceutical Samples Permit**  |
| [ ]  | Declaration signed and dated by applicant (nominated Permit holder) and witnessed (Section 6) |
| **Part 2: Personal information, fitness and probity for applicant (nominated Permit holder)** |
| [ ]  | Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 7.2) See Appendix A for a list of persons authorised to witness a signature  |
| [ ]  | Attach **copies** of a CV and/or qualifications which demonstrate your suitability as a Permit holder for a Pharmaceutical Samples Permit (Section 8) |
| [ ]  | If applicable, a Statutory Declaration relating to an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory (Section 10) |
| [ ]  | Declaration about personal information of applicant signed and dated. (Section 12) |
| **Part 4: Declaration and Payment** |
| [ ]  | Payment details completed with correct signature if paying by credit card (Section 13) |

**Please keep a copy of the completed application form for reference**

Please email completed form and other requested documentation to mprb@health.wa.gov.au

#

# Part 4: Appendix

## Appendix A: Certifying true copies of photographic identification

Suggested wording for certification is as follows:

I certify that this appears to be a true copy of the document produced to me on <date>

Signature

Name

Profession or occupation group

| **Persons who can certify documents** |
| --- |
| Academic (tertiary institution) | Medical practitioner |
| Accountant | Member of Parliament |
| Architect | Minister of religion |
| Australian Consular Officer | Nurse |
| Australian Diplomatic Officer | Optometrist |
| Bailiff | Patent attorney |
| Bank manager | Pharmacist |
| Chartered secretary | Physiotherapist |
| Chiropractor | Podiatrist |
| Company auditor or liquidator | Police officer |
| Court officer (judge, master, magistrate, registrar or clerk) | Post Office manager |
| Defence Force officer | Psychologist |
| Dentist | Public servant |
| Engineer | Public notary |
| Industrial organisation secretary | Real Estate agent |
| Insurance broker | Settlement agent |
| Justice of the Peace | Sheriff or deputy Sheriff |
| Lawyer | Surveyor |
| Local government CEO or deputy CEO | Teacher |
| Local government councillor | Tribunal officer |
| Loss adjuster | Veterinarian |
| Marriage celebrant |  |