



Application to change a Health Service Permit (Immunisation)

Medicines and Poisons Act 2014



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INSTRUCTIONS and INFORMATION

- 1.** This form is for requesting changes to an existing **Immunisation Service Permit** issued under the *Medicines and Poisons Act 2014*.

This form MUST be completed by the current Permit holder or incoming Permit holder who is suitably qualified and understands the requirements and terminology contained in this application.

If the Permit holder is a corporation or partnership, this form must be completed by the corporate officer or partner who originally applied for the Permit.

All communication will ONLY be with the Permit holder, corporate officer or partner.
- 2. Types of changes that cannot be applied for using this form**
DO NOT USE THIS FORM, if:

 - The Permit holder is changing from an individual person to a Permit held by a corporation or partnership, or
 - The Permit 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 an Immunisation Service Permit, found at: [Application forms for Licences and Permits](#)

Permits cannot be transferred between one business entity and another.
- 3.** There are five parts to this form:

Part 1 – Sections 1 to 19: Application to change an Immunisation Service Permit.
Part 2 – Sections 20 to 26: Personal Information: new individual Permit holder, corporate officer or partner
Part 3 – Sections 27 to 31: Personal Information: new responsible person for a premises
Part 4 – Sections 32 to 33: Payment and checklist.
Part 5 – Appendix
- 4.** Fees are **not** payable for the following type of changes to an Immunisation Service Permit:

 - Change of postal addresses or other contact details
 - Change to a person responsible for a premises
 - Removal of premises from the Permit
 - Removal of certain vaccines from the Permit
 - Upgrade of storage or security such as installation of CCTV.
- 5.** A fee of **\$92** is payable for the following type of changes to an Immunisation Service Permit:

 - Change of individual Permit holder (no change of ownership of the business)
 - Change of a corporate officer (only for Permits issued to a body corporate and not an individual person)
 - Increase the quantity of vaccines on the Permit
 - Addition of vaccines to the Permit
 - Relocation of an existing premises to a new location
 - Addition of a new premises to the to the Permit
 - Change of business or trading name without changing legal entity (no change of ownership)
 - Variation in the activities undertaken under the Permit

Note: some variations may require a new application and issue of a different Permit type.



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

The person nominated as the new Permit holder must also complete Part 2 Personal Information: Identification, Fitness and Probity and sign the declaration at Section 26.

6.1 Qualifications and/or experience of person nominated as the new Permit holder:

The new Permit holder must:

- be either a **medical practitioner** or **nurse practitioner**¹ only, registered with the Australian Health Practitioner Regulation Agency (AHPRA)
- have authority within the business to determine policies and procedures in relation to handling and managing vaccines on the Permit and managing patients undergoing vaccinations
- consider their personal scope of practice and suitability when applying for this type of permit.

6.2 Permit holder responsibilities

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

The new Permit 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 Permit for every premises listed on the Permit. The Department may request further information in relation to this capacity.

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

¹ If a nurse will be the new Permit holder or is a clinical director employed by a corporation or partnership, they must **attach** evidence showing their advanced nursing practice experience is applicable to an immunisation service.

7. Preferred new Permit holder, administration of vaccines, SASAs

It is preferable that the new Permit holder is a medical practitioner who is the medical director for the immunisation service as this ensures the Permit holder is the same person who will be authorising the Structured Administration and Supply Arrangement (SASA)¹ document.

[Information about SASAs](#) is available on the Department of Health website. Applicants should read this information before submitting their application.

The following types of health practitioners can authorise **administration** of Schedule 4 vaccines:

a) Medical practitioner who can:

- give a direct order to a health practitioner² or health professional³ to administer vaccines to each individual patient or
- authorise a Structured Administration and Supply Arrangements (SASA) on behalf of the immunisation service where vaccine administration can be initiated by the type of health practitioner² or health professional³ named in the SASA without a prescription or direction by a medical practitioner for each individual patient.
 - The SASA must be signed by the most senior medical practitioner employed in the immunisation service and
 - must be approved by a clinical governance committee which must include a medical practitioner, registered nurse and a pharmacist. Names and AHPRA registration numbers will be required.

Only a medical practitioner can authorise a SASA.

Copies of SASAs issued under Health Service Permits must be sent to the Department of Health, however they do not have to accompany this Application Form and the permit may be issued prior to the receipt of SASAs **OR**

b) Nurse practitioner⁴ who can give a direct order to a health practitioner² or health professional³ to administer vaccines to each individual patient. Nurse practitioners cannot sign off on a SASA.

¹ Information about SASAs can be found at: [Information about SASAs](#)

² the type of health *practitioner* who can administer vaccines is a person who is registered with AHPRA and also has authorisation under the Medicines and Poisons Regulations 2016 to administer Schedule 4 medicines, e.g. registered nurse, enrolled nurse, registered paramedic.

³ the type of health *professional* who can administer vaccines is a person who has authorisation under the Medicines and Poisons Regulations 2016 to administer Schedule 4 medicines. A health professional is not registered with AHPRA. e.g. medic.

⁴ If a nurse practitioner will be the new Permit holder, they must **attach** evidence showing their advanced nursing practice experience is applicable to an immunisation service.



8.	Changing the person responsible for a premises listed on the Permit A new responsible person will have overall responsibility for and manage the vaccines on a day to day basis and be the contact person if the Permit holder is not available. The responsible person for a premises must: • be employed or contracted by the Permit holder • reside in WA • complete Part 3: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 31. 8.1 Responsible person for a Permit issued to an individual person The responsible person for a premises when a Permit is issued to an individual medical practitioner or nurse practitioner can be the: a) permit holder, only if, the permit is issued to an individual person and not a corporation/partnership or b) the most senior medical practitioner, nurse practitioner or registered nurse at the premises. 8.2 Responsible person for a permit issued to a corporation or partnership The responsible person for a premises when a Permit is issued to a corporation or partnership can be: a) the most senior medical practitioner, nurse practitioner or registered nurse at the premises or b) the Medical Director or Clinical Director employed by the corporation or partnership who has authority to determine policies and procedures to manage the vaccines and vaccinations. Please note: a responsible person must consider whether they have capacity to oversee the day to day management of the medicines 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.	Changing a corporate officer or partner for a Permit that is held by a corporation or partnership. A new partner or corporate officer (directors, company secretary, chief executive officer or general manager and chief financial officer) must also complete Part 2: Personal Information: Identification, Fitness and Probity and sign the declaration at Section 26.
10.	Relocation or addition of a premises If a premises listed on an existing Immunisation Service Permit: • is being <u>relocated</u> to a different premises or • another premises is being <u>added</u> to the existing Immunisation Service Permit: and the relocated or added premises (second premises) is currently listed on a different Permit: ○ the application will not be processed until the Permit holder at the second premises has submitted an application to the Department to have their premises removed from their Permit. ○ In such cases, Permit holders requesting the relocation or addition of a new premises may wish to liaise with the Permit holder at the second premises to ensure the Department of Health is appropriately advised.
11.	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.



12.	Signatures All signatures must be signed in ink or via a verifiable electronic signature. An electronic signature is only acceptable if the submitted application allows the Department to verify the signature. A “signature” that is copied and pasted and a “signature” that is the person’s name in a font style resembling hand writing will not be accepted. The current Permit holder must sign the Declaration for making a change to the Permit at Section 18. 12.1 Who can sign for a change to an Immunisation Service Permit: If the Immunisation Service Permit is held by an individual person and the change is to request a new individual Permit holder within the same business and the current Permit holder is no longer employed by the business: • the new Permit holder should sign the Declaration and provide the reason the current Permit holder cannot sign the Declaration. If the Immunisation Service Permit is held by a partnership or body corporate, the person who signed the original Permit application should sign the Declaration.
13.	Approving a change to a Permit Applying for a change to an existing Permit does not guarantee the requested changes will be approved.
14.	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).
15.	Extra information When applying for a change to an existing Permit, refer to the: Guide to applying for a Licence or Permit
16.	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 an IMMUNISATION SERVICE PERMIT

1. General information		
Permit number:	Name of current Permit 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 addresses or other contact details	Part 1: Sections 2,19	
☐ Change to a person responsible for a premises	Part 1: Sections 3,19 Part 3: Sections 27 to 31	
☐ Remove a premises from the Permit	Part 1: Sections 4,6,19	
☐ Remove certain vaccines from the Permit	Part 1: Sections 5,6,19	
☐ Upgrade to storage and security	Part 1: Sections 7,19	
Changes with a fee of \$92		
☐ Change of individual Permit holder	Part 1: Sections 8, 19 Part 2: Sections 20 to 26 Part 4: Section 32	
☐ Change of corporate officer or partner	Part 1: Sections 9,19 Part 2: Sections 20,23,24,25,26 Part 4: Section 32	
☐ Increase quantity of vaccines already listed on the Permit	Part 1: Sections 10,19 Part 4: Section 32	
☐ Addition of certain vaccines to the Permit.	Part 1: Sections 11,19 Part 4: Section 32	
☐ Relocation of an existing premises to a new premises	Part 1: Sections 12,14,15,16,19 Part 4: Section 32	
☐ Addition of another new premises to the Permit	Part 1: Sections 13,14,15,16, 19 Part 4: Section 32	
☐ Change of business or trading name without any change of the legal entity	Part 1: Section 17,19 Part 4: Section 32	
☐ Variation in the activities undertaken under the Permit, including the use of the medicines	Part 1: Section 18,19 Part 4: Section 32	
Note: if making multiple changes, only pay one fee of \$92		
1.2 Additional information to support application (optional): 		



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
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. Change the person responsible for a premises listed on the Permit

Refer to instruction number 7 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:

3.1 Details about the new person responsible for a premises listed on the Permit

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

☐ 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

4. Remove a premises from the Permit

Premises name:
Address: Suburb: Postcode:
Date the business will cease trading at these premises:
Is the business at the premises being sold to another Immunisation Service?

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

The Department requires the person taking over the Immunisation Service to either:

- apply to add this premises to their current Immunisation Service Permit, if they already have a Permit, or
- apply for a new Permit in their name.

Applications from the person buying the business must be received by the Department prior to removing this premises from your Permit.

4.2 ☐ No, is there any remaining stock of vaccines or other medicines left?

☐ No

☐ Yes: please also complete Sections 6.



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
Changes without a fee

5. Remove certain vaccines from the Permit

Premises name:

Address:

Suburb:

Postcode:

5.1 List of vaccines to be removed:

5.2 Is there any remaining stock left of the vaccines being removed from the Permit at the above-named premises

☐ No

☐ Yes: please also complete Section 6.

6. Information about disposal of vaccines

If there is any remaining stock of vaccines after removing a premises from a Permit or removing certain vaccines from a premises listed on the Permit, please indicate how the stock will be disposed of.

Check all that apply:

☐ Returned to wholesaler for disposal — Name of wholesaler:

☐ Transferred to other premises on the Permit — Name of premises:

☐ Disposed of using a licensed waste management service — Name:

¹ Pharmacies and hospitals are not obligated to accept medicines for disposal if they have not supplied the medicine
More information on disposal of medicines is found at: [Disposal of medicines](#)

7. Upgrading storage and security

Premises name:

Address:

Suburb:

Postcode:

Describe the change to the way the medicines are stored or the change to premises security:



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
Changes with a fee

8. Change of individual Permit holder

Complete this section only if the new Permit holder is an individual medical practitioner or nurse practitioner.

Refer to instruction number 6, for information on the requirements for being an individual Permit holder.

8.1 Name of new incoming permit holder:

Title: Forename(s): Surname:
Address: Suburb: Postcode
Telephone /Mobile: Email:
Position in business:

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

9. Change of corporate officer or partner

Note: Only applicable if the permit has been issued to a body corporate or company and not to an individual person.

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 (if applicable)

Title: Forename(s): Surname:

9.3 Please **attach** a copy of the Current and Historical Company Extract from ASIC which includes details of all past and current corporate officers.

10. Increase quantity of vaccines

Premises name:

Address: Suburb: Postcode:

10.1 Vaccines having their quantities increased at the above-named premises

Vaccines	Quantity on current Permit	Increase quantity to:



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
Changes with a fee

11. Addition of vaccines

Premises name:

Address:

Suburb:

Postcode:

11.1 Vaccines to be added to the above-named premises

List of vaccines and quantities to be added to the above-named premises on the Permit:

- 11.2** ☐ Please confirm the new vaccines will be stored in a purpose built vaccine refrigerator with a built in temperature monitoring data logger as per Section 3.1 of the [National Vaccine Storage Guidelines Strive for 5](#).

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

12.3 Plus, complete Sections 14,15,16,19 and 32 (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: Permit will be issued with "Valid from" date on or after this date.

13.2 Plus, complete Sections 14,15,16,19 and 32 (payment)



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT

Changes with a fee

14. Information about the relocated or new added premises

Is this premises being bought from another immunisation service business? See instruction number 10.

- ☐ No
- ☐ Yes: Name of previous immunisation service business:
- The Department requires the previous Permit holder at the relocated or new added premises to remove the premises from their Permit. The application to remove the premises from the previous Permit holder's Permit must be received by the Department prior to adding the relocated or new added premises to your Permit.

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 Permit or
- the Permit 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

☐ Other - please specify:

14.2.1 Is local government approval required to operate an Immunisation Service from the premises?

- ☐ Yes: **Attach** evidence of local government approval to operate the service 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 an IMMUNISATION SERVICE PERMIT
Changes with a fee

15. Information about the vaccines at relocated or new added premises

Please check which vaccines will be required:

- ☐ Influenza vaccine only
- ☐ All vaccines on WA Immunisation Schedule
- ☐ Vaccines listed below

Please list other vaccines and any local anaesthetics and rescue medicines, such as adrenaline that will be required.

Name of vaccine or other medicine	Approximate quantity required

Note: all permits for immunisation services will also be issued as including adrenaline injection in Schedule 3.

15.1 Storage and temperature monitoring of scheduled medicines at relocated or new added premises

- 15.1.1 Please **attach** a diagram of the premises, showing where the vaccines and adrenaline will be stored.
- 15.1.2 Storage of adrenaline in Schedule 3 (Please check which one applies)
- ☐ Locked room ☐ Locked cupboard
- Please **attach** photos of locked room or locked cupboard
- 15.1.3 Storage of refrigerated vaccines (Please check which one applies)
- ☐ Locked room with a purpose-built vaccine refrigerator ☐ Locked purpose-built vaccine refrigerator
- Please **attach** photos of locked room with vaccine refrigerator in situ or locked vaccine refrigerator in situ.
- 15.1.4 ☐ Please confirm vaccines will be stored in a purpose built vaccine refrigerator with a built in temperature monitoring data logger as per Section 3.1 of the [National Vaccine Storage Guidelines Strive for 5](#).

15.2 Storage area for Schedule 3 adrenaline and Schedule 4 vaccines at relocated or new added premises

Please provide information for all areas storing adrenaline and vaccines at the premises

Floor number, room number/room name	Floor number, room number/room name

15.3 Access to vaccines and adrenaline

- ☐ Please check to confirm that only AHPRA registered health practitioners or health professionals authorised under the *Medicines and Poisons Act 2014* to possess scheduled medicines and employed by the immunisation service will have unsupervised access to the medicines and keys/entry codes to storage rooms and refrigerators.

Section 15 continues next page



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
Changes with a fee

15.4 Preventing access to vaccines and adrenaline

Please describe how non-authorized staff such as reception staff, cleaners and members of the public (including family members and children) will be prevented from having access to scheduled medicines:

15.5 Standard operating procedures (SOP's)

Will the SOPs for handling and using vaccines and adrenaline at the relocated or new added premises be the same as for another premises listed on the Permit?

- ☐ Yes: SOP is the same as: _____ (premises name)
- ☐ No: please **confirm** the immunisation service at the relocated or new added premises has the following SOPs
- ☐ **SOP** used for **ordering** vaccines and adrenaline from wholesalers or pharmaceutical companies which must support the following:
- a) Orders must be approved by the Permit holder, registered health practitioner or health professional who has been authorised to approve orders by the permit holder. If the permit holder does not personally authorise each order, they must regularly review the vaccines being ordered for the business.
 - b) Only registered health practitioners or health professionals authorised to administer vaccines should receive vaccines and adrenaline when delivered by wholesalers/manufacturers. Other staff such as reception staff cannot be designated as responsible for this task.
 - c) Vaccines and adrenaline must be ordered from a licensed pharmaceutical wholesaler or manufacturer.
 - d) Orders will be sent directly to the premises by the wholesaler or an alternative arrangement is described.
- ☐ **SOP** for **recording the administration** of vaccines to patients which must support the following:
- a) Record of administration is made for each individual patient in the Patient Record. Minimum details including vaccine name, strength, dose administered and batch number.
 - b) Records include name of registered health practitioner or health professional administering doses and person making the entry and date of administration.
 - c) Name and signature of person administering vaccine or, if records are kept electronically, the system will identify the person administering the vaccine through their logon ID.
 - d) Details of any adverse events
 - e) All records for the administration of medicines in Schedule 4 are kept for a minimum of 2 years.
 - f) Details of each instance of patient immunisation are entered into the Australian Immunisation Register.
- ☐ **SOP** which shows that all **adverse events** following immunisation (AEFI) will be reported according to [Adverse event following immunisation \(AEFI\) \(health.wa.gov.au\)](http://health.wa.gov.au) and supports AEFI being reported by using [WA Vaccine Safety Surveillance \(WAVSS\) system](http://health.wa.gov.au).
- ☐ **SOP** for **storage** and **transport** of vaccines which shows compliance with the [National Vaccine Storage Guidelines Strive for 5](http://health.wa.gov.au). The SOP supports the following requirements:
- a) Vaccines are stored in a purpose-built vaccine fridge that is only accessible to authorised registered health practitioners or health professionals.
 - b) Vaccines are consistently stored and transported at 2-8 °C.
 - c) Storage temperatures during transport are continuously monitored for temperature excursions
 - d) Ice packs or gel pack are conditioned, and the cooler is packed appropriately.
 - e) Temperature monitoring of vaccines occur in the cooler and action is taken for cold chain breaches
 - f) Unused stock is returned to vaccine fridge



16. Authorising administration of vaccines at relocated or new added premises

16.1 How will the administration of vaccines be authorised? Check only one option

- a. ☐ A face to face consultation between a medical practitioner or nurse practitioner and each patient occurs every time and administration of a vaccine is authorised at this time **or**
- b. ☐ A telemedicine consultation between a medical practitioner or nurse practitioner and each patient occurs every time and administration of a vaccine is authorised at this time **or**
- c. ☐ A combination of a and b – consultation method may be either face to face or via telemedicine but there is always a consultation between a prescriber and the patient and administration of a vaccine is authorised at this time **or**
- d. ☐ Each patient completes a medical history and consent form and a medical practitioner or nurse practitioner reviews the form before authorisation is given to administer the vaccine for each patient **or**
- e. ☐ SASAs signed by the most senior medical practitioner employed or contracted by the immunisation service authorises health professionals without prescribing rights to initiate administration of a vaccine. A consultation between every patient and a prescriber does not occur prior to vaccination. Complete Sections 16.2 and 16.3 **or**
- f. ☐ Other method (please describe):

16.2 Details of medical practitioner signing SASAs

Name of authorising medical practitioner:

Usual practice address:

Suburb:

Postcode:

Telephone:

Fax:

Email:

AHPRA registration number:

16.3 SASAs and Clinical Governance Committee:

Name of medical practitioner:

AHPRA registration number:

Name of registered nurse:

AHPRA registration number:

Name of pharmacist:

AHPRA registration number:



PART 1: APPLICATION to change an IMMUNISATION SERVICE PERMIT
Changes with a fee

16.4 Qualifications of staff administering vaccines at relocated or new added premises

Which type of person will be administering vaccines?

a. Health practitioner registered with AHPRA: tick which health practitioner/s will be administering vaccines:

- ☐ medical practitioner ☐ nurse practitioner ☐ registered nurse ☐ enrolled nurse
☐ registered paramedic ☐ Aboriginal and Torres Strait Islander health practitioner
☐ Other registered health practitioner, please describe:

b. Health professional not registered with AHPRA but described in the Medicines and Poisons Regulations 2016

- ☐ medic ☐ Aboriginal and Torres Strait Islander health worker
☐ Other registered health professional, please describe:

16.5 Training

Will all staff administering vaccines have completed accredited or RTO delivered immunisation training?

- ☐ Yes
☐ No

17. Change of business or trading name

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 Permit is required.

17.1 Previous business or trading name:

New business or trading name:

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

17.2 Australian Business Number:

18. Variation in the activities undertaken under the Permit

Please describe the proposed change in the way the vaccines will be used:

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



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Changes with a fee

19. Declaration by Permit holder

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

Please refer to Instruction 12 for information on acceptable signatures.

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

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

If the current permit 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 PERMIT HOLDER

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

If the new Permit holder is an individual medical practitioner or nurse practitioner, all sections of Part 2 must be completed.

If the Permit is held by a corporation or partnership, and there is a new corporate officer or partner, all sections of Part 2 except Sections 21 and 22 must be completed by each new corporate officer or each new partner.

20. Identification of new Permit holder, corporate officer or partner

20.1 Personal Details

Title: Forename/s: Surname: Date of birth:
Address: Suburb: Postcode:
Postal address: Suburb: Postcode:
Mobile number: Email:
Position in business:

20.2 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)

20.3 Role in relation to the Permit

☐ A new medical practitioner or nurse practitioner who will be the new Permit 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 23, 24, 25 and 26 of Part 2 and **attach** a CV¹

☐ a new partner

Complete Sections 23, 24, 25 and 26 of Part 2 and **attach** a CV¹

¹A 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*.

21. Qualifications and experience of new Permit holder

Complete this section if you are an individual person (medical practitioner or nurse practitioner) applying to be the new Permit holder.

Do not complete this section, if the Permit has been issued to a corporation or partnership.

Refer to instruction number 6 for information on the requirements for being an individual Permit holder.

21.1 The new Permit holder must be a medical practitioner or nurse practitioner– tick which one applies:

- ☐ Medical practitioner
- ☐ Nurse practitioner: must **attach** evidence showing their advanced nursing practice experience is applicable to an immunisation service.

AHPRA registration number:

Registration expiry date:

21.2 **Attach** a copy of your current annual registration certificate or wallet card provided to you by AHPRA.

Note: please **do not** provide an extract of the information available on AHPRA's public website.



PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

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

Complete this section if you will be the new individual Permit holder, i.e. medical practitioner or nurse practitioner. Do **not** complete this section, if the Permit holder is a corporation or partnership.

- ☐ Please check to confirm that as the new Permit holder, you will have authority within the immunisation service to determine policies and procedures on the management, storage and administration of vaccines and adrenaline.
- ☐ Please check to confirm that you will always have access to vaccines and adrenaline listed on the Permit.
- ☐ Please check to confirm that only yourself, responsible person or other authorised employees of the business will have unsupervised access to the vaccines and adrenaline.

22.1 Confirmation of SOPs by new Permit holder

As the new Permit holder, check to **confirm** the immunisation service has the following SOPs at all premises:

- ☐ **SOP used for ordering** vaccines and adrenaline from wholesalers or pharmaceutical companies which must support the following requirements:
 - a) Orders must be approved by the Permit holder, registered health practitioner or health professional who has been authorised to approve orders by the permit holder. **If** the permit holder does not personally authorise each order, they must regularly review the vaccines being ordered for the business.
 - b) Only registered health practitioners or health professionals authorised to administer vaccines should receive vaccines and adrenaline when delivered by wholesalers/manufacturers. Other staff such as reception staff cannot be designated as responsible for this task.
 - c) Vaccines and adrenaline must be ordered from a licensed pharmaceutical wholesaler or manufacturer
 - d) orders will be sent directly to the premises by the wholesaler or an alternative arrangement is described
- ☐ **SOP for recording the administration** of vaccines to patients which must support the following requirements:
 - a) Record of administration is made for each individual patient in the Patient Record. Minimum details include: vaccine name, strength, dose administered and batch number.
 - b) Records include name of health practitioner administering doses and person making the entry.
 - c) Date of administration
 - d) Name and signature of person administering vaccine or, if records are kept electronically, the system will identify the person administering the vaccine through their login ID.
 - e) Details of any adverse events
 - f) All records for the administration of medicines in Schedule 4 are kept for a minimum of 2 years.
 - g) Details of each instance of patient immunisation are entered into the Australian Immunisation Register (AIR)
- ☐ **SOP** which shows that **adverse events** following immunisation (AEFI) will be reported via the [Western Australian Vaccine Safety Surveillance \(WAVSS\)](#) system and supports the following requirements:
 - a) AEFI is reported by one of the following methods:
 - o Electronically using the WAVSS system or call the Central Immunisation Clinic on 9321 1312
 - o Complete WAVSS adverse reaction reporting form and return by:
Fax: 9426 9408 or Post: Central Immunisation Clinic, PO Box 8172, Perth Business Centre, WA 6849
- ☐ **SOP for storage and transport** of vaccines which shows compliance with the [National Vaccine Storage Guidelines Strive for 5](#) and supports the following requirements:
 - a) Vaccines are stored in a purpose-built vaccine fridge, only accessible to authorised registered health practitioners or health professionals.
 - b) Vaccines are consistently stored and transported at 2-8 °C.
 - c) Storage temperatures during transport are continuously monitored for temperature excursions
 - d) Ice packs or gel pack are conditioned, and the cooler is packed appropriately
 - e) Temperature monitoring of the vaccines occur in the cooler and action taken during cold chain breaches
 - f) Unused stock is returned to vaccine fridge



PART 2: PERSONAL INFORMATION: new PERMIT HOLDER

23. Prior permits/licences for medicines/poisons

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

23.1 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:

23.2 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:

24. Criminal check for new Permit holder, corporate officer or partner

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

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. Financial resources of new Permit holder, corporate officer or partner

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

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

☐ No

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

25.2 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: new PERMIT HOLDER

26. Declaration by new Permit holder, corporate officer or partner

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

Please refer to Instruction 12 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 an Immunisation Service Permit. These searches may include (without limitation) corporate searches, checks with health professional registration boards (including registration status and release of information on any current or ongoing investigations) and criminal record checks. I also understand I may be requested to provide further information relevant to determining fitness and probity.
- 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 Schedule 2 medicines and will ensure compliance with the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016, and compliance with conditions placed on the Permit.
- 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 Permit.

Signature:

Name:

Date:



PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

27. Identification of new responsible person

The role of the responsible person is to manage the vaccines and adrenaline on a day to day basis and be the contact person, if the Permit holder is not available.

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

27.1 Is the new responsible person, also the Permit holder or responsible for another premises listed on the Permit?

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

There is no requirement to complete Part 3.

☐ No: complete remainder of Part 3.

27.2 Personal details of responsible person

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

Postal Address: Suburb: Postcode:

Mobile number: Email:

Position in business:

27.3 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).

28. Qualifications and experience of new responsible person

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

28.1 Which type of health practitioner will be the responsible person

☐ Medical practitioner ☐ Nurse practitioner ☐ Most senior registered nurse at the premises

28.2 AHPRA registration number:

Registration expiry date:

Attach a copy of your current annual registration certificate or wallet card provided to you by AHPRA.

Note: please **do not** provide an extract of the information available on AHPRA's public website.



PART 3: PERSONAL INFORMATION: new RESPONSIBLE PERSON

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

29.1 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:

29.2 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 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:

30. Criminal check for new responsible person

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. Declaration by new responsible person

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

Please refer to Instruction 12 for information on acceptable signatures.

- a) I acknowledge my role is to manage the vaccines and adrenaline on a day to day basis and be the contact person, if the Permit 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 Immunisation Service Permit. 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

32. Payment (where required)

Fee: \$92

1. ☐ Credit Card – American Express and Diners not accepted

Card type: ☐ MasterCard ☐ Visa

Name on card: Card number:

Expiry date: Amount: **\$92**

Signature of cardholder: Date:

2. ☐ Direct debit to bank

Please quote Permit number and business name in the reference when making a direct debit payment

Bank: Commonwealth Bank: **BSB: 066 040 Account number: 13300018 Amount: \$92**

Receipt Number: Payment date: Payment date:

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

Please keep a copy of the completed application form for reference

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

A fee of \$92 is payable for the following types of changes to an Immunisation Service Permit:

- Change of individual permit holder (no change of ownership of the business)
- Change of a corporate officer (only for Permits issued to a corporation and not an individual person)
- Increase quantity of vaccines or adrenaline
- Add vaccines to the Permit for an existing premise
- Relocation of an existing premises to a new location
- Addition of a new premises
- Change of business or trading name without changing legal entity (no change of ownership).
- Variation in the activities undertaken under the permit, including the use of the medicines

Note: if making multiple changes, only pay one fee of \$92

Fees are not payable for the following type of changes to an Immunisation Service Permit:

- Change of postal address and other contact details
- Change to a person responsible for a premises
- Removal of a premises from the permit
- Removal of medicines from the permit
- Upgrading storage or security



PART 4: PAYMENT and CHECKLIST

33. Checklist

Please ensure all the appropriate requested documentation is attached for:

Part 1 Application to change an Immunisation Service Permit

- ☐ If changing a responsible person for a premises: completed Part 3: Personal Information (Section 3.1)
- ☐ If changing an individual Permit holder: completed Part 2: 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 Permit, and the responsible person is not responsible for any other premises or is not the Permit holder: completed Part 3: Personal Information-Form (Section 14.1)
- ☐ If applicable, evidence local government approval to operate an immunisation service from premises (Section 14.2.1)
- ☐ Diagram of the premises, showing where the vaccines and adrenaline will be stored (Section 15.1.1)
- ☐ Photos of locked room or locked cupboard (Section 15.1.2)
- ☐ Photos of locked purpose-built vaccine refrigerator or locked room with refrigerator in situ (Section 15.1.3)
- ☐ 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 17.1)
- ☐ Declaration signed and dated by individual Permit holder, corporate officer or partner (Section 19)

Part 2: Personal information, fitness and probity for new Permit 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 20.2). See Appendix A for a list of persons authorised to witness a signature
- ☐ If there is a new corporate officer or partner, attach a CV and copies of qualifications for each new corporate officer or partner (Section 20.3)
- ☐ If the new individual Permit holder is a nurse practitioner - attach evidence showing advanced nursing practice experience is applicable to an immunisation service. (Section 21.1)
- ☐ If the new Permit holder is an individual medical practitioner or nurse practitioner, attach a copy of the person's current annual registration certificate or wallet card provided by AHPRA. **Do not** provide an extract of the information available on AHPRA's public website (Section 21.2)
- ☐ 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 24)
- ☐ Declaration signed and dated by new Permit holder, new corporate officer or partner (Section 26)

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 27.3). See Appendix A for a list of persons authorised to witness a signature
- ☐ The responsible person's current annual registration certificate or wallet card provided by AHPRA. **Do not** provide an extract of the information available on AHPRA's public website (Section 28.2)
- ☐ 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 30)
- ☐ Declaration signed and dated by new responsible person (Section 31)

Part 4: Payment and checklist

- ☐ Payment details completed with correct signature if paying by credit card (Section 32)



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	