

Responsible Persons (Pharmacy)

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This guidance outlines the Responsible Person role and defines their key responsibilities. The guidance applies to all pharmacy licence holders and applicants for a licence to operate pharmacy.

Who can be a Responsible Person?

A Responsible Person is:

- the pharmacist proprietor(s)¹ - note, if majority share capital and effective control of a company that operates a pharmacy is held by more than one pharmacist, all pharmacists must be appointed as Responsible Persons; or
- the pharmacy manager if the pharmacy is operated by a hospital; or
- an individual who is appointed to be in charge of a pharmacy business – see note below.

Note: Medsafe recognises that there are different types of pharmacy ownership. In particular, there are cases where a pharmacy may not be operated by a pharmacist or a company (for example, an administrator of the estate of a deceased pharmacist). In these cases, the licence holder must contact Medsafe for further guidance.

A Responsible Person must:

1. be a pharmacist² or a person authorised to hold a licence to operate pharmacy under the Medicines Act 1981; and
2. not have any additional conditions on their annual practising certificate (APC) that would prevent them from exerting appropriate control and supervision in the operation of the pharmacy. Any additional conditions on a pharmacist's APC will be considered by the Licensing Authority who must be satisfied that the pharmacist is able to exert appropriate control and carry out their duties as a Responsible Person; and
3. be able to demonstrate that they hold sufficient knowledge of the obligations of a licensee and of the hazards associated with medicines; and
4. not be subject to any disqualifications under the Medicines Act 1981, or any other convictions or offences that would deem them unfit to be a Responsible Person.

An individual may be a Responsible Person on more than one pharmacy licence.

¹ **Pharmacist proprietor** means a pharmacist who operates a pharmacy either as an individual or who holds majority share capital and effective control of a company operating a pharmacy.

² **Pharmacist** means a pharmacist who is registered with the Pharmacy Council of New Zealand and who holds a current annual practising certificate in the pharmacist or pharmacist prescriber scope of practice.

Responsibilities

A Responsible Person's responsibilities include, but are not limited to:

- overall responsibility of the day-to-day operations of the pharmacy
- ensuring that the pharmacy is operated in accordance with the duties and obligations in the Medicines Act 1981 and all other relevant statutory requirements
- ensuring that the pharmacy complies with the conditions of the licence
- ensuring that pharmacy services provided by the pharmacy are safe and appropriate, and are provided in accordance with the Code of Health and Disability Consumers' Rights
- ensuring that the pharmacy has appropriate and up-to-date procedures and policies in place for the provision of pharmacy services
- ensuring appropriate quality and risk management systems **are** in place for the operation of the pharmacy, including **for** all types of services delivered at that pharmacy
- ensuring that the pharmacy is suitably resourced, and that staff members are appropriately qualified or authorised to provide pharmacy services
- ensuring there is appropriate supervision of non-pharmacist staff providing pharmacy services
- the general security of the premises and pharmaceuticals held on the premises
- the maintenance at the premises of the required pharmacy equipment
- ensuring that adequate arrangements are made for the making, maintaining, and safekeeping of adequate records in respect of medicines that are manufactured, stored, packed, labelled, or sold on the premises
- ensuring ongoing compliance with the pharmacy quality audit framework
- holding a current APC with the Pharmacy Council of New Zealand, with no conditions that would impact on their ability to fulfil the responsibilities detailed in this guidance. A Responsible Person must notify the Licensing Authority immediately should a condition be imposed on their APC.

Pharmacist proprietors cannot delegate their professional obligations

A pharmacist proprietor who is a Responsible Person cannot delegate his or her professional obligations, even if they are not regularly present at the pharmacy.

If the pharmacist proprietor is not the pharmacist usually supervising pharmacy practice at the pharmacy, they must be able to demonstrate that they are actively involved and aware of the pharmacy practice being conducted at the premises, ensuring that it is operated in accordance with the conditions of the licence, and the duties and obligations in the Medicines Act 1981 and all other relevant statutory requirements.

If the pharmacist proprietor identifies that the pharmacy is not operated in accordance with professional and regulatory requirements, they must intervene, in a timely manner, to ensure that the pharmacy business is appropriately conducted.

Appointment of a Responsible Person

It is expected that the licence holder has had a discussion with, and sought permission from, an individual prior to appointing them as a Responsible Person.

When submitting an application for licence to operate pharmacy (including applications to amend a licence), the applicant is required to declare that the individuals nominated to be Responsible Persons have provided their explicit consent and hold the appropriate knowledge and qualifications to meet the requirements of a Responsible Person.

The appointment of a Responsible Person must be regularly reviewed by the licence holder to ensure that they continue to meet the requirements set out in this document, the Medicines Act 1981, and any relevant statutory requirements.

Changes to a Responsible Person(s)

Should an amendment to the Responsible Person(s) on a pharmacy licence be required, an application for amendment to the licence must be made to Medsafe. The application is required to be submitted by a pharmacist with effective control of the licensee (if the licence holder is a company) or an existing Responsible Person.

The licence holder is responsible for notifying Medsafe of any change in the details that relate to the application for that licence, including the Responsible Persons on the licence. Changes must be notified to Medsafe as soon as practicable.

Note: A company must immediately advise Medsafe if there are any changes in the ownership of the share capital of the company that means that more than 50% of the share capital is no longer owned by a pharmacist or pharmacists.

Contact Medsafe

Should you have any questions regarding pharmacy licensing, please contact the Medicines Control Branch (email medicinescontrol@health.govt.nz).