

Licence to Operate Pharmacy Application for a New Licence

A

Medicines Act 1981

INFORMATION FOR APPLICANTS

- This form is used to make an application for a new Licence to Operate Pharmacy, including the establishment of a pharmacy at a new premises, the relocation of an existing pharmacy to a new premises, or the change of ownership of an existing pharmacy.
- The applicant must be an individual who is nominated to be a Responsible Person for the licence.
- For the application to be considered, all applicable sections of the application form must be completed.
- Before filling out this application you must make yourself familiar with the provisions of the Medicines Act 1981 and Medicines Regulations 1984, in particular those provisions relating to licensing and operating pharmacies.
- A pharmacist is defined as a health practitioner registered with the Pharmacy Council of New Zealand as a practitioner of the profession of pharmacy, holding a valid annual practising certificate.
- The Licensing Authority may require you to supply additional information at a later date (see section 55B of the Medicines Act 1981). If you do not supply that information within 30 days of the request, the application will lapse.

APPLICATION FEE

- Medsafe will issue an invoice to the applicant for the application fee (\$1,097.00).
- Applicants are advised to pay the application fee on receipt of the invoice. The payment must include reference to the correct invoice number (this ensures that the application fee paid is correctly matched to the application). Please note the application fee is non-refundable.
- The application will not be processed until the application fee is received by Medsafe.

APPLICATION FORM SUBMISSION

- This application form can be completed electronically using a pdf reader. The current version of Adobe Reader, available free of charge from the Adobe website (<https://get.adobe.com/reader>) is recommended.
- The completed application form should be submitted with any supporting documents, by the applicant, to Medsafe through the Medicines Control Online System (MCOLS).
- Whilst the submission of applications through MCOLS is encouraged, applications are also accepted by email (medicinescontrol@health.govt.nz). A copy of the form should be retained for the applicant's records.

Section 1: Applicant

The Applicant is the individual completing this form, who is nominated to be a Responsible Person for the licence.

1.1. Title:

1.2. First name:

1.3. Middle name(s):

1.4. Preferred name:

1.5. Surname:

1.6. Position title:

Contact details

1.7. Email:

1.8. Phone:

Pharmacist registration details

1.9. HPI-CPN:

Section 2: Application Details

This section relates to the type of application being made.

2.1. This Application is being made to (select one):

- Establish a new pharmacy at a premises that is not currently licensed (go to Question 2.3)
- Relocate an existing licensed pharmacy to a new premises (go to Question 2.2)
- Change ownership at an existing licensed pharmacy (go to Question 2.2)

2.2. Existing pharmacy details:

Current licence ID (RI number):

Legal entity name (operator):

Pharmacy name (trading name):

2.3. Date licence required

Note: You should ensure the Application is being made at least 8 weeks ahead of this date. An initial licensing audit of a new premises will be conducted as part of the assessment process.

Section 4: Premises

The premises describes the location where the pharmacy practice activities are proposed to be conducted.

4.1. Pharmacy trading name:

4.2. Street address:

Note: The street address must reflect an authorised source (refer for example the address finder on the NZ Post website).

Level/unit:

Street number & name:

Suburb:

Town/City:

Postcode:

4.3. Site description:

occupies all of the street address specified in Question 4.2 (go to Question 4.4)

as described below:

Note: For example, 'occupies 100 square metres on the north side of the building'. References to a direction or orientation (e.g. 'north side') must reflect a compass bearing or direction.

4.4. Pharmacy contact details:

Email:

Phone:

Postal address:

Is the postal address the same as the street address?

Yes

No (please specify):

Level/unit:

Street name & number:

Suburb:

Town/City:

Postcode:

Section 5A: Eligibility (Legal Entity)

This section relates to the eligibility of the legal entity applying to be licensed (refer sections 55D and 55E of the Medicines Act 1981)

5A.1. The legal entity is eligible to hold a licence because it is (select one):

- An individual pharmacist (sole trader) (go to Question 5A.4)
- A partnership of pharmacists (go to Question 5A.4)
- A company where at all times more than 50% of the share capital of the company is owned by pharmacist(s), and effective control of the company is vested in those pharmacist(s) (go to Question 5A.2)

Note: Guidance on the effective control principles used to guide assessment of an application are available on the Medsafe website (www.medsafe.govt.nz).

- Health New Zealand operating a pharmacy in a hospital owned or operated by Health New Zealand (go to Section 5B)
- A company operating a pharmacy in a hospital owned or operated by the company (go to Question 5A.2)
- Other (describe, and then complete all other applicable questions in Section 5A):

5A.2. Company shareholding: List all shareholders in the company, the number of shares they hold, whether the shareholder is a pharmacist with effective control, whether the shareholder is a trust, and the voting rights attached to each share if applicable. Please ensure that you check your company details on the New Zealand Companies Office website, as this information must be the same as the Companies Office Register.

Shareholder	Number of shares	Effective control?	Trust?	Voting rights?
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5A.3. Do any of the shareholders specified in question 5A.2 hold more than 50% shares in any other pharmacy (excluding the pharmacy that this application relates to, as specified in question 4.1)? If so, please list details below.

Pharmacy trading name	Shareholder	Interest held (%)

5A.4. Does the legal entity operate any other pharmacies? If so, list details below.

Pharmacy trading name	For sale?
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>

Section 5B: Eligibility (Prescriber Interest)

This section relates to authorised prescribers and delegated prescribers holding interest in pharmacies (refer sections 5A and 42C of the Medicines Act 1981).

5B.1. Do authorised prescriber(s) and/or delegated prescriber(s) hold an interest in the pharmacy to which this Application relates?

- No (go to Section 5C)
 Yes (list details below, as applicable)

Prescriber 1: Name:

HPI-CPN:

Regulatory Authority:

Describe the interest held:

Prescriber 2: Name:

HPI-CPN:

Regulatory Authority:

Describe the interest held:

Prescriber 3: Name:

HPI-CPN:

Regulatory Authority:

Describe the interest held:

Section 5C: Eligibility (Responsible Persons)

This section relates to Responsible Persons.

Note: Refer to the published guidance 'Responsible Persons (Pharmacy)' available on the Medsafe website. All pharmacists in whom effective control is vested must be listed as Responsible Persons.

5C.1. Responsible Person 1 (this is the Applicant, refer Section 1):

Responsible Person 1:

Name:

I have reviewed and understood the Responsible Persons guidance

Current APC issued by the Pharmacy Council of New Zealand?

Does this APC include conditions on the scope of practice?

5C.2. Are there additional Responsible Persons?

No (go to Section 6)

Yes (complete below for each individual, as applicable)

I confirm, as the Applicant, that each of the following individual(s) have provided their explicit consent and hold the appropriate knowledge and qualifications to meet the requirements of a Responsible Person. Each individual has reviewed and understood the Responsible Persons guidance.

Responsible Person 2:

Title:

First name:

Middle name(s):

Preferred name:

Surname:

HPI-CPN:

Current APC?

Conditions on scope of practice?

Responsible Person 3:

Title:

First name:

Middle name(s):

Preferred name:

Surname:

HPI-CPN:

Current APC?

Conditions on scope of practice?

Responsible Person 4:

Title:

First name:

Middle name(s):

Preferred name:

Surname:

HPI-CPN:

Current APC?

Conditions on scope of practice?

Responsible Person 5:

Title:

First name:

Middle name(s):

Preferred name:

Surname:

HPI-CPN:

Current APC?

Conditions on scope of practice?

Responsible Person 6:

Title:

First name:

Middle name(s):

Preferred name:

Surname:

HPI-CPN:

Current APC?

Conditions on scope of practice?

Responsible Persons 7+:

There are additional Responsible Persons

For each additional individual provide the above details as an attachment to your application.

Section 6: Activities

This section relates to the practices and procedures at the Pharmacy.

6.1. Practices and procedures will be in place to ensure that any pharmacist who is employed or engaged in duties in the pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice.

Do you agree that the following statement accurately reflects the practices and procedures in place within your Pharmacy?
"The practices and procedures of the P state that the pharmacists employed by the company will be expected to operate within the profession's standards of pharmacy practice, the profession's Code of Ethics, the Health Information Privacy Code and all other applicable legislation, codes and guidelines."

- Yes (go to Section 7)
- Yes - and I have further practices and procedures specified below
- No - please specify your practices and procedures below

The following practices and procedures will be in place to ensure that any pharmacist who is employed or engaged in duties in the Pharmacy to which this application relates is not requested or required to act in a way that is inconsistent with the applicable professional or ethical standards of the pharmacy practice (specify relevant practices and procedures):

Section 7: Supporting Information

This section outlines the supporting information that is required to be submitted with the Application.

7.1. A copy of the current version of the following documents are required to be submitted with the Application:

Premises:

Note: Check the corresponding box to confirm the document is being submitted with the Application.

- Premises site plan (outlining the layout of the Pharmacy)

Legal entity eligibility:

Note: Check the corresponding box to declare that the document exists (leave the corresponding box unchecked if the document does not exist).

- Constitution (where the legal entity is a company)
- Shareholders' agreement (where the legal entity is a company)
- Lease agreement (where the Pharmacy is located within a medical centre)

Change of ownership:

Note: For an application relating to a change of ownership, check the corresponding box to confirm the document is being submitted with the Application.

- Executed sale and purchase agreement

7.2. Are there any agreements, arrangements or otherwise, in place (in addition to those specified in Question 7.1) that may affect the ability of pharmacist(s) to hold effective control of the applicant company, or that may affect the management and control of pharmacy practice activities conducted by the legal entity at the premises (for example including, but not limited to, management or franchise agreements)?

- No (go to Section 8)
- Yes (specify, and submit a copy of any corresponding document(s) with the Application):

Section 8: Declaration

8.1. Applicant declaration

Note: Completion of the Applicant declaration is mandatory for all applications.

I confirm that I am authorised to complete this Application and I:

1. Solemnly and sincerely declare that the statements made in this Application are true and correct;
2. Confirm that I am aware of the provisions of section 76 of the Medicines Act 1981; and
3. Agree to provide any further information as required by the Licensing Authority.

Date:

Note: To sign this document electronically apply a digital signature, or attach a signature image file, or use an on-screen signing function (for example 'Fill & Sign' in Adobe Reader). If completing the signature electronically is not possible, print the form and sign in pen.

Digital Signature

Click below to apply

OR

Signature Image File

Click below to attach

OR

Signature

Sign below

8.2. Statutory declaration

Note: Completion of the statutory declaration is only required for applications that are not submitted by the Applicant through the Medicines Control Online System (MCOLS), using their MCOLS login. To complete the statutory declaration, print out the completed application form and present to the person witnessing your declaration.

I, the Applicant *(Enter your full name)*

of *(Enter the address where you live)*

(Enter your occupation - for example, pharmacist)

solemnly and sincerely declare that the statements made in the above Application are true and correct.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Note: Do not complete the following section until you are with the person witnessing your declaration.

Your signature

Declared at *(Place, for example town or city)*

(Day/month/year)

Before me *(Name of official witness)*

Signature of official witness

(For example, a Justice of the Peace, solicitor or another person authorised to take a statutory declaration).