Application to change a

Pharmaceutical Samples Permit

*Medicines and Poisons Act 2014*

Table of Contents

[INSTRUCTIONS and INFORMATION i](#_Toc118810067)

[PART 1: APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT 1](#_Toc118810068)

[1. General information 1](#_Toc118810069)

[Changes without a fee 2](#_Toc118810070)

[2. Change of postal address and other contact details 2](#_Toc118810071)

[3. Remove a premises from the Permit 2](#_Toc118810072)

[4. Remove certain medicines from the Permit 2](#_Toc118810073)

[5. Information about disposal of medicines 2](#_Toc118810074)

[Changes with a fee 3](#_Toc118810075)

[6. Increase quantity of medicines 3](#_Toc118810076)

[7. Addition of medicines 3](#_Toc118810077)

[8. Relocation of an existing storage premises 4](#_Toc118810078)

[9. Addition of another new premises 4](#_Toc118810079)

[10. Information about the relocated or new added premises 5](#_Toc118810080)

[11. Information about the medicines at the relocated or new added premises 6](#_Toc118810081)

[12. Declaration by Permit holder 6](#_Toc118810082)

[PART 2: PAYMENT and CHECKLIST 7](#_Toc118810083)

[13. Payment (where required) 7](#_Toc118810084)

[14. Checklist 7](#_Toc118810085)

|  |
| --- |
| INSTRUCTIONS and INFORMATION |
|  | This form is for requesting changes to an existing **Pharmaceutical Samples Permit** issued under the *Medicines and Poisons Act 2014*. This form MUST be completed by the current Permit holder who is suitably qualified and understands the requirements and terminology contained in this application.**All communication will ONLY be with the Permit holder.** |
|  | Fees are **not** payable for the following type of changes to a Pharmaceutical Samples Permit:* Change of postal addresses and other contact details
* Removal of premises from the Permit
* Removal of certain medicines from the permit.
 |
|  | Fees are **not** payable for the following type of changes to a Pharmaceutical Samples Permit:* Change of postal addresses or other contact details
* Removal of a premises from the Permit
* Removal of certain medicines from the Permit.
 |
|  | A fee of **$90** is payable for the following type of changes to a Pharmaceutical Samples Permit:* Increase quantity of medicines already listed on the Permit
	+ A maximum of 100 samples each, of up to 5 medicines may be stored at a premises.
* Addition of certain medicines to the Permit
* Relocation of an existing premises to a new location or addition of a new premises to the Permit.
 |
|  | **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 hand writing will not be acceptedThe Permit holder must sign the Declaration for making a change to the Permit. |
|  | **Approving a change to a Permit** Applying for a change to an existing Permit does not guarantee the requested changes will be approved. |
|  | **Processing applications** Applications will be processed in order of receipt after payment has been confirmed by Finance. To ensure a timely decision about your application please: * Complete all required sections of the application,
* **Attach** all requested documentation to the application,
* 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,
* Do not submit your application as a digital image (photograph).
 |
|  | **Extra information** When applying for a change to an existing Permit, refer to: [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 to change a PHARMACEUTICAL SAMPLES PERMIT

|  |
| --- |
| General information |
| Permit number:  |       | Name of Permit holder: |       |  |
| Postal address: |       | Suburb: |       | Postcode: |       |  |
| Telephone: |       | Fax: |       | Email: |       |  |
|  |
| **1.1 Type of change** |
| Please check whichever applies: |
| **Changes without a fee** | **Complete Sections**  |
| **[ ]**  | Change of postal addresses or other contact details | 2, 12 |
| **[ ]**  | Remove a premises from the Permit | 3, 5, 12 |
| **[ ]**  | Remove certain medicines from the Permit | 4, 5, 12 |
| **Changes with a fee of $90** |
| **[ ]**  | Increase quantity of medicines already listed on the Permit  | 6, 12,13  |
| **[ ]**  | Addition of certain medicines to the Permit  | 7, 12, 13 |
| **[ ]**  | Relocation of an existing storage premises to a new premises  | 8, 10, 12,13 |
| **[ ]**  | Addition of another new storage premises to a Permit | 9, 10,12, 13 |
| **Note: if making multiple changes, only pay one fee of $90** |
| **1.2** Additional information to support application (optional): |
|  |       |  |
|  |       |  |
|  |       |  |
|  |       |  |
|  |

**PART 1: APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT**

|  |
| --- |
| Changes without a fee |

|  |
| --- |
| Change of postal address and other contact d**etails**  |
| Postal Address\*:  |       | Suburb:  |       | Postcode:  |       |  |
| Telephone:  |       | Fax |       | Email: |       |  |
| ‘\* Renewal reminders will be sent to this address. |

|  |
| --- |
| Remove a premises from the Permit |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| Date medicines will no longer be stored at this premises: |       |  |
| Are the premises being handed over to another representative of the pharmaceutical company to store samples? |
| **3.1** [ ]  Yes: please provide the name of the representative: |       |  |
|  | The Department requires the pharmaceutical representative taking possession of the medicines at this premises to either apply to add this premises to their current Pharmaceutical Samples Permit, if they already have a Permit, or apply for a new Permit in their name. Applications from the person taking possession of the medicines at the premises must be received by the Department prior to removing this premises from your Permit. |
| **3.2** [ ]  No: is there any remaining stock of medicines left? |
|  | [ ]  No |
|  | [ ]  Yes: please also complete Sections 5 |

|  |
| --- |
| Remove certain medicines from the Permit |
| Premises name: |       |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
|  **4.1** | Please indicate the Schedule of the medicines being removed from the Permit |
|  | [ ]  Schedule 2 [ ]  Schedule 3 [ ]  Schedule 4 |
|  | If only a small number of specific individual medicines are to be removed, please list below: |
|  |       |  |
|  |       |  |
| **4.2** | Is there any remaining stock left of the medicines being removed from the Permit? |
|  | [ ]  No [ ]  Yes: please also complete Sections 5 |

|  |
| --- |
|  Information about disposal of medicines |
| If there is any remaining stock of Schedule 2, 3 or 4 medicines after removing a premises form a Permit or removing certain medicines from a premises listed on the Permit, please indicate how the stock will be disposed of.Check all that apply: |
| [ ]  Taken to pharmacy or hospital for disposal1 — | Name of pharmacy/hospital: |       |  |
| [ ]  Returned to wholesaler for disposal — | Name of wholesaler: |       |  |
| [ ]  Transferred to other premises on the Permit — | Name of premises: |       |  |
| [ ]  Disposed of using a licensed waste management service — | Name: |       |  |
| 1 Pharmacies and hospitals are not obligated to accept medicines for disposal if they have not supplied the medicineMore information on disposal of medicines is found at: [Disposal of medicines](https://ww2.health.wa.gov.au/Articles/A_E/Disposal-of-medicines) |

**PART 1: APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT**

|  |
| --- |
| Changes with a fee |

|  |
| --- |
|  Increase quantity of medicines  |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| **6.1 Medicines having their quantity increased at the above-named premises** |
| Medicine | Quantity on current Permit | Increase quantity to: |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| \*Note: a maximum of 100 samples each, of up to 5 medicines may be stored at a premises. |

|  |
| --- |
|  **Addition of** medicines |
| Premises name: |       |  |
| Address:  |       | Suburb:  |       | Postcode:  |       |  |
| **7.1**  | **Pharmaceutical samples to be added to the above-named premises**  |
|  | List of samples and quantities to be added to the above-named premises on the Permit: |
|  | **Name, strength and form of medicine** | **S2, S3 or S4** | **Approximate number of boxes or bottles to be kept on hand** |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  | \*Note: a maximum of 100 samples each, of up to 5 medicines may be stored at a premises |
| **7.2**  | **Storage of Schedule 2, 3 or 4 medicines being added to the Permit** |
|  | Please check how non- refrigerated and refrigerated medicines being added to the Permit will be stored. |
|  | Non-refrigerated medicines: | [ ]  Locked room | [ ]  Locked cupboard/drawer |
|  | Refrigerated medicines: | [ ]  Locked room with refrigerator | [ ]  Locked refrigerator |
|  | Please indicate how continuous monitoring of temperature sensitive medicines is managed: |
|  | [ ]  refrigerator designed specifically for storing vaccines |
|  | [ ]  use of a data logger which alarms if the temperature is outside the designated range (with downloadable data) |
|  | Note: Manual thermometers are not sufficient for continuous monitoring of temperature sensitive medicines |

**PART 1 APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| Relocation of an existing storage premises |
| **8.1** | Is the relocated premisesm=, at which the pharmaceutical samples will be stored, listed on a different Permit?  |
|  | [ ]  No |
|  | [ ]  Yes: The Department requires the Permit holder at the relocated premises to remove the premises from their Permit and the application to remove the premises must be received by the Department prior to adding the relocated premises to your Permit.  |
| **8.2** | **Current address of premises:** |
|  | Premises name: |       |  |
|  | Address: |       | Suburb:  |       | Postcode:  |       |  |
| **8.3** | **New address of relocated premises:** |
|  | Premises name: |       |  |
|  | Address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax: |       | Email: |       |  |
|  | Date of possession of the premises (settlement date/lease commencement/handover of premises): |       |  |
|  | Note: Permit will be issued with “Valid from” date on or after this date. |
| **8.4**  | **Plus,** complete Sections 10, 11 and 13 (payment) |

|  |
| --- |
| Addition of another new premises  |
| **9.1** | Is the new premises being added to your Permit currently listed on another Permit  |
|  | [ ]  No |
|  | [ ]  Yes: The Department requires the Permit holder at the new premises to remove the premises from their Permit and the application to remove the premises must be received by the Department prior to adding the relocated premises to your Permit |
|  | Premises name: |       |  |
|  | Premises Address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax: |       | Email: |       |  |
|  | Date of possession of the premises (settlement date/lease commencement/handover of premises) |        |  |
|  | Note: Permit will be issued with “Valid from” date on or after this date. |
| **9.2**  | **Plus,** complete Sections 10, 11 and 13 (payment) |

**PART 1: APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
|  Information about the relocated or new added premises |
| **10.1** List of pharmaceutical samples and quantities to be stored at relocated or new added premises: |
|  | **Name, strength and form of medicine** | **S2, S3 or S4** | **Approximate number of boxes or bottles to be kept on hand** |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  |       |       |       |  |
|  | \*Note: a maximum of 100 samples each, of up to 5 medicines may be stored at a premises |  |
| **10.2** Please confirm which type of premises the relocated or new added premises will be:  |
| [ ]  | Residential premises of applicant  |
|  | Street address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Please check how non- refrigerated and refrigerated pharmaceutical samples will be stored. |
|  | Non-refrigerated pharmaceutical samples: | [ ]  Locked room | [ ]  Locked cupboard |
|  | Refrigerated pharmaceutical samples: | [ ]  Locked room with refrigerator | [ ]  Locked refrigerator |
|  | Please indicate how continuous monitoring of temperature sensitive medicines will be managed: |
|  | [ ]  refrigerator designed specifically for storing vaccines |
|  | [ ]  use of data logger which alarms if the temperature is outside the designated range (with downloadable data) |
|  | Note: Manual thermometers are not sufficient for continuous monitoring of temperature sensitive medicines |
|  | **[ ]** Please confirm if you will be the only person with access to samples stored at your residential address |
|  | Please explain how unauthorised persons, including household members, will be prevented from accessing samples |
|  |       |  |
|  |       |  |
| [ ]  | Self-locked storage unit  |
|  | Name of storage facility: |       |  |
|  | Street address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Is the storage unit temperature controlled? |
|  | **[ ]** Yes |
|  | **[ ]** No: describe how you will ensure the samples are held at the manufacturer’s recommended temperature? |
|  |       |  |
|  |       |  |
|  | Storage unit stores: | **[ ]** Only my samples | **[ ]** My samples plus those of other representatives |
|  | **If** the unit stores samples of other representatives, how are the samples kept separate? SEE INSTRUCTION 5 |
|  |       |  |
|  |       |  |
|  | Who will sign for deliveries of samples at the storage unit (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, will have 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. |
| **[ ]**  | Licensed wholesaler located in Western Australia  |
|  | Name of licensed wholesaler: |       |  |
|  | Street address: |       | Suburb:  |       | Postcode:  |       |  |
|  |

**PART 1: APPLICATION to change a PHARMACEUTICAL SAMPLES PERMIT**

|  |
| --- |
| **Changes with a fee** |

|  |
| --- |
| Information about the medicines at the relocated or new added premises |
| Pharmaceutical samples that will be stored at relocated or added premises: |
| **Name, strength and form of medicine** | **Schedule (S2, S3 or S4)** | **Approximate number of boxes or bottles to be kept on hand** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| \*Note: a maximum of 100 samples each, of up to 5 medicines may be stored at a premises. |

|  |
| --- |
| Declaration by Permit holder |
| This declaration must be signed by the Permit holder.Please refer to Instruction 5 for information on acceptable signatures |
| I am the: | [ ]  current Permit holder |
| 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:  |       |  |
|  |

# PART 2: PAYMENT and CHECKLIST

|  |
| --- |
| Payment (where required) |
| **Fee: $90** |
| * + 1. [ ]  Credit Card – American Express and Diners not accepted
 |
|  | Card type: | [ ]  MasterCard | [ ]  Visa  |
|  | Name on card: |       | Card number:  |        |  |
|  | Expiry date: |       | Amount:  **$90** |
|  | Signature of cardholder: |       | Date:  |       |  |
|  |
| * + 1. [ ]  Direct debit to bank
 |
|  | **Please quote Permit number and business name in the reference when making a direct debit payment**  |
|  | Bank: Commonwealth Bank: | **BSB**: 066 040  | **Account number:** 13300018 | Amount: **$90** |
|  | Receipt Number: |       | Payment date:  |       |  |
|  |
| * + 1. [ ]  Cheque or money order – made payable to DEPARTMENT OF HEALTH
 |

**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

|  |
| --- |
| **A fee of $90 is payable** for the following types of changes to a Pharmaceutical sample Permit |
| * Increase quantity of medicines already listed on the Permit
 |
| * Addition of certain medicines to the Permit
 |
| * Relocation of an existing storage premises to a new premises
 |
| * Addition of a new storage premises to a Permit
 |
| **Note: if making multiple changes, only pay one fee of $90** |
| **Fees are not payable** for the following type of changes to a Pharmaceutical samples Permit |
| * Change of postal addresses or other contact details
 |
| * Removal of a premises from the Permit
 |
| * Removal of medicines from the Permit
 |

|  |
| --- |
| Checklist |
| [ ]  | Declaration signed and dated (Section 12) |
| [ ]  | Payment details completed with correct signature if paying by credit card (Section 13) |