Wholesale/Manufacture Licence

Application Form

*Medicines and Poisons Act 2014*

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| INSTRUCTIONS and INFORMATION  |
|  | This application form is for a new **Wholesale/Manufacture Licence** for a business located in WA to supply medicines and/or poisons. This application form **MUST** be completed by the nominated applicant who will be:* an individual (sole trader) Licence holder or
* a corporate officer, if the Licence is being issued to a body corporate or
* a partner, if the Licence is to be issued to a partnership

The applicant must be suitably qualified and understand the requirements and terminology contained in this application form.**All communication will ONLY be with the nominated Licence holder, corporate officer or partner.**To request a change to an existing Licence, please complete an Application to Change an existing Wholesale/Manufacture Licence 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 five parts to this form:Part 1: Application form for a Wholesale/Manufacture Licence.Part 2: Personal Information: Identification, Fitness and Probity to be completed by the nominated applicant.Part 3: Personal Information: Identification, Fitness and Probity to be completed by the nominated responsible person.Part 4: Payment and checklist.Part 5: Appendix |
|  | **Licence holder****2.1** **Licences can be issued to:**1. Individual applicants (sole traders only), who must:
	* complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 17.
	* have at least 5 years’ experience in wholesaling medicines/poisons
	* have enough knowledge and skills to assess whether a client is authorised to purchase medicines/poisons and be able to comply with record-keeping requirements
	* determine policies and procedures in relation to conducting a wholesale/manufacture business involving the medicines/poisons on the Licence
	* provide a National Police Clearance (NPC) certificate less than 12 months old.

**OR**1. Body corporate (corporation) or partnership and:
	* each corporate officer (directors, general manager, company secretary, chief executive officer, chief financial officer and chief operating officer) or each partner must complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 17.
	* each corporate officer or partner must provide a National Police Clearance (NPC) certificate which is less than 12 months old.

**2.2 Licences issued to a corporation or partnership**The corporation or partnership must always employ a person who must:* have at least 5 years’ experience in wholesaling medicines/poisons
* have enough knowledge and skills to assess whether a client is authorised to purchase medicines /poisons and understands record-keeping requirements and
* have authority within the business to determine policies and procedures in relation to conducting a wholesale/manufacture business involving the medicines/poisons on the Licence.

**2.3 Licence holder responsibilities**The holder of a Wholesale/Manufacture Licence is required to determine that the person or business to which they are supplying the medicines/poisons is authorised to purchase those medicines/poisons and keep records of all sales in a manner compliant with the requirements of the Medicines and Poisons legislation.The Licence 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 Licence.Compliance with all relevant parts of the [Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8](https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8) is required for wholesale/manufacture licences dealing with human medicines.Compliance with Notices issued under [Section 72 of the Medicines and Poisons Act 2014](https://ww2.health.wa.gov.au/Articles/N_R/Notices-Section-72) is required for licences dealing with Schedule 7 poisons.The Licence holder must also consider whether they have capacity to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Licence for every premises listed on the Licence. The Department may request further information in relation this capacity.If the Licence is issued, it is the responsibility of the applicant (Licence holder) to ensure compliance with the *Medicines and Poisons Act 2014* and Regulations 2016 and any conditions placed on the Licence.There are penalties under the Act for providing false or misleading information when applying for a Licence. |
|  | **Person responsible for a premises** An individual person must be nominated as a responsible person to have overall responsibility for *each* premises to be included on the Licence. The role of the responsible person is to manage the medicines/poisons on a day to day basis and be the contact person if the Licence holder is not available.Each premises can have a different responsible person.The responsible person for a premises must:* be employed or contracted by the Licence holder
* reside in WA
* complete Part 3: Personal Information: Identification, Fitness and Probity
* provide a National Police Clearance (NPC) certificate which is less than 12 months old and
* sign the declaration at Section 22.

**3.1** **Responsible person for a Licence issued to an individual person (sole trader)** can be:1. Licence holder (sole trader)

**or** 1. the most senior person at the premises who has experience working in a medicine/poison wholesale/manufacture business.

**3.2 Responsible person for a Licence issued to a corporation or partnership** can be:1. the most senior person at the premises who must have at least at least 5 years’ experience in wholesaling medicines/poisons and has knowledge and skills to assess whether a client is authorised to purchase medicines/poisons and be able to comply with record-keeping requirements.

**or** 1. the person employed by the corporation or partnership as per instruction 2.2

Please note: a responsible person must consider whether they have capacity to oversee the day to day management of a wholesale/manufacture business at every premises for which they are responsible. Where a single person is responsible for multiple premises, the Department may request further information in relation this capacity. |
|  | **Purchasing a wholesale/manufacture business** If you are purchasing an existing wholesale/manufacturing business, the current Licence holder must remove the premises from their Licence by completing an Application to Change an existing Wholesale/Manufacture Licence. The application to remove the premises from the other Licence must be received by the Department prior to adding this premises to your Licence. You may have to liaise with the other wholesale/manufacture business so that the change in ownership is coordinated, this ensures the medicines/poisons stored at the premises are always covered by a Licence.*The Department does not coordinate the change in Wholesale/Manufacture Licences.* *It is the responsibility of the wholesale/manufacture businesses to manage the change in a timely manner.* |

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|  | **Required documents** The applicant and responsible person are 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 driver’s 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.The nominated Licence holder must sign the Declaration at Section 11 for obtaining a Licence. If the Licence will be held by a corporation or partnership, a corporate officer or partner must sign the Declaration. |
|  | **Standard Operating Procedures (SOPs).**This application requires the applicant to confirm the wholesale/manufacture business has a number of SOPs. The Department may request that SOPs be made available for auditing purposes. The issuing of a Licence does not imply approval or otherwise of the SOPs. |
|  | **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,
* 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 do not submit your application as a digital image (photograph).
 |
|  | **Issuing a Licence**Applying for a Licence does not guarantee a Licence 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 Licence. If the Licence 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 Licence holder’s responsibility to inform the Department if the postal address changes.

If the Licence is not issued:* the applicant will be provided with details of the reasons in writing,
* the yearly Licence fee will be refunded,
* the application fee is non-refundable.

 |
|  | **Extra Information**When applying for a Licence, please refer to the: [Guide to applying for a Permit or Licence](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 WHOLESALE/MANUFACTURE LICENCE

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| Details of applicant (nominated Licence holder) |
| Refer to instruction number 2, for information on the requirements for being a Licence holder. |
| Name of Legal Entity (may be different to business or trading name): |       |  |
| Business or trading name:  |       |  |
| Type of Licence (tick which one applies): |
| [ ]  Individual person (sole trader only). Complete section 1.1 and 1.3 to 1.7 |
| [ ]  Body Corporate (corporation) or partnership. Complete Section 1.2 and 1.3 to 1.7 |
| **1.1** | **Licence to be issued to an individual person** (applicable to sole traders only) |
|  | Title: |        | Forename/s: |        | Surname: |        |  |
|  | Postal address: |        | Suburb: |        | Postcode:  |        |  |
|  | Telephone: |        | Fax: |        | Email: |        |  |
|  | Position in business: |        |  |
|  | The applicant **must complete Part 2:** Personal Information: Identification, Fitness and Probity. |
| **1.2** | **Corporation or partnership.** Tick which one applies |
|  | [ ]  | **Corporation** |
|  |  | Each corporate officer: directors, general manager, company secretary, chief executive officer, chief financial officer, chief operating officer must complete Part 2: Personal Information: Identification: Fitness and Probity; and |
|  |  | 1.2.1 **Attach** a copy of Current Company Extract from ASIC (with details of company directors and secretary) |
|  | [ ]   | **Partnership** |
|  |  | Each partner must complete Part 2, Personal Information: Identification: Fitness and Probity. |
|  | Section 2 must be completed if the Licence is to be issued to a corporation or partnership. |
| **1.3** | **Business/Trading name** |
|  | **If** the business has a Business/Trading Name, **attach** a copy of certificate of Record of Registration for Business Name or Current Business Name Extract (from Australian Securities and Investment Commission [ASIC]). |
| **1.4** | **Australian Business Number**: |       |  |
| **1.5** | **Australian Company Number** (ACN) or Australian **Registered Body Number** (ARBN), if applicable: |  |
|  |       |  |
| **1.6** | **Registered business address of applicant:** |
|  | [ ]   | Same as postal address shown above or: |
|  | Address: |       | Suburb:  |       | Postcode:  |       |  |
|  |
| **1.7 Inspection of premises by Deprtment of Health** |
|  | This premises is: | [ ] ready for inspection now | [ ]  will be ready for inspection after:  |       |  |
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**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

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| Licences issued to a corporation or partnership |
| Is the applicant a corporation or partnership? |
| [ ]  No |
| [ ]  Yes: complete Section 2.1 and 2.2 |
| **2.1**  | [ ]  **Check** to confirm the corporation or partnership always employs a person who has: |
|  | * at least 5 years’ experience in wholesaling medicines/poisons
* enough knowledge and skills to assess whether a client is authorised to purchase medicines/poisons and understands record-keeping requirements and
* authority within the business to determine policies and procedures in relation to conducting a wholesale/manufacture business involving the medicines/poisons on the Licence.
 |
| **2.2**  | **Name of current employee meeting above criteria and their job title:** |
|   | Title: |       | Forename(s): |       | Surname: |       |  |
|  | Job title:  |       |  |  |
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| Premises and building security details |
| Section 3 must be completed for every premises listed on the Licence |
| Are you obtaining an existing wholesale/manufacturing business?  |
| [ ]  No  | [ ]  Yes: Name of business:  |       |  |
|  | The Licence holder for the existing business must remove this premises from their Licence before this premises can be added to your Licence. See instruction number 4. |
| **3.1**  | **Premises details** |
|  | Premises name (**if** applicable): |       |  |
|  | Premises address: |       | Suburb:  |       | Postcode:  |       |  |
|  | Telephone: |       | Fax: |       | Email: |       |  |
|  | Date of possession of the premises (settlement date/lease commencement/handover of building): |       |  |
|  | Note: Licence will be issued with “Valid from” date on or after this date |
| **3.2** | **Person responsible for premises** |
|  | Refer to instruction number 3, for information on the requirements for being a responsible person for a premise |
|  | Title: |       | Forename(s): |       | Surname: |       |  |
|  | Nominated responsible person **must complete Part 3**: Personal Information: Identification, Fitness  |
| **3.3**  | **Location of premises** |
|  | [ ]  Commercial | [ ]  Industrial | [ ]  Rural |  |
|  | [ ]  Other- please specify: |       |  |
|  | 3.3.1 Is local government approval required to operate the wholesale/manufacture business from the premises? |
|  |  | [ ]  | Yes: **attach** evidence of local government approval to operate the business from the premises. |
|  |  | [ ]  | No: Local government may be asked to comment on applications which may increase processing time |
| **3.4** | **Building security**: Please check all that apply: |
|  | [ ]  Dedicated monitored alarm system | [ ]  Video surveillance system (CCTV) | [ ]  Motion detectors  |
|  | [ ]  Perimeter fence with lockable gate | [ ]  Perimeter alarm |
|  | [ ]  Other – please describe: |       |  |
| **3.5** | **Liquid spills** |
|  | Are liquid medicines /poisons stored in a bunded area? | [ ]  Yes [ ]  No |
|  | [ ]  Check to confirm if there is a Standard Operating Procedure for managing a spill clean-up and first aid. |

**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

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| Medicines/poisons to be supplied via a Wholesale/Manufacture Licence |
| Section 4 must be completed for every premises listed on the Licence |
| Address of premises: |       | Suburb: |       | Postcode: |       |  |
| **4.1 Purpose of Wholesale/Manufacture Licence** |
|  | [ ]  Wholesaling only [ ]  Manufacturing and wholesaling |
| **4.2** Please check all types and schedules of medicines/poisons that will be manufactured and/or supplied: |
|  | 4.2.1 [ ]  Human medicines |
|  | [ ]  Schedule 2 (Pharmacy Medicine)  | [ ]  Schedule 3 (Pharmacist Only Medicine) |
|  | [ ]  Schedule 4 (Prescription Only Medicine) | [ ]  Schedule 8 (Controlled Drug): complete Section 5 |
|  | 4.2.2 [ ]  Veterinary medicines/poisons |
|  | [ ]  Schedule 4 (Prescription Only Medicine) | [ ]  Schedule 8 (Controlled Drug): complete Section 5 |
|  | [ ]  Schedule 71(Dangerous Poison) |
|  | 4.2.3 [ ]  Schedule 71 (Dangerous Poison) |
|  | [ ]  Bulk industrial chemicals | [ ]  Pre-packaged industrial chemicals |
|  | [ ]  Pesticides/agricultural chemicals |  |
|  | 4.2.4 Other, specify: |       |  |
|  |  |       |  |
|  |  |       |  |
|  | **If** the business manufactures/supplies individual products rather than multiple products within a schedule, please list: |
|

|  |  |
| --- | --- |
| **Medicine/poison** | **Schedule** |
|       |       |
|       |       |
|       |       |
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| **1Note:** If wholesaling Schedule 7 poisons: Consult Notices issued under Section 72 of the *Medicines and Poisons Act 2014* at: [Section 72 of the Medicines and Poisons Act 2014](https://ww2.health.wa.gov.au/Articles/N_R/Notices-Section-72) |
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**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

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| Schedule 8 medicines  |
| Section 5 must be completed for every premises listed on the Licence that will be storing Schedule 8 medicines. |
| Address of premises: |       | Suburb: |       | Postcode: |       |  |
| Is this premises being bought from another wholesale/manufacturing business? See instruction 4. |  |
| [ ]  No |
| [ ]  Yes:  | Name of previous wholesaler/manufacturer: |       |  |
|  | Are Schedule 8 medicines being transferred from the previous wholesaler/manufacturer? |
|  | [ ]  No [ ]  Yes: [ ]  please confirm an inventory of Schedule 8 medicines will be conducted at handover. |
| **5.1 Multiple strong rooms**  |
|  | Will Schedule 8 medicines be stored in multiple strong rooms at the premises? |
|  | [ ]  No: complete remainder of Section 5 i.e. 5.2 to 5.9 |
|  | [ ]  Yes: complete remainder of Section 5 i.e. 5.2 to 5.9 for the first strong room and Sections 5.2, 5.3, 5.4 and 5.5 for every other strong room. |
| **5.2 Location of strong room and required Schedule 8 medicines**  |
|  | 5.2.1 | Location of strong room: room number/name:  |       |  |
|  | 5.2.2 | Will all Schedule 8 medicines be wholesaled or manufactured? |
|  |  | [ ]  Yes: Licence will list “Schedule 8 medicines” and not specific individual medicines  |
|  |  | [ ]  No: **if** specific individual S8 medicines will be wholesaled or manufactured, please list them below for the strong room at the location named in Section 5.2.1 |
|  |  |  | Name, strength and form of medicine | Name, strength and form of medicine |  |
|  |  |  |       |       |  |
|  |  |  |       |       |  |
|  |  |  |       |       |  |
|  |  |  |       |       |  |
| **5.3 Strong room**  |
|  | [ ]  | Check to confirm the Schedule 8 medicines will be stored in a strong room |
|  |  | Is the strongroom compliant with Resistance Grade VII of ANZ Standard 3809:1998 Safes and Strong Rooms1? |
|  |  | [ ]  Yes |
|  |  | [ ]  No |
|  |  | Is the strongroom compliant with any other relevant Standard? |
|  |  | [ ]  Yes: please indicate the standard and rating used: |       |  |
|  |  | [ ]  No: You will be asked to provide extra information during the assessment process |
| **5.4 Motion detection device** |
|  | [ ]  | Check to confirm the strong room is covered by a motion detector which is linked to a continuously monitored alarm system |
|  |  | Is the continuously monitored alarm system compliant with AS 2201.3‑1991*Intruder alarm systems, Part 3:* *Detection devices for internal use.* |
|  |  | [ ]  Yes |
|  |  | [ ]  No: is the motion detector device compliant with any other standard? |
|  |  |  | [ ]  Yes: please indicate the standard used: |       |  |
|  |  |  | [ ]  No: Extra information will be required during the assessment process |

**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

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| **5.5 Photos of strong room and motion detection device** |
|  | Please **attach** the following photos of the strongroom showing: |
|  | 1. The outside of the strong room with the door closed.
2. The outside of the strongroom with the door open.
3. The inside of the strong room.
4. The location of the motion detection device in relation to the strong room.
 |
| **5.6 Access to Schedule 8 medicines** |
|  | [ ]  | Please check to confirm only the Licence holder, responsible person and authorised staff will have unsupervised access to S8 medicines and keys/entry codes to the strong room |
| **5.7 Record keeping for Schedule 8 medicines**  |
|  | Which type of drug register will be used to record the receival and supply of S8 medicines2 |
|  | [ ]  Paper Schedule 8 register – HA210 OR  |
|  | [ ]  Department of Health approved Electronic Schedule 8 register |
|  | Name of approved electronic Schedule 8 register: |       |  |
|  | [ ]  Check to confirm records supply and registers will be kept for a minimum of 5 years |
| **5.8 Inventory, loss, theft and discrepancies of Schedule 8 medicines** |
|  | [ ]  Check to confirm an inventory (balance check) of S8 medicines will be conducted at least monthly3. |
|  | [ ]  Check to confirm any *discrepancies* that have not been accounted for are reported to MPRB ASAP3 |
|  | [ ]  Check to confirm *loss / theft* of S8 medicines will be reported to MPRB and police ASAP3 |
| **5.9 Disposal/destruction of Schedule 8 medicines** |
|  | 5.9.1 [ ]  Check to confirm an inventory of S8 medicines will be conducted prior to being disposed of or destroyed. |
|  | 5.9.3 Please indicate how expired or substandard Schedule 8 medicines will be disposed of: |
|  | [ ]  | Returned to supplier for disposal |
|  |  | Name of supplier: |       |  |
|  |  | **or** |
|  | [ ]  | *Destroyed* at the premises, placed into a suitable clinical and related wastes container, collected by a licensed clinical waste disposal serviceand incinerated4 |
|  |  | Name of licensed clinical waste disposal service: |       |  |
|  |  | Please confirm the following: |
|  | [ ]  | Schedule **8** medicines will be *destroyed* by making them unidentifiable and unusable4 |
|  | [ ]  | destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 20165 |
|  | [ ]  | destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 20165 |
|  |
| 1ANZ Standard 3809:1998 Safes and strongrooms has been withdrawn, however the strongroom must still comply with the requirements of this standard.2 [Recording of Schedule 8 transactions in an approved register](https://ww2.health.wa.gov.au/Articles/N_R/Recording-S8-and-S9-transactions) 3 [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) 4 [Disposal of medicines](https://ww2.health.wa.gov.au/Articles/A_E/Disposal-of-medicines)5 Persons authorised to destroy S8 medicines and witnesses include the Licence holder, health professionals such as medical practitioners, registered nurses, dentists, pharmacists and must be two different people. |

**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

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| SOP for stock control procedures |
| Please check to **confirm** the wholesale/manufacture business has the following Standard Operating Procedures (SOP): |
| [ ]   | **SOP** for **ensuring medicines/poisons** are **stored at correct temperatures.** SOP must support the following requirements: |
| 1. All medicines/poisons are stored at the correct temperature nominated by the manufacturer.
 |
| 1. Pharmaceuticals are stored according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8 (applicable to medicines for human use).
 |
|  |
| [ ]   | **SOP** ensuring that stock returned from customers or substandard stock is quarantined. SOP must support thefollowing requirements: |
| 1. Returned or substandard stock is kept in designated quarantine area, appropriately labelled and accounted for.
 |
| 1. Returned or substandard stock is returned to manufacturer or destroyed. All pharmaceutical stock is incinerated by a licenced clinical waste disposal company.
 |
| 1. Returned or substandard pharmaceutical stock is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8 (applicable to medicines for human use).
 |
|  |
| [ ]   | **SOP** addressing manufacturer recalls. SOP must support the following requirements: |
| 1. For pharmaceuticals, manufacturer recalls are managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8
 |
|  |
| [ ]   | **SOP** for **recording supply** of medicines/poisons to **customer**s, including use of Schedule 8 Registers **if** applicable. SOP must support the following requirements: |
| 1. Ifwholesaling Schedules 2, 3, and 4 medicines, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016.
 |
| 1. Ifwholesaling Schedule 7 poisons, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016 and the SUSMP Part 2.
 |
| 1. If wholesaling Schedule 8 medicines, recording complies with Regulation 144 of the WA Medicines and Poisons Regulations 2016.
 |
|  |
| [ ]   | **SOP** for **checking** and **recording** an **inventory** of **Schedule 8** medicines (**if** Schedule 8 medicines will be stored). SOP must support the following requirements: |
| 1. An inventory for Scheule 8 medicines is conducted according to Regulations 144 and 148 of the WA Medicines and Poisons Regulations 2016.
 |
|  |
| [ ]  | **SOP** for **reporting loss, discrepancies** or **theft** of **stock**, to licence holder and WA Department of Health. SOP must support the following requirements |
| 1. Loss or theft of S4, S7 and S8 medicines are reported to the WA Department of Health according to Regulation 106 of the WA Medicines and Poisons Regulations 2016.
 |

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| SOP for access and authorisation  |
| Please check to **confirm** the wholesale/manufacture business has the followingStandard Operating Procedures (SOP):  |
| [ ]   | **SOP** for **preventing unauthorised staff** accessing medicines/poisons and ordering systems. SOP must support the following requirements: |
| 1. Ifwholesaling medicines, managing access to medicines is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.
2. Only individual Licence holders, responsible person or other authorised staff employed by the business will have unsupervised access to stock, ordering systems and records.
 |
|  |
| [ ]   | **SOP** for **ensuring only authorised persons,** are **supplied** with the **approved quantity** of medicines/poisons listed on their licence or permit. SOP must support the following requirements: |
| 1. If wholesaling Schedule 4 and 8 medicines, the wholesaler/manufacturer complies with Regulation 77 of the WA Medicines and Poisons Regulations 2016.
 |
| 1. If wholesaling Schedule 7 poisons, the wholesaler/manufacturer complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016 and SUSMP Part 2 Section 5(1)(e).
 |
| [ ]  | **SOP** for ensuring all individual Licence holders, responsible persons and other authorised staff have a **National Police Clearance** certificate that is less than 12 months old at any point in time. |

**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

|  |
| --- |
| SOP for transport and collection  |
| Please check to **confirm the** wholesale/manufacture business has the followingStandard Operating Procedures (SOP): |
| [ ]   | **SOP** for ensuring the person collecting an order (**calling orders)** is **authorised** to do so. SOP must support the following requirements: |
|  | 1. If wholesaling medicines, ensuring a person collecting a calling order is authorised to do so is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.
 |
|  | 1. If wholesaling poisons in Schedule 7, the bona fides of the person calling for the products is checked and the reason for the calling order is documented.
 |
|  |
| [ ]   | **SOP** for **ensuring** that **orders** are only **delivered** to an **authorised site**. SOP must support the following requirements: |
|  | 1. Delivery is only made to the premises listed on the permit/licence.
 |
| Please check to **confirm** which transport/collection methods are used: |
|  | [ ]   | Calling orders |  [ ]  Delivery using company employees |  [ ]  Delivery using courier service |
|  | [ ]   | Is delivery completedby company employees? please check to confirm that drivers delivering Schedule 4 and 8 medicines and Schedule 7 poisons have provided a National Police Certificate. |
|  |  | [ ]  No |
|  |  | [ ]  Yes: |
|  |  | [ ]  | please check to **confirm** drivers delivering S4 and S8 medicines and S7 poisons have provided a National Police Certificate. |

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| SOP for disposal of medicine/poisons |
| [ ]   | Please **confirm** the wholesale/manufacture business has aStandard Operating Procedure (SOP) for the **disposal** of **unused, excess** or **unsaleable stock**, including Schedule 8 medicines **if** applicable. **SOP must support** the following requirements: |
| 1. Disposing of unused, excess or unsaleable stock of medicines in Schedule 8 complies with Regulation 145 of the WA Medicines and Poisons Regulations 2016 and the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.
 |
| 1. Disposing of unused, excess or unsaleable stock of medicines in Schedule 2, 3 and 4 is conducted according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.
 |
| 1. Disposing of unused, excess or unsaleable stock of poisons in Schedule 7 is conducted according to the recommendations of the manufacturer.
 |

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| Multiple premises |
| Will the wholesale/manufacture business be conducted at multiple premises under this Licence?  |
| [ ]  No |
| [ ]  Yes: complete Sections 10.1 and 10.2  |
| **10.1** Will the responsible person for the other premises be the same as the individual Licence holder or a person responsible for the premises named in Section 3.1? |
|  | [ ]  Yes |
|  | [ ]  No: Complete and **attach** Part 3: Personal Information: Identification, Fitness for the nominated responsible person for the other premises. |
| **10.2** Will responses to Sections 6,7,8 and 9 be the same for the other premises as for the premises named in Section 3.1  |
|  | [ ]  Yes: Complete and **attach** Sections 3,4 and 5 (if storing S8 medicines) for all other premises. |
|  | [ ]  No: Complete and **attach** Sections 3,4,5 (if storing S8 medicines),6 7,8 and 9 for all other premises. |
|  |

**PART 1:** APPLICATION **for a WHOLESALE/MANUFACTURE LICENCE**

|  |
| --- |
| Declaration by applicant to obtain a Licence |
| This declaration relates to the application itself (Part 1) and must be signed by the individual (sole trader) or if the Licence is being issued to a corporation or partnership, the declaration must be signed by one of the corporate officers or partners.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) |
|  |

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|  |
| --- |
| PART 2: PERSONAL INFORMATION: LICENCE HOLDER |

**Part 2** assesses identification, fitness and probity of the Licence holder.

If the Licence holder is an individual person (sole trader),all sections of Part 2 must be completed.

If the Licence holder is a corporation or partnership all sections of Part 2 except Section 13 must be completed by each corporate officer or each partner.

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| I**dentification of** applicant |
| Refer to instruction number 2, for information on the requirements for being a Licence holder. |
| **12.1 Personal Details** |
| Title: |     | Forename/s: |       | Surname: |       | Date of birth: |       |  |
| Address: |       | Suburb: |       | Postcode: |      |  |
| Postal address:  |       | Suburb: |       | Postcode: |      |  |
| Mobile number: |       | Email:  |       |  |
| Position in business: |       |  |
| **12.2 Certified true copy of a photographic identification document** |
| **ATTACH** a certified 1 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). |
| **12.3 Role in relation to Licence**  |
|  | [ ]  | The individual who will hold the Licence (sole trader). Complete remainder of Part 2. |
|  | [ ]  | A corporate officer: only applicable if the Licence will be issued to a body corporate. Type of corporate officer: |
|  |  | [ ]  Director | [ ]  General Manager | [ ]  Company secretary | [ ]  CEO | [ ]  CFO | [ ]  COO |
|  |  | Complete Sections 14,15,16 and 17 in Part 2 and **attach** a CV1  |
|  | [ ]  | A partner: only applicable if the Licence will be issued to a partnership |
|  |  | Complete Sections 14,15,16 and 17 in Part 2 and **attach** a CV1  |
|  |  | 1The CV will be used to assess whether each corporate officer or partner meets the requirements of the *Medicines and Poisons Act 2014.* |

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| Qualifications and experience of applicant applying as an individual person (sole trader) |
| Complete this section if you are an individual person (sole trader) applying for a Licence.Do not complete this section, if the Licence is being issued to a corporation or partnership. |
| Refer to instruction number 2 for information on the requirements for being an individual Licence holder. |
| **13.1** Please **attach** copies of:* any qualifications or training relevant to managing a wholesale/manufacture business **and**
* CV demonstrating your suitability as a Licence holder with at least 5 years’ experience in wholesaling medicines/poisons.
 |
|  | You may also be asked to provide extra information regarding your qualifications / training /experience. |
| **13.2 Access to stock, ordering systems and records and authority within the business** |
|  | **[ ]**  | Check to confirm that you will always have access to stock, ordering systems and records at the premises listed on the Licence. |
|  | **[ ]**   | Please check to confirm that, you will have authority within the business to determine policies and procedures in relation to managing stock, ordering systems and records. |
|  |

**PART 2: PERSONAL INFORMATION: LICENCE HOLDER**

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| Prior permits/licences for medicines/poisons held by applicant |
| To be completed by the nominated individual Licence holder, each corporate officer or each partner |
| **14.1** | Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence, 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 Permit or Licence 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: |
|  |       |  |
|  |       |  |
| **14.2** | Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence 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 Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in: |
|  |       |  |
|  |       |  |
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| Criminal check and NPC for applicant |
| To be completed by the nominated individual Licence holder, each corporate officer or each partner.  |
| **15.1** | **Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory** |
|  | 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
 |
| **15.2** | Please **attach** a copy of your National **Police Clearance (**NPC), which is less than 12 months old. |
| **15.3** | Have you been convicted of, or have charges pending for indictable1 offences since the date on your NPC? |
|  | [ ]  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
 |
|  | 1 Minor traffic offences are not classified as indictable offences |

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| Financial resources ofapplicant |
| To be completed by the nominated Licence holder (sole trader), each corporate officer or each partner |
| **16.1** | Have you been declared bankrupt or a debtor under any bankruptcy law?  |
|  | [ ]  No |
|  | [ ]  Yes: What date was/will your bankruptcy be discharged? |       |  |
| **16.2** | 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 |
|  |

**PART 2: PERSONAL INFORMATION: LICENCE HOLDER**

|  |
| --- |
| Declaration by applicant |
| This declaration must be signed by the applicant (individual applicant, corporate officer or partner) 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 in relation to holding a Wholesale/Manufacture Licence. 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 use of the medicines/poisons and will ensure compliance with the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016, and compliance with conditions placed on the Licence. |
|  | I will notify the Department of Health if I am no longer operating/employed by the business, a corporate officer (if the applicant is a corporation) or a partner (if the applicant is a partnership) |
| Signature: |       | Name: |       | Date: |       |  |
|  |

# PART 3: PERSONAL INFORMATION: RESPONSIBLE PERSON

**Part 3** must be completed by the responsible person and assesses identification, fitness and probity

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| --- |
| Identification of responsible person |
| The role of the responsible person is to manage the wholesale/manufacture business on a day to day basis and be the contact person, if the Licence holder is not available.  |
| Refer to instruction number 3, for information on the requirements for being a responsible person for a premises. |
| **18.1** Will the individual applicant applying to be Licence holder also be responsible for the premises named in Section 3.1? |
|  | [ ]  Yes: Confirm name: | Title: |       | Forename/s: |       | Surname: |       |  |
|  | There is no requirement to complete Part 3 |
|  | [ ]  No: complete remainder of Part 3. |
| **18.2 Personal details of responsible person**  |
|  | Title: |     | Forename/s: |       | Surname: |       | Date of birth: |       |  |
|  | Postal Address: |       | Suburb: |        | Postcode: |      |  |
|  | Mobile number: |       | Email: |       |  |
|  | Position in business: |       |  |
| **18.3 Certifiedtrue copy of a photographic identification document** |
|  | **ATTACH** a certified 1 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. |
|  | 1 Copy 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). |
|  |

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| --- |
| Qualifications and experience of responsible person |
| Refer to instruction number 3 for information on the requirements for being a responsible person for a premises. |
| **19.1** Please **attach** copies of:* any qualifications or training relevant to your position as a responsible person for a wholesale/manufacture business **and**
* CV demonstrating your suitability as a responsible person
 |
|  | You may also be asked to provide extra information regarding your qualifications / training /experience. |

**Part 3: Personal Information: Responsible Person**

|  |
| --- |
| Prior permits/licences for medicines/poisons held by responsible person |
| **20.1** | Have you (or a company of which you were a corporate officer or a partner) previously held a Permit or Licence, 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 Permit or Licence 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: |
|  |       |  |
|  |       |  |
|  |       |  |
|  |
| **20.2** | Have you (or a company of which you were a corporate officer) ever been refused a Permit or Licence 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 Permit or Licence you applied for, why your application was refused and which state or territory the refusal occurred in: |
|  |       |  |
|  |       |  |
|  |       |  |
|  |

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| --- |
| Criminal check and NPC for responsible person |
| **21.1** | **Offences under the *Medicines and Poisons Act 2014* or a repealed corresponding law, or a corresponding law in another state or territory** |
|  | 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
 |
| **21.2** | Please **attach** a copy of your **National Police Clearance certificate** (NPC) which is less than 12 months old**.** |
| **21.3** | Have you been convicted of, or have charges pending for indictable1 offences since the date shown on your NPC? |
|  | [ ]  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
 |
|  | 1 Minor traffic offences are not classified as indictable offences |

**Part 3: Personal Information: Responsible Person**

|  |
| --- |
| Declaration by responsible person  |
| This declaration must be signed by the nominated responsible person and includes probity check consent.Please refer to Instruction 6 for information on acceptable signatures. |
| 1. I acknowledge my role is to manage the medicines/poisons on a day to day basis and be the contact person, if the Licence holder is not available.
 |
| 1. I give consent to the Western Australian Department of Health to carry out all relevant searches to determine my fitness and probity to be named as the responsible person on a Wholesale/Manufacture Licence. These searches may include (without limitation) corporate searches, and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity.
 |
| 1. I am at least 21 years of age.
 |
| 1. The information contained in this application form is true and correct.
 |
|  Signature: |       | Name: |       | Date: |       |  |
|  |

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| --- |
| PART 4: PAYMENT and CHECKLIST |

|  |
| --- |
| Payment:  |
| **Fee: $603** |
| Comprising a non-refundable application fee of $329 and 1 year Licence of fee $274Licence fee only will be refunded if the Licence is not issued. |
| * + 1. [ ]  Credit Card – American Express and Diners not accepted
 |
|  | Card type: | [ ]  MasterCard | [ ]  Visa  |
|  | Name on card: |       | Card number:  |        |  |
|  | Expiry date: |       | Amount:  **$603** |
|  | 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: **$603** |
|  | 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

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

**PART 4: PAYMENT and CHECKLIST**

|  |
| --- |
| Checklist  |
| Please ensure all the appropriate requested documentation is attached for: |
| **Part 1 Application for a Wholesale/Manufacture Licence** |
| [ ]  | If the Licence is being issued to a corporation, attach a copy of the Current Company Extract from ASIC (with details of all company directors and secretary (Section 1.2.1) |
| [ ]  | If the business has a Business or Trading Name, attach a copy of certificate of Record of Registration for Business Name or Current Business Name Extract (Section 1.3) |
| [ ]  | Completed Part 3 Personal Information: Identification, Fitness and Probity for responsible person **if** different from the Licence holder (Section 3.2) |
| [ ]  | If applicable, evidence of local government approval to operate the business from the premises (Section 3.3.1) |
| [ ]  | If storing Schedule 8 medicines, photos of strong room as required in Section 5.5 |
| [ ]  | Copy of relevant sections if there are multiple premises (Section 10) |
| [ ]  | Declaration signed and dated by **applicant** (individual Licence holder, corporate officer or partner)(Section 11) |
| **Part 2: Personal information, fitness and probity for applicant (nominated Licence holder):****Individual applicant, each corporate officer or each partner** |
| [ ]  | Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 12.2) See Appendix A for a list of persons authorised. |
| [ ]  | If the applicant is a corporation or partnership, attach a CV for each corporate officer or partner (Section 12.3) |
| [ ]  | If applying as an individual person, attach copies of qualifications/ training and CV. (Section 13.1) |
| [ ]  | 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 15.1) |
| [ ]  | A copy of the NPC Certificate which is less than 12 months old (Section 15.2) |
| [ ]  | If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 15.3) |
| [ ]  | Declaration about personal information signed by applicant (individual Licence holder, corporate officer or partner (Section 17) |
| **Part 3: Personal information, fitness and probity for responsible person** |
| [ ]  | Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 18.3) See Appendix A for a list of persons authorised. |
| [ ]  | Copies of qualifications/ training and CV. (Section 19.1) |
| [ ]  | 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 21.1) |
| [ ]  | A copy of the NPC Certificate which is less than 12 months old (Section 21.2) |
| [ ]  | If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 21.3) |
| [ ]  | Declaration about personal information signed by responsible person (Section 22) |
| **Part 4: Declaration and Payment** |
| [ ]  | Payment details completed with correct signature if paying by credit card (Section 23) |

#

# PART 5: 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 |  |