Application to change a Wholesale/Manufacture Licence

Medicines and Poisons Act 2014

Contents

INSTRUCTIONS and INFORMATION	
1.	This form is for requesting changes to an existing **Wholesale/Manufacture Licence** issued under *the Medicines and Poisons Act 2014.* This form MUST be completed by the current Licence holder or incoming Licence holder who is suitably qualified and understands the requirements and terminology contained in this application. If the Licence holder is a corporation or partnership, this form must be completed by the corporate officer or partner who originally applied for the Licence. **All communication will ONLY be with the Licence holder, corporate officer or partner.**
2.	**Types of changes that cannot be applied for using this form** DO NOT USE THIS FORM, if: • The Licence holder is changing from an individual person to a Licence held by a corporation or partnership, or • The Licence holder is changing from a corporation or partnership to an individual person or • The business has a new owner. These types of changes require the submission of a completely new application for a Wholesale/Manufacture Licence found at: Application forms for Licences and Permits Licences cannot be transferred between one business entity and another.
3.	There are five parts to this form: Part 1 - Sections 1 to 20: Application to change a Wholesale/Manufacture Licence. Part 2 – Sections 21 to 27: Personal Information: new individual Licence holder, corporate officer or partner Part 3 - Sections 28 to 32: Personal Information: new responsible person for a premises Part 4 - Sections 33 to 34: Payment and checklist. Part 5 – Appendix
4.	Fees are **not** payable for the following type of changes to a Wholesale/Manufacture Licence: • Change of postal addresses or other contact details • Removal of premises from the Licence • Removal of certain scheduled medicines or poisons from the Licence. • Upgrade of storage or security such as installation of CCTV.
5.	A fee of **$90** is payable for the following type of changes to a Wholesale/Manufacture Licence: • Change of individual Licence holder (no change of ownership of the business) • Change to a person responsible for a premises • Change of a corporate officer (only for Licences issued to a body corporate and not an individual person) • Increase the quantity of certain scheduled medicines or poisons on the Licence • Addition of certain scheduled medicines or poisons to the Licence • Relocation of an existing premises to a new location • Addition of a new premises to the to the Licence • Change of business or trading name without changing legal entity (no change of ownership) • Variation in the activities undertaken under the Licence (Note: some variations may require a new application and issue of a different Licence type)

6. Changing the Licence holder for a Licence held by an individual person

The person nominated as the new Licence holder must complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 27.

6.1 New Licence holder

The new Licence holder must:

- have at least 5 years' experience in wholesaling medicines or poisons
- have knowledge and skills to assess whether a client is authorised to purchase medicines and poisons and be able to comply with record-keeping requirements
- have authority within the business to determine policies and procedures in relation to conducting a Wholesale/Manufacture business involving medicines or poisons on the Licence and
- provide a National Police Clearance (NPC) certificate which is less than 12 months old

6.2 Licence holder responsibilities

It is the responsibility of the new Licence holder to ensure compliance with *the Medicines and Poisons Act 2014* and Regulations 2016 and compliance with conditions placed on the Licence.

The new Licence holder is required to determine that the person or business to which they are supplying the medicines or poisons is authorised to purchase those medicines or poisons and keep records of all sales in a manner compliant with the requirements of the Medicines and Poisons legislation.

The new 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 is required for Wholesale/Manufacture licences dealing with human medicines.

Compliance with Notices issued under Section 72 of the Medicines and Poisons Act 2014 is required for licences dealing with Schedule 7 poisons.

The new 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.

There are penalties under the Act for providing false or misleading information when applying for a change to an existing Licence.

7. Changing a corporate officer or partner for a Licence that is held by a corporation or partnership

A new partner or corporate officer (directors, general manager, company secretary, chief executive officer chief financial officer and chief operating officer) must also complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 27.

Instructions continues next page

8. Changing the person responsible for a premises listed on the Licence

A new responsible person will have overall responsibility for each premises included on the Licence.
The role of the responsible person is to manage the medicines or 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 new 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 32.

8.1 New responsible person for a Licence issued to an individual person can be:

a) the Licence holder, only if the Licence is issued to an individual person and not a corporation or partnership.
or
b) the most senior person at the premises who has experience working in a medicines or poisons Wholesale/Manufacture business.

8.2 New responsible person for Licences issued to a corporation or partnership can be:

a) the most senior person at the premises who must have at least at least 5 years' experience in wholesaling medicines or poisons and has knowledge and skills to assess whether a client is authorised to purchase medicines and poisons and be able to comply with record-keeping requirements
or
b) a person employed by the corporation or partnership who must:
   - have at least 5 years' experience in wholesaling medicines or poisons
   - have enough knowledge and skills to assess whether a client is authorised to purchase medicines and 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 medicines or poisons on the Licence.

Please note: a responsible person must consider whether they have capacity to oversee the day to day management of the poisons 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 to this capacity.

9. Relocating to another premises or adding a premises

If you are relocating a premises to another site **or** adding another premises to the Wholesale/Manufacture Licence and the relocated or added premises (second premises) is currently listed on a different Licence:

- the application will not be processed until the Licence holder at the second premises has submitted an application to the Department to have the premises removed from their Licence.
- in such cases, Licence holders relocating or adding a premises may wish to liaise with the Licence holder at the second premises to ensure the Department of Health is appropriately advised.

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.

10. 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.

11.	**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 current Licence holder must sign the declaration for making a change to the Licence at Section 20. **11.1 Who can sign for a change to a Wholesale/Manufacture Licence** If the Wholesale/Manufacture Licence is held by an individual person and the change is to request a new individual Licence holder within the same business and the current Licence holder is no longer employed by the business: • the new Licence holder should sign the Declaration and provide the reason the current Licence holder cannot sign the Declaration. If the Wholesale/Manufacture Licence is held by a partnership or body corporate, the person who signed the original Licence application should sign the Declaration.
12.	**Approving a change to a Licence** Applying for a change to an existing Wholesale/Manufacture Licence does not guarantee the requested changes will be approved.
13.	**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).
14.	**Extra information** When applying for a change to an existing Licence, refer to the: Guide to applying for a Licence or Permit
15.	**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 WHOLESALE/MANUFACTURE LICENCE

1. General information

Licence number: Name of current Licence holder:

Postal address: Suburb: Postcode:

Telephone: Fax: Email:

1.1 Type of change

Please check whichever applies:

Changes without a fee	**Complete**
☐ Change of postal address or other contact details	Part 1: Sections 2,20
☐ Remove a premises from the Licence	Part 1: Sections 3,5,20
☐ Remove certain medicines or poisons form the Licence	Part 1: Sections 4,5,20
☐ Upgrade to storage and security	Part 1: Sections 6,20
Changes with a fee of $90	
☐ Change of individual Licence holder	Part 1: Sections 7,20 Part 2: Sections 21 to 27 Part 4: Section 33
☐ Change the person responsible for a premises	Part 1: Sections 8,20 Part 2: Sections 28 to 32 Part 4: Section 33
☐ Change of corporate officer or partner	Part 1: Sections 9,20 Part 2: Sections 21,24,25,26,27 Part 4: Section 33
☐ Increase quantity of medicines or poisons already listed on the Licence	Part 1: Sections 10,20 Part 4: Section 33
☐ Addition of certain medicines or poisons to the Licence:	Part 1: Sections 11, 20 Part 4: Section 33
☐ Relocation of an existing premises to a new premises	Part 1: Sections 12,14,15,16,17, 20 Part 4: Section 33
☐ Addition of a new premises to the Licence	Part 1: Sections 13,14,15,16,17,20 Part 4: Section 33
☐ Change of business or trading name without any change of the legal entity	Part 1: Sections 18,20 Part 4: Section 33
☐ Variation in activities undertaken under the Wholesale/Manufacture Licence	Part 1: Sections 19,20 Part 4: Section 33

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 WHOLESALE/MANUFACTURE LICENCE
Changes without a fee

2. Change of postal address and other contact details

New Postal Address*: Suburb: Postcode:

Telephone: Fax: Email:

* Renewal reminders will be sent to this address.

3. Remove a premises from the Licence

Premises name:

Address: Suburb: Postcode:

Date the business/store will cease trading at these premises:

Is the business at the premises being sold to another business selling the same medicines/poisons for the same purpose?

3.1 ☐ Yes: please provide the name of the new business:

The Department requires the person taking over the business to either:

- apply to add this premises to their current Wholesale/Manufacture Licence, if they already have a Licence, or
- apply for a new Licence in their name.

An application from the person buying the business must be received by the Department prior to removing this premises from your Licence.

3.2 ☐ No, is there any remaining stock of medicines/poisons left?

☐ No

☐ Yes: please also complete Sections 5.

4. Remove certain medicines/poisons from the Licence

Premises name:

Address: Suburb: Postcode:

4.1 Please list the medicines/poisons to be removed from the Licence:

4.2 Is there any stock left of the medicines/poisons being removed from Licence at the above-named premises

☐ No

☐ Yes: please also complete Section 5.

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes without a fee

5. Information about disposal of medicines/poisons

If there is any remaining stock of medicines/poisons left at the premises which is being removed from the Licence as per Section 3 or is there any remaining stock of certain medicines/poisons being removed from the Licence as per Section 4.

☐ No ☐ Yes: complete Section 5.1 and 5.2

5.1 What will happen to the remaining medicine/poisons

☐ Transferred to the wholesaler/manufacturer taking over the business

Name of new wholesaler/manufacturer:

☐ Transferred to a different premises listed on the Licence

Address:

☐ Disposed of using a licensed clinical waste management service

Name of clinical waste management service:

☐ Other method:

Provide details:

5.2 Schedule 8 medicines (Controlled Drug)

Is there any stock left of Schedule 8 medicines?

☐ No

☐ Yes:

☐ Please confirm an inventory of **S8** medicines will be conducted before being leaving the premises or removing the Schedule 8 medicines from the Licence

What will happen to the remaining Schedule 8 medicines?

☐ they will be transferred to the wholesaler/manufacturer taking over the business:

Name of business:

☐ they will be transferred to a different premises on the Licence **or**

Address of premises:

☐ they will be destroyed at the premises and collected by a licenced clinical waste disposal service – please confirm the following:

☐ **S8** medicines will be *destroyed* by making them unidentifiable and unusable[1]

☐ destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 2016[2]

☐ destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 2016[2]

[1] Disposal of medicines

[2] Persons authorised to destroy S8 medicines and witnesses include the License holder, health professionals such as medical practitioners, registered nurses, pharmacists and must be two different people.

6. Upgrading storage and security

Premises name:

Address: Suburb: Postcode:

Describe the change to the way the medicines/poisons will be stored or the change to premises security:

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

7. Change of individual Licence holder

Complete this section only if the new Licence holder is an individual person.

Refer to instruction number 6 for information on the requirements for being a Licence holder.

7.1 Name of new incoming Licence holder:

Title: Forename(s): Surname:

Address: Suburb: Postcode:

Telephone /Mobile: Email:

Position in business:

A new Licence holder must complete and **attach** Part 2: Personal Information: Identification, Fitness and Probity.

8. Change the person responsible for a premises listed on the Licence

Refer to instruction number 8 for information on the requirements for being a responsible person for a premises.

Premises name:

Address: Suburb: Postcode:

Name of new incoming responsible person for this premises:

Title: Forename(s): Surname:

8.1 Details about the new person responsible for a premises listed on the Licence

Is the new responsible person also the Licence holder or responsible for another premises listed on the Licence?

☐ Yes: Confirm name: Title: Forename/s: Surname:

There is no requirement to complete Part 3.

☐ No: the new responsible person for the above-named premises, must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity.

9. Change of corporate officer or partner

Only applicable if the Licence has been issued to a body corporate or partnership and not to an individual person.

Refer to instruction number 7.

9.1 Name of new incoming corporate officer or partner

Title: Forename(s): Surname:

Address: Suburb: Postcode:

Telephone/Mobile: Email:

Corporate officer/partner must complete and **attach** Part 2: Personal Information: Identification, Fitness and Probity

9.2 Name of outgoing corporate officer or partner

Title: Forename(s): Surname:

9.3 Attach copy of Current and Historical Company Extract from ASIC with details of past and current corporate officers.

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

10. Increase quantity of medicines/poisons currently listed on the Licence

Premises name:

Address: Suburb: Postcode:

10.1 Scheduled medicines or poisons having their quantities increased at the above-named premises

Medicines/poisons	Current quantity	Increase quantity to:

11. Addition of medicines/poisons

Premises name:

Address: Suburb: Postcode:

11.1 Please check all schedules of medicines/ poisons being added to the Licence

11.1.1 ☐ Human medicines

- ☐ Schedule 2 (Pharmacy Medicine)
- ☐ Schedule 3 (Pharmacist Only Medicine)
- ☐ Schedule 4 (Prescription Only Medicine)
- ☐ Schedule 8, **plus, complete Section 16**

11.1.2 ☐ Veterinary medicines/poisons

- ☐ Schedule 4 (Prescription Only Medicine)
- ☐ Schedule 8, **plus, complete Section 16**
- ☐ Schedule 7[1](Dangerous Poison)

11.1.3 ☐ Schedule 7[1] poisons (Dangerous Poison)

- ☐ Bulk industrial chemicals
- ☐ Pre-packaged industrial chemicals
- ☐ Pesticides/agricultural chemicals

11.1.4 Other, specify:

11.2 List of individual products (if applicable):

If adding individual medicines/poisons rather than multiple products within a schedule, please list below:

[1] Notices issued under Section 72 of the *Medicines and Poisons Act 2014*

11.3 Supply of medicines/poisons being added to the Licence

Will medicines/poisons being added, be supplied for the same purpose as other medicines/poisons on the Licence?

☐ Yes ☐ No: Complete Section 19

Some variations in the supply of medicines/ poisons will require a new application for a different Licence.

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

12. Relocation of an existing premises

12.1 **Current address of premises:**

Premises name:

Address: Suburb: Postcode:

12.2 **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: Licence will be issued with "Valid from" date on or after this date.

12.3 **Plus,** complete Sections 14,15,16 (if storing Schedule 8 medicines) 17, 20 and 33 (payment)

13. Addition of another new premises

13.1 Premises name:

Premises Address: Suburb: Postcode:

Telephone: Fax: Email:

Date of possession of the premises (settlement date/lease commencement/handover of premises)

Note: Licence will be issued with "Valid from" date on or after this date.

13.2 **Plus,** complete Sections 14,15,16 (if storing Schedule 8 medicines) 17, 20 and 33 (payment)

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

14. Information about the relocated or new added premises

Is this premises being bought from another wholesale/manufacture business? See instruction number 9.

☐ No

☐ Yes: Name of previous wholesale/manufacture business:

The Department requires the previous Licence holder at the relocated/new added premises to remove the premises from their Licence. The application to remove the premises from the previous Licence must be received by the Department prior to adding the relocated or new added premises to your Licence.

14.1 Person responsible for the relocated or new added premises

Title: Forename(s): Surname:

Position in business:

Is the responsible person for the relocated or new added premises also?

- responsible for the premises at the current address or
- responsible for another premises listed on the Licence or
- the Licence holder?

☐ Yes

☐ No: the responsible person for the relocated or new added premises must complete and **attach** Part 3: Personal Information: Identification, Fitness and Probity.

14.2 Location of relocated or new added premises

☐ Commercial ☐ Industrial ☐ Rural

☐ Other-please specify:

14.2.1 Is local government approval required to operate the 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.

14.3 Building /premises security for relocated or new added premises. 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:

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

15.Information about medicine/poisons at the relocated or new added premises

15.1 List of medicines/poisons required

Please check all schedules of medicines/poisons being added to the Licence

15.1.1 ☐ Human medicines

- ☐ Schedule 2 (Pharmacy Medicine)
- ☐ Schedule 3 (Pharmacist Only Medicine)
- ☐ Schedule 4 (Prescription Only Medicine)
- ☐ Schedule 8: **plus, complete Section 16**

15.1.2 ☐ Veterinary medicines/poisons

- ☐ Schedule 4 (Prescription Only Medicine)
- ☐ Schedule 8 **plus, complete Section 16**
- ☐ Schedule 7[1] (Dangerous Poison)

15.1.3 ☐ Schedule 7[1] poisons (Dangerous Poison)

- ☐ Bulk industrial chemicals
- ☐ Pre-packaged industrial chemicals
- ☐ Pesticides/agricultural chemicals

15.1.4 Other, specify:

15.2 List of individual products (if applicable):

If adding individual medicines/poisons rather than multiple products within a schedule, please list below:

[1]**Note:** If wholesaling S7 poisons: Consult Notices issued under Section 72 of the *Medicines and Poisons Act 2014*

Some variations in the supply of medicines/ poisons will require a new application for a different Licence.

15.3 Storage and security of medicines/poisons at relocated or new added premises

15.3.1 Please indicate where medicines/poisons are stored, inside or outside the main building (check all that apply):

☐ Inside: medicines or poisons stored inside are stored as follows: (Please check all that apply)

- ☐ Locked cupboard
- ☐ Locked room
- ☐ Locked caged area
- ☐ Behind counter
- ☐ Other, please specify:

☐ Outside: for Schedule 7 poisons only (Please check all that apply)

- ☐ Locked shed
- ☐ Locked caged area in shed
- ☐ Other, please specify:

15.3.2 Will Schedule 7 poisons stored outdoors, under cover? ☐ Yes ☐ No

15.4 Usage of the medicines at the relocated or new added premises

Will the medicines/poisons at the relocated or new premises be wholesaled/manufactured for the same purpose as at the previous premises or other premises on the Licence

☐ Yes

☐ No: please describe the purpose for which the medicines/poisons be wholesaled/manufactured:

Some variations in the conditions of use may require a new application for a different type of Licence.

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

16. Schedule 8 medicines

Complete all of Section 16 if adding Schedule 8 medicines to the Licence as per Section 11.1
Complete all of Section 16 if a relocated premises will be storing Schedule 8 medicines as per Section 15.1
Complete all of Section 16 if a new added premises will be storing Schedule 8 medicines as per Section 15.1

Is this premises being bought from another wholesale/manufacture business? See instruction 9.

☐ No ☐ Yes: name of previous business:

Are Schedule 8 medicines being transferred from the previous business?

☐ No ☐ Yes: please confirm an inventory of S8 medicines will be conducted at the time of handover.

16.1 Multiple strong rooms

Will S8 medicines be stored in multiple strong rooms at the relocated or new added premises?

☐ No: complete remainder of Section 16, i.e. 16.2 to 16.9

☐ Yes: complete remainder of Section 16 for the first strong room and Sections 16.2, 16.3, 16.4 and 16.5 for every other strong room.

16.2 Location of strong room and required Schedule 8 medicines

16.2.1 Location of strong room: room number/name:

16.2.2 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 16.2.1

Name, strength and form of medicine	Name, strength and form of medicine

16.3 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 Rooms[1]?

☐ 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

16.4 Motion detection device

☐ Check to confirm the strong room is covered by a motion detector 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 to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

16.5 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.

16.6 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

16.7 Record keeping for Schedule 8 medicines

Which type of drug register will be used to record the receival of and administration or supply of S8 medicines[2]

☐ 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

16.8 Inventory, loss, theft and discrepancies of Schedule 8 medicines

☐ Check to confirm an inventory (balance check) of S8 medicines will be conducted at least monthly[3].

☐ Check to confirm any *discrepancies* that have not been accounted for are reported to MPRB ASAP[3]

☐ Check to confirm *loss / theft* of S8 medicines will be reported to MPRB and police ASAP[3]

16.9 Disposal/destruction of Schedule 8 medicines

16.9.1 ☐ Check to confirm an inventory of S8 medicines will be conducted prior to being disposed of or destroyed.

16.9.3 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 service and incinerated[4]

Name of licensed clinical waste disposal service:

Please confirm the following:

☐ Schedule **8** medicines will be *destroyed* by making them unidentifiable and unusable[4]

☐ destruction will be **conducted** by persons authorised by Medicines and Poisons Regulations 2016[5]

☐ destruction will be **witnessed** by persons authorised by Medicines and Poisons Regulations 2016[5]

[1]ANZ 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

[3] Reporting loss or theft of medicines and poisons

[4] 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 to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

17. Standard Operating Procedures at relocated or new added premises

Will SOPs for the business at the premises be the same as for another premises listed on the Licence?

☐ Yes: SOP is the same as:

☐ No: please check to **confirm** the wholesale/manufacture business has the following SOPs

17.1 SOP for stock control procedures

☐ **SOP** for **ensuring medicines/poisons** are **stored at correct temperatures.** SOP must support the following requirements:

a) All medicines/poisons are stored at the correct temperature nominated by the manufacturer.

b) Pharmaceuticals are stored according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.

☐ **SOP** ensuring that stock returned from customers or substandard stock is quarantined. SOP must support the following requirements:

a) Returned or substandard stock is kept in designated quarantine area, appropriately labelled and accounted for.

b) Returned or substandard stock is returned to manufacturer or destroyed. All pharmaceutical stock is incinerated by a licenced clinical waste disposal company.

c) Returned or substandard pharmaceutical stock is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.

☐ **SOP** addressing manufacturer recalls. SOP must support the following requirements:

a) 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:

a) **If** wholesaling Schedules 2, 3, and 4 medicines, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016.

b) **If** wholesaling Schedule 7 poisons, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016 and the SUSMP Part 2 Section 5 (1).

c) **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:

a) 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

a) 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.

Section 17 continues next page

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

Please check to **confirm** the wholesale/manufacture business has the following SOPs

17.2 SOP for access and authorisation

☐ **SOP** for **preventing unauthorised staff** from accessing medicines/poisons and ordering systems. SOP must support the following requirements:

a) **If** wholesaling medicines, managing access to medicines is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.
b) 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:

a) **If** wholesaling Schedule 4 and 8 medicines, the wholesaler/manufacturer complies with Regulation 77 of the WA Medicines and Poisons Regulations 2016.
b) **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 one time.

17.3 SOP for transport and collection

☐ **SOP** for ensuring the person collecting an order (**calling orders)** is **authorised** to do so. SOP must support the following requirements:

a) **If** wholesaling medicines, ensuring a person collecting a caller 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.
b) **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:

a) 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 completed by 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.

17.4 SOP for disposal of medicine/poisons

☐ Please check to **confirm** the wholesale/manufacture business has a Standard Operating Procedure (SOP) for the **disposal** of **unused, excess** or **unsaleable stock**, including Schedule 8 medicines **if** applicable. **SOP must support** the following requirements:

a) 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.
b) 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.
c) Disposing of unused, excess or unsaleable stock of poisons in Schedule 7 is conducted according to the recommendations of the manufacturer.

PART 1: APPLICATION to change a WHOLESALE/MANUFACTURE LICENCE
Changes with a fee

18. Change of business or trading

Complete this Section if the business or trading name will change without any change in legal entity.
If there is a change in ownership, an application for a new Licence is required.

18.1 Previous business or trading name:

New business or trading name:

18.2 Attach a copy of the Current and Historical Business Name Extract from ASIC

Australian Business Number (if applicable):

19. Variation in the activities undertaken under the Licence

In some cases, medicines/poisons can be supplied for different purposes under the same Wholesale/Manufacture Licence while other purposes may require a different type of Licence.

19.1 Will the medicines/poisons at the relocated, new added premises or the medicines/poisons being added to the Licence be supplied for a different purpose or activity that is being undertaken currently **OR**

Will the medicines/poisons currently listed on the Licence at the current premises be used for a different activity or purpose?

☐ No ☐ Yes

Note: Some variations in the conditions of use will require a new application and issue of a different Licence type.

20. Declaration by Licence holder

This declaration relates to the application to change the Licence and must be signed by the individual Licence holder, or if the Licence is issued to a corporation or partnership, the declaration must be signed by a corporate officer of partner.

Please refer to instruction number 11 for information on acceptable signatures.

I am the: ☐ current Licence holder ☐ incoming Licence holder

☐ the corporate officer or partner who signed the original Licence application.

If the current Licence holder cannot sign please provide the reason:

I (provide full name):

of (provide full address):

hereby declare:

i. The information contained in this application form is true and correct

ii. 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: PERSONAL INFORMATION: new LICENCE HOLDER

Part 2 assesses identification, fitness and probity of the Licence holder.
If the new Licence holder is an individual person, all sections of Part 2 must be completed.
If the Licence is held by a corporation or partnership, and there is a new corporate officer or partner, all sections of Part 2 except Sections 22 and 23 must be completed by each new corporate officer or new partner.

21. Identification of new Licence holder, corporate officer or partner

21.1 Personal Details

Title: Forename/s: Surname: Date of birth:

Address: Suburb: Postcode:

Postal address: Suburb: Postcode:

Mobile number: Email:

Position in business:

21.2 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.

[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)

21.3 Role in relation to the Licence

☐ the individual who will be the new Licence holder on behalf of the business. Complete remainder of Part 2.

☐ a new corporate officer. Type of corporate officer:

☐ Director ☐ General Manager ☐ Company secretary ☐ CEO ☐ CFO ☐ COO

Complete Sections 24,25,26,27 of Part 2 and **attach** a CV[1]

☐ a new partner

Complete Sections 24,25,26,27 of Part 2 and **attach** a CV[1]

[1]A new **corporate officer or partner must provide a CV and qualifications.** These will be used to assess whether the corporate officer or partner meets the requirements of the *Medicines and Poisons Act 2014.*

22. Qualifications and experience of new individual Licence holder

Complete this section if you are an individual person applying to be the new Licence holder.
Do not complete this section, if the Licence has been issued to a corporation or partnership.
Refer to instruction number 6 for information on the requirements for being an individual Licence holder.

22.1 Please attach copies of:

- any qualifications or training relevant to the medicines/poisons on the Licence and
- CV demonstrating your suitability as a Licence holder, or describe your suitability as a Licence holder below:
  You may also be asked to provide extra information regarding your qualifications / training /experience.

PART 2: PERSONAL INFORMATION: new LICENCE HOLDER

23. Authority, access, standard operating procedures (SOPs)

Complete this section if you will be the new individual Licence holder.

Do **not** complete this section, if the Licence holder is a corporation or partnership.

☐ Please check to confirm that as the new Licence holder, you will have authority within the business to determine policies and procedures in relation to wholesaling and manufacturing medicines /poisons

☐ Please check to confirm that you will always have access to the medicines /poisons listed on the Licence

☐ Please check to confirm that only yourself, responsible person or other authorised employees of the business will have unsupervised access to the medicines/poisons.

23.1 Confirmation of Standard Operating Procedures (SOPs) by new Licence holder

As the new Licence holder, please **confirm** the wholesale/manufacture business has the following SOPs

23.1.1 SOP for stock control procedures

☐ **SOP** for **ensuring medicines/poisons** are **stored at correct temperatures.** SOP must support the following requirements:

a) All medicines/poisons are stored at the correct temperature nominated by the manufacturer.

b) Pharmaceuticals are stored according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.

☐ **SOP** ensuring that stock returned from customers or substandard stock is quarantined. SOP must support the following requirements:

a) Returned or substandard stock kept in designated quarantine area, appropriately labelled and accounted for.

b) Returned or substandard stock is returned to manufacturer or destroyed. All pharmaceutical stock is incinerated by a licenced clinical waste disposal company.

c) Returned or substandard pharmaceutical stock is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.

☐ **SOP** addressing manufacturer recalls. SOP must support the following requirements:

a) 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:

a) **If** wholesaling Schedules 2, 3, and 4 medicines, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016.

b) **If** wholesaling Schedule 7 poisons, recording complies with Regulation 78 of the WA Medicines and Poisons Regulations 2016 and the SUSMP Part 2 Section 5 (1).

c) **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:

a) **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

a) 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

Section 23 continues next page

PART 2: PERSONAL INFORMATION: new LICENCE HOLDER

23 Authority access, standard operating procedures (SOPs) continued

As the new Licence holder, please **confirm** the wholesale/manufacture business has the following SOPs

23.1.2 SOP for access and authorisation

☐ **SOP** for **preventing unauthorised staff** from accessing medicines/poisons and ordering systems. SOP must support the following requirements:

a) **If wholesaling** medicines, managing access to medicines is managed according to the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.

b) 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 Licence. SOP must support the following requirements:

a) **If wholesaling** Schedule 4 and 8 medicines, the wholesaler/manufacturer complies with Regulation 77 of the WA Medicines and Poisons Regulations 2016.

b) **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 one time.

23.1.3 SOP for transport and collection

☐ **SOP** for ensuring the person collecting an order (**calling orders)** is **authorised** to do so. SOP must support the following requirements:

a) **If** wholesaling medicines, ensuring a person collecting a caller 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.

b) **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:

a) 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 completed by 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.

23.1.4 SOP for disposal of medicine/poisons

☐ Please **confirm** the wholesale/manufacture business has a Standard Operating Procedure (SOP) for the **disposal** of **unused, excess** or **unsaleable stock**, including Schedule 8 medicines **if** applicable. **SOP must support** the following requirements:

a) 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.

b) 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.

c) Disposing of unused, excess or unsaleable stock of poisons in Schedule 7 is conducted according to the recommendations of the manufacturer.

PART 2: PERSONAL INFORMATION: new LICENCE HOLDER

24. Prior permits/licences for medicines/poisons held by applicant

To be completed by the nominated individual Licence holder, each corporate officer or each partner

24.1 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:

24.2 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:

25. Criminal check and NPC for new Licence holder, corporate officer or partner

To be completed by the nominated individual Licence holder, each corporate officer or each partner.

25.1 **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

25.2 Please **attach** a copy of your National **Police Clearance (**NPC), which is less than 12 months old.

25.3 Have you been convicted of, or are charges pending for indictable[1] 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

PART 2: PERSONAL INFORMATION: new LICENCE HOLDER

26. Financial resources of new Licence holder, corporate officer or partner

To be completed by a new Licence holder, new corporate officer or new partner

26.1 Have you been declared bankrupt or a debtor under any bankruptcy law?

☐ No

☐ Yes: What date was/will your bankruptcy be discharged?

26.2 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

27. Declaration by new Licence holder, corporate officer or partner

This declaration must be signed by the new individual Licence holder, corporate officer or partner and is about personal information and includes probity check consent.

Please refer to instruction number 11 for information on acceptable signatures.

a. 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.

b. I am at least 21 years of age.

c. The information contained in this application form is true and correct.

d. I am aware there are penalties under the *Medicines and Poisons Act 2014* for providing false or misleading information.

e. I am aware of my responsibility or the responsibility of the body corporate (if applicable) for the safe storage and sale of the medicines or 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.

f. I will notify the Department of Health **if** I leave the employment of the business or I am no longer a corporate officer of the company that holds the Licence.

Signature: Name: Date:

PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

Part 3 must be completed by a new responsible person: assesses identification, fitness and probity

28. Identification of new responsible person

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.
Refer to instruction number 7 for information on the requirements for being a responsible person for a premises.

28.1 Is the new responsible person, also the Licence holder or responsible for another premises listed on the Licence?

☐ Yes: Confirm name: Title: Forename/s: Surname:

There is no requirement to complete Part 3.

☐ No: complete all of Part 3.

28.2 Personal details of responsible person

Title: Forename/s: Surname: Date of birth:

Postal Address: Suburb: Postcode:

Mobile number: Email:

Position in business:

28.3 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.

[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).

29. Qualifications and experience of new responsible person

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: new RESPONSIBLE PERSON

30. Prior permits/licences for medicines/poisons held by responsible person

30.1 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:

30.2 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:

31. Criminal check and NPC for new responsible person

31.1 **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

31.2 Please **attach** a copy of your **National Police Clearance certificate** (NPC) which is less than 12 months old**.**

31.3 Have you been convicted of, or have pending charges for indictable[1] 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: new RESPONSIBLE PERSON

32. Declaration by new responsible person

This declaration must be signed by the new responsible person and includes probity check consent.

Please refer to instruction number 11 for information on acceptable signatures.

a) 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.

b) 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 the 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.

c) I am at least 21 years of age.

d) The information contained in this application form is true and correct.

Signature: Name: Date:

PART 4: PAYMENT and CHECKLIST

33. 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: _____

2. ☐ Direct debit to bank

   Please quote Licence 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: _____

3. ☐ Cheque or money order – made payable to DEPARTMENT OF HEALTH

Please keep a copy of the completed application from 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 Wholesale/Manufacture Licence:

- Change of individual Licence holder (no change of ownership of the business)
- Change to a person responsible for a premises
- Change of a corporate officer (only for Licences issued to a body corporate and not an individual person)
- Increase quantity of medicines/poisons already listed on the Licence
- Addition of certain medicines/poisons to the Licence
- Relocation of an existing premises to a new location
- Addition of a new premises to the Licence
- Change of business or trading name without changing legal entity (no change of ownership)
- Variation in the activities undertaken under the Licence

Note: if making multiple changes, only pay one fee of $90

Fees are not payable for the following type of changes to a Wholesale/Manufacture Licence

- Change of postal address and other contact details
- Removal of a premises from the Licence
- Removal of certain medicine/poisons from the Licence
- Upgrading storage or security

PART 4: PAYMENT and CHECKLIST

34. Checklist

Please ensure all the appropriate requested documentation is attached for:

Part 1 Application to change a Wholesale/Manufacture Licence

- ☐ If changing a individual Licence holder: completed Part 2: Personal Information (Section 7.1)
- ☐ If changing a responsible person for a premises: completed Part 3: Personal Information (Section 8.1)
- ☐ If changing a corporate officer/partner: completed Part 2: Personal Information (Section 9.1)
- ☐ If changing a corporate officer/ partner: copy of the Current and Historical Company Extract from ASIC (Section 9.3)
- ☐ If a premises is relocated or a new premises is added to the Licence, and the responsible person is not responsible for any other premises or is not the Licence holder: completed Part 3: Personal Information-Form (Section 14.1)
- ☐ If applicable, evidence of local government approval to operate the business from the premises (Section 14.2.1)
- ☐ If storing Schedule 8 medicines, attach photos of strong room as required in Section 16.5
- ☐ If there is a change of business or trading name without a change of legal entity: copy of the Current and Historical Business Name Extract from ASIC (Section 18.2)
- ☐ Declaration signed and dated by Licence holder, corporate officer or partner (Section 20)

Part 2: Personal information, fitness and probity for new Licence holder, corporate officer or partner

- ☐ Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 21.2). See Appendix A for a list of persons authorised to witness a signature
- ☐ If there is a new corporate officer/ partner, attach a CV and qualifications for each new officer /partner (Section 21.3)
- ☐ If the new Licence holder is an individual person, attach copies of qualifications/ training and a CV. (Section 22.1)
- ☐ If applicable, a Statutory Declaration relating to an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law or corresponding law in another state or territory (Section 25.1)
- ☐ A copy of the NPC Certificate which is not more than 12 months old (Section 25.2)
- ☐ If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 25.3)
- ☐ Declaration signed and dated by new Licence holder, corporate officer or partner (Section 27)

Part 3: Personal information, fitness and probity for new responsible person

- ☐ Copy of photographic identification which must be certified as a true copy by a person authorised to witness statutory declarations (Section 28.3). See Appendix A for a list of persons authorised to witness a signature
- ☐ Copies of qualifications/training and CV. (Section 29)
- ☐ If applicable, a Statutory Declaration relating to an offence under the *Medicines and Poisons Act 2014* or a repealed corresponding law or corresponding law in another state or territory (Section 31.1)
- ☐ A copy of the NPC Certificate which is not more than 12 months old (Section 31.2)
- ☐ If applicable, a Statutory Declaration relating to an indictable offence since the date on the NPC. (Section 31.3)
- ☐ Declaration signed and dated by new responsible person (Section 32)

Part 4: Payment and checklist

- ☐ Payment details completed with correct signature if paying by credit card (Section 33)

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	