




The Pharmacy Regulator
An Rialtóir Cógaisíochta



PSI Guidance on
**Pharmacy
Governance
Roles**

The top half of the cover features a photograph of a pharmacist in a white coat and a customer in a yellow jacket. The pharmacist is holding a tablet, and the customer is holding a smartphone, both appearing to be in a pharmacy setting with shelves of products in the background. A large teal circular graphic is overlaid on the left side of this image, containing the title text.

Version: 1.0
February 2024

The bottom half of the cover features a photograph of a pharmacist in a blue uniform and a customer in a grey sweater. The pharmacist is holding a blue inhaler, and the customer is looking at it. They are sitting on a green armchair in a bright, modern pharmacy setting. The text 'Version: 1.0' and 'February 2024' is located in the bottom right corner of this section.

Content

Introduction

Background	2
Legal Basis	2
Purpose of this Guidance	2

Pharmacy Governance

Pharmacy Governance Roles	3
Pharmacy Governance Principles	4

Governance Roles and Responsibilities

Responsibilities for all Pharmacists	7
Responsibilities for Pharmacy Owners	9
Responsibilities for the Superintendent Pharmacist	11
Responsibilities for the Supervising Pharmacist	13
Supervising Pharmacist - Whole-Time Charge	15

Introduction

Background

Effective governance is an important aspect of all businesses and healthcare settings and is determined by the type of activity undertaken and the risks involved. As retail pharmacy businesses provide services that can carry significant risk, including the sale and supply of medicines, it is appropriate that specific governance roles have been set out in law to protect patients and the public. Pharmacists and those in pharmacy governance roles are responsible for providing consistent standards of safe and quality pharmacy services to patients and the public. One of the functions of the PSI as a regulator is to ensure that the law in relation to pharmacy governance is complied with.

To support compliance and provide clarity on pharmacy governance roles, PSI has developed this principle-based guidance on the responsibilities of those in governance roles and all pharmacists working in retail pharmacy businesses.

Legal Basis

The Pharmacy Act 2007 (as amended) (“the Act”) requires each retail pharmacy business to have nominated persons (or, in some cases, legal entities) acting in three specified governance roles. Regulations and rules made under the Act give further detail on the responsibilities associated with these roles. The statutory governance roles are:

- Pharmacy Owner
- Superintendent pharmacist
- Supervising pharmacist

In addition to the statutory governance roles, the Act and associated regulations require each pharmacy to have a registered pharmacist at the pharmacy to supervise the sale and supply of medicines. **Therefore, all pharmacists working in a retail pharmacy business are considered to have responsibilities in relation to pharmacy governance.**

Purpose of this Guidance

This guidance provides a principle-based outline of the governance responsibilities of the pharmacy owner, superintendent pharmacist, supervising pharmacist, and all pharmacists involved in the operation of a retail pharmacy business. As the focus of this guidance is on governance, it will not cover all responsibilities and should therefore be considered alongside the Pharmacy Act 2007 (as amended), pharmacy and medicines legislation, the PSI Code of Conduct, PSI guidance and guidelines, and all other relevant legislation. Where a pharmacy owner is a corporate body such as a limited company, the legislation under which the corporate body has been formed will also be relevant. Where the term “pharmacy” is used in this guidance, it refers to a retail pharmacy business as defined in the Act.

Pharmacy Governance Roles

Pharmacy governance involves those in the statutory governance roles working together with all pharmacists practising at the pharmacy to implement safe and compliant systems to consistently deliver safe, quality care for patients and the public.

These four roles form the four pillars of pharmacy governance.

Pharmacy Owner: A person (or corporate body) carrying on a retail pharmacy business who has **overall responsibility for ensuring the safe and compliant operation of the business**. The owner nominates a superintendent pharmacist and a supervising pharmacist.

Superintendent pharmacist: A pharmacist with three or more years of post-registration experience who has **overall responsibility for the management and administration** of the sale and supply of medicines from the pharmacy. A superintendent pharmacist can act for more than one pharmacy.

Supervising pharmacist: A pharmacist with three or more years of post-registration experience who is in whole-time charge (see section 3.4.1) and is **responsible for the day-to-day operation** of the pharmacy. A supervising pharmacist can only act for one pharmacy.

Pharmacist: A pharmacist who is registered with the PSI and governed by the principles and ethical standards of the PSI **Code of Conduct** (the Code).



Optimum pharmacy governance structures, acknowledge the roles of the pharmacy owners, superintendent pharmacists and supervising pharmacists in having a shared responsibility and accountability, operating in tandem and in partnership with PSI as the pharmacy regulator and regulatory structures designed by the Oireachtas to assure quality, safety and best outcomes for patients.

While the four pillars of pharmacy governance are essential, how they are arranged can vary between pharmacies. One person may be the owner, superintendent, and supervising pharmacist, or separate individuals may occupy these roles. An owner may be a pharmacist, partnership, representative, or a corporate body (such as a limited company) and own one or multiple pharmacies. The pharmacist(s), support staff, staff skill mix, and the services provided will also be unique to each pharmacy. Regardless of the specific arrangements, the same key governance principles apply to every pharmacy. Pharmacy governance is effective when all four pillars work together to ensure the **patient is at the centre of all decisions**.

Pharmacy Governance Principles

The responsibilities of those occupying pharmacy governance roles are derived from the Act, regulations, guidance, and standards. When the responsibilities are considered collectively, it becomes clear that there are four overarching governance principles:

Principle 1: Safe and compliant pharmacy systems with patients at the centre



The pharmacy owner and superintendent pharmacist establish systems and procedures to support the pharmacy in delivering safe, quality pharmacy services and patient-centred care. The supervising pharmacist puts these systems into action by ensuring they are followed on a day-to-day basis in the pharmacy. Operating within safe systems and procedures guides the pharmacy team to work in a way that puts the patient first and complies with legislation, guidance, standards, and the Code of Conduct.

Principle 2: Effective leadership, delegation, and clear accountability

The superintendent pharmacist and supervising pharmacist provide leadership at senior management level and day-to-day level. The owner provides the necessary staffing, environment, and resources and works with the superintendent pharmacist and supervising pharmacist to address any needs that arise. The superintendent pharmacist establishes clear roles and responsibilities for everyone at the pharmacy, meaning each member of the team knows what they are doing, who they report



to, and the standard expected. The supervising pharmacist oversees that the team fulfil their responsibilities. Everyone is accountable for their actions and inactions.

Principle 3: Managing risk and driving continuous improvement

The pharmacy owner supports the superintendent pharmacist and supervising pharmacist in establishing and implementing robust processes for identifying, assessing and managing risk, dealing with complaints, acting on medicine safety alerts, and driving the ongoing improvement of all aspects of services delivered. The supervising pharmacist monitors the operation of these processes on a day-to-day basis, and all pharmacists working at the pharmacy contribute effectively and equally. Working together, those in the governance roles embed an open safety culture where issues are discussed and reviewed with a focus on learning, improvement and prevention.



Principle 4: Competent pharmacy teams, acting with honesty and integrity

The pharmacy owner supports the superintendent pharmacist and supervising pharmacist to develop a pharmacy team with the skills, competence, and knowledge they need to deliver compliant, safe, and quality services. Pharmacists and team members identify their training needs, take action to address these needs and seek support when necessary. The pharmacy owner, superintendent pharmacist, and supervising pharmacist lead with integrity. Pharmacists are encouraged to use their professional judgment and make decisions in accordance with the Code of Conduct.



Governance Roles and Responsibilities

The pharmacy owner, superintendent pharmacist, supervising pharmacist, and all pharmacists working at the pharmacy have specific responsibilities under each of the four overarching principles of effective pharmacy governance. While some responsibilities may be shared across several roles, they apply at different levels depending on the nature of the role. For example, pharmacy owners will tend to have overall responsibility for ensuring the safe and compliant operation of the business; the superintendent pharmacist will be responsible at a management level, the supervising pharmacist will be responsible for the day-to-day operation of the pharmacy, and all pharmacists working at the pharmacy will be responsible for adhering to legislation, guidance, procedures, and the Code of Conduct in their practice. A person acting in a governance role can delegate aspects of their duties to another; however, responsibility for ensuring the task has been completed appropriately remains with the person in the governance role.

The four principles of pharmacy governance require all pharmacists and those in pharmacy governance roles to work collectively and collaboratively on a continual and consistent basis.

The sections which follow set out:

3.1 Responsibilities for all Pharmacists

3.2 Responsibilities for Pharmacy Owners

3.3 Responsibilities for Superintendent Pharmacists

3.4 Responsibilities for Supervising Pharmacists

Responsibilities for all Pharmacists

As a pharmacist working in a pharmacy, you will have core responsibilities in relation to pharmacy governance. These responsibilities apply to all pharmacists, including locums, those in supporting roles, and those who also hold statutory governance roles.



Principle 1: Safe and compliant pharmacy systems with patients at the centre

- 1.1 You follow the systems and procedures established at the pharmacy and lead the pharmacy team to do the same.
- 1.2 You supply medicines, deliver pharmacy services, and provide appropriate advice and counselling in line with legislation, guidance, and pharmacy procedures.
- 1.3 In your practice, you ensure the quality and integrity of all medicines being supplied. You verify medicines, check expiry dates, ensure appropriate licencing, and respond to medicine safety alerts and recalls.
- 1.4 You complete pharmacy records in line with the legislation, guidance, and procedures. You lead the pharmacy team to do the same.



Principle 2: Effective leadership, delegation, and clear accountability

- 2.1 Before providing services at the pharmacy, you ensure you are appropriately registered and fit to practise.
- 2.2 You are aware of your specific role, responsibilities, and accountability, and you take steps to clarify any uncertainty.
- 2.3 You communicate effectively and professionally and follow the pharmacy's communication and escalation processes.
- 2.4 You cooperate with those in governance roles, the PSI, and other bodies with statutory authority.
- 2.5 When working as the sole pharmacist at the pharmacy, you ensure the sale and supply of medicines, provision of services, and access to medicines and pharmacy records remain under your supervision. When working with other pharmacists, you ensure there is a clear understanding as to each individual pharmacist's roles and responsibilities.
- 2.6 Before leaving the pharmacy at any time other than when it is closing, you ensure another pharmacist has assumed responsibility, or alternatively, procedures approved by the superintendent pharmacist are put in place to ensure non-pharmacists (including members of staff) do not have access to the pharmacy except in the presence of a pharmacist.



Principle 3: Managing risk and driving continuous improvement

- 3.1 You follow and contribute to the pharmacy's risk management, quality improvement, and complaint handling processes, and you lead the pharmacy team to do the same.
- 3.2 Where you identify quality or risk issues, you take any necessary steps to resolve them and escalate them as appropriate to the supervising pharmacist.



Principle 4: Competent pharmacy teams, acting with honesty and integrity

- 4.1 You maintain the clinical skills and knowledge you need to fulfil your role in the pharmacy. You address your training needs and seek support when needed.
- 4.2 You practise within your competence and refer patients to others as appropriate.
- 4.3 You consider the competence of the pharmacy team working alongside you and delegate and supervise accordingly.
- 4.4 You take care to maintain your physical and mental wellbeing, and you take appropriate rest breaks while working in the pharmacy. You raise any concerns about your ability to perform your role with those in governance roles and the PSI where necessary.
- 4.5 You are open and honest, act with integrity, and take accountability for your actions and inactions.
- 4.6 You use your professional judgement and decision-making in your practice and do not allow targets or incentives to determine decisions on patient care.
- 4.7 You follow the Code of Conduct, practice in accordance with legislation, guidance, and practice standards, and put the patient's best interests at the centre of your decisions.

Responsibilities for Pharmacy Owners

As a pharmacy owner, you have **overall responsibility** for the governance and compliance of the pharmacy. You have **shared responsibility** with the superintendent pharmacist and supervising pharmacist for ensuring appropriate management, leadership, and accountability are established, and you have a **responsibility to support** the superintendent pharmacist and supervising pharmacist in discharging their duties.



Principle 1: Safe and compliant pharmacy systems with patients at the centre

- 1.1 You ensure the superintendent pharmacist develops clear, structured procedures for the pharmacy, which are specific, compliant with legislation and guidance, and establish safe systems of operation and service provision.
- 1.2 You ensure the supervising pharmacist implements the pharmacy procedures and oversees that staff are trained and competent to follow them.
- 1.3 You ensure the pharmacy is managed in a way that delivers the safe sale and supply of medicines, provision of patient counselling, and provision of other services, in line with legislation and guidance, and under the supervision of a pharmacist.
- 1.4 You ensure the pharmacy is managed so that medicines are sourced, stored, and disposed of in a safe and compliant manner. Medicines supplied by the pharmacy are verified, in-date, and appropriately licenced, and medicine safety alerts and recalls are received and actioned.
- 1.5 You ensure contingency plans have been developed to respond to issues affecting the pharmacy's operation and to support patients' continued access to care.
- 1.6 You ensure pharmacy records are maintained in compliance with legislation and guidance.
- 1.7 You ensure that where the pharmacy is involved in internet supply, veterinary medicines, residential care supply, vaccination services or any other additional services, these are conducted in line with legislation and guidance.
- 1.8 You maintain all aspects of the pharmacy's registration and notify the PSI of changes.



Principle 2: Effective leadership, delegation, and clear accountability

- 2.1 You appoint appropriately experienced and competent pharmacists to act as the superintendent pharmacist and supervising pharmacist for the pharmacy. You use succession planning to ensure the continuity of statutory governance roles.
- 2.2 You have overall responsibility for ensuring the pharmacy team are provided with the necessary staff, premises, procedures, and equipment required for the pharmacy to

deliver safe and effective patient-centred care and pharmacy services. You ensure rest breaks are facilitated for all staff.

- 2.3 You communicate regularly and effectively with the superintendent pharmacist and supervising pharmacist and ensure that effective communication procedures are in place in the pharmacy.
- 3.1 You respond to and resolve issues you are made aware of, including the appropriateness of staffing levels, staff training, and pharmacist cover at the pharmacy.
- 3.2 You cooperate with the PSI and other statutory bodies with relevant authorisation, and lead all those involved in the pharmacy to do the same.



Principle 3: Managing risk and driving continuous improvement

- 3.3 You maintain the pharmacy premises, equipment, and resources in accordance with legislation and PSI guidance, and you address any deficiencies that arise.
- 3.4 You ensure systems are established in relation to risk management, quality improvement and the handling of complaints.
- 3.5 You respond to and resolve any issues you are made aware of, including those in relation to risk management, safety issues, complaints, and quality improvement matters.
- 3.6 You support the superintendent pharmacist and supervising pharmacist in establishing an open and honest safety culture¹ in the pharmacy with a focus on learning for improvement.



Principle 4: Competent pharmacy teams, acting with honesty and integrity

- 4.1 You support pharmacists in the pharmacy to use their professional autonomy and judgement. You don't use targets or incentives which could adversely influence decisions affecting patient care.
- 4.2 You ensure the patient's best interests are at the centre of all decisions. You lead all involved in the pharmacy to do the same.

¹ A safety culture exists when issues relating to patient safety and staff are critically reviewed and discussed within a pharmacy team.

Responsibilities for the Superintendent Pharmacist

As a superintendent pharmacist, you have **specific statutory responsibilities**. You **control the management and administration** of pharmacy services and the sale and supply of medicines from the pharmacy/pharmacies, and you have overall control of the **professional and clinical policy management**.



Principle 1: Safe and compliant pharmacy systems with patients at the centre

- 1.1 You develop clear, structured procedures for the pharmacy, which are specific, compliant with legislation and guidance, and establish safe systems of operation and service provision.
- 1.2 You review, audit, and update procedures on an ongoing basis to ensure they remain reflective of the practices in the pharmacy and are in line with any relevant legislation and guidance.
- 1.3 You work with the supervising pharmacist to ensure procedures are implemented and followed at the pharmacy.
- 1.4 You put systems in place to ensure the sale and supply of medicines, provision of services, and provision of patient counselling at the pharmacy are carried out safely, in compliance with legislation and guidance, and under the personal supervision of a pharmacist.
- 1.5 You put systems in place to ensure medicines are sourced, stored, and disposed of in a safe and compliant manner. Medicines supplied by the pharmacy are verified, in-date, and appropriately licenced, and medicine safety alerts and recalls are received and actioned.
- 1.6 You develop a pharmacy contingency plan to respond to issues affecting the pharmacy's operation and to support patients' continued access to care.
- 1.7 You ensure pharmacy records are maintained in compliance with legislation and guidance, and you maintain any records relevant to you as the superintendent pharmacist.



Principle 2: Effective leadership, delegation, and clear accountability

- 2.1 You ensure pharmacy procedures provide all members of the team (including locum pharmacists) with clarity on their roles and responsibilities.
- 2.2 You ensure the staffing levels, skill mix, and level of pharmacist cover are sufficient for the services being provided at the pharmacy, bearing in mind busy periods and the provision of additional services. You ensure all staff are given appropriate rest breaks.

- 2.3 You review and resolve, where possible, any issues you are made aware of relating to staffing levels, training needs, resources, premises, or equipment. You escalate to the pharmacy owner where necessary.
- 2.4 You communicate regularly and effectively with the pharmacy owner and supervising pharmacist and develop effective communication and escalation processes for the pharmacy team (including locums).
- 2.5 You cooperate with the PSI and other statutory bodies with relevant authorisation and lead all those involved in the pharmacy to do the same.



Principle 3: Managing risk and driving continuous improvement

- 3.1 You develop systems to monitor and manage risks at the pharmacy, including the recording and investigation of near-misses and errors. You work with the supervising pharmacist to develop action plans to mitigate risks and prevent a recurrence.
- 3.2 You put systems in place to continually monitor the quality and compliance of pharmacy services, including conducting internal audits and self-assessments.
- 3.3 You put systems in place to manage complaints and concerns raised by patients, the public, pharmacy staff, other health professionals or organisations, including the PSI.
- 3.4 You review and resolve, where possible, any issues you are made aware of relating to risk management, safety issues, complaints, and quality improvement matters, and you escalate to the pharmacy owner where necessary.
- 3.5 You establish an open and honest safety culture in the pharmacy where staff are encouraged to discuss errors, incidents, and near-misses with a focus on learning for improvement.



Principle 4: Competent pharmacy teams, acting with honesty and integrity

- 4.1 You ensure staff have the knowledge, skills, and competence they need to perform their roles. You work with the supervising pharmacist to facilitate appropriate training and development to support staff to fulfil their role.
- 4.2 You exercise professional autonomy and professional judgement in your work and support other pharmacists at the pharmacy to do the same. You don't use targets or incentives which could adversely influence decisions affecting patient care.
- 4.3 You put the patient's best interests at the centre of all decisions. You lead all involved in the pharmacy to do the same.

Responsibilities for the Supervising Pharmacist

As a supervising pharmacist, you have specific **statutory responsibilities** and occupy a key governance role in the pharmacy. You are the pharmacist in **'whole-time charge'** and are **responsible for the day-to-day management and operation** of one pharmacy only.



Principle 1: Safe and compliant pharmacy systems with patients at the centre

- 1.1 You implement the pharmacy procedures by ensuring they are being followed on a day-to-day basis in the pharmacy. You therefore ensure that the pharmacy is operating in a safe and compliant manner and consistently delivering safe, quality care for patients and the public.
- 1.2 You ensure the pharmacy procedures remain reflective of the current practices in the pharmacy. You address any deviation from procedures by staff, and you advise the superintendent pharmacist of any changes in process at the pharmacy as they evolve.
- 1.3 You ensure that the sale and supply of medicines, provision of pharmacy services, and provision of patient advice and counselling at the pharmacy are carried out in line with legislation and guidance and under the personal supervision of a pharmacist.
- 1.4 You ensure medicines at the pharmacy are sourced, stored, and disposed of in a safe and compliant manner. Medicines supplied by the pharmacy are verified, in-date, and appropriately licensed, and medicine safety alerts and recalls are received and actioned.
- 1.5 You put the pharmacy's contingency plan into action when needed and ensure steps are taken to support patients' continued access to care.
- 1.6 You maintain the pharmacy record keeping in line with legal requirements. You maintain all records which require your input and lead others to do the same. You monitor, investigate, and address non-compliance.



Principle 2: Effective leadership, delegation, and clear accountability

- 2.1 You ensure all staff have a clear understanding of their specific roles and responsibilities. And you ensure they work in accordance with procedures which are relevant to them.
- 2.2 You monitor staffing at the pharmacy on a day-to-day basis to ensure the correct personnel (including pharmacists) and skills are available to support the safe provision of quality care for patients. You plan for busy periods and the provision of additional services. You ensure all staff (including pharmacists) are given appropriate rest breaks.
- 2.3 You communicate regularly and effectively with the superintendent pharmacist and pharmacy owner. You ensure effective communication and escalation processes are

being followed in the pharmacy by all members of the pharmacy team (including locum pharmacists).

2.4 You review and resolve, where possible, any issues you are made aware of, including those relating to staffing levels, training needs, resourcing, premises, and equipment, and you escalate to the superintendent pharmacist where necessary.

2.5 You cooperate with the PSI and other bodies with statutory authority and lead all those involved in the pharmacy to do the same.



Principle 3: Managing risk and driving continuous improvement

3.1 You monitor and manage risks at the pharmacy on a continual basis. You ensure near-misses, incidents and errors are recorded, investigated, and reviewed. You take action to mitigate risks and prevent recurrence and escalate to the superintendent pharmacist where necessary.

3.2 You continually monitor the quality and compliance of pharmacy services. You audit and assess performance against the relevant guidance and standards. Where improvements are needed, you develop action plans with specific objectives and timelines and escalate to the superintendent pharmacist where necessary.

3.3 You manage complaints and concerns raised at the pharmacy by patients, the public, pharmacy staff, other health professionals or organisations, including the PSI. You review complaints, gather relevant information, take any actions required, and escalate to the superintendent pharmacist where necessary.

3.4 You operate an open and honest safety culture by encouraging members of the pharmacy team to discuss errors, incidents, and near-misses with a focus on learning for improvement. You lead by example in discussing your own errors and near misses with the pharmacy team.



Principle 4: Competent pharmacy teams, acting with honesty and integrity

4.1 You ensure all staff are trained to follow pharmacy procedures and fulfil their roles, and you maintain records of staff training.

4.2 You monitor the ongoing competence and performance of pharmacists and staff to ensure they maintain the knowledge, skills, and competence needed for their role. Where deficiencies or development needs are identified, you arrange appropriate training and support. You escalate to the superintendent where necessary.

4.3 You exercise professional autonomy and professional judgement in your work and support other pharmacists at the pharmacy to do the same. You don't use targets or incentives which could adversely influence decisions affecting patient care.

4.4 You put the patient’s best interests at the centre of all decisions. You lead all involved in the pharmacy to do the same.

Supervising Pharmacist - Whole-Time Charge

While there is no specific definition of “whole-time charge” in pharmacy legislation, the nature of the role determines that the supervising pharmacist needs to be **practising in the pharmacy on a consistent and continuous basis during the pharmacy opening hours**. The supervising pharmacist, therefore, needs to work in the pharmacy on a **regular basis** so that they can effectively fulfil their responsibility to oversee the day-to-day operations and implement safe and compliant systems to consistently deliver safe, quality care for patients and the public. This is illustrated in Figure 1 below.

As all pharmacies vary, the PSI has not set a required minimum number of weekly hours for a supervising pharmacist to be present. Instead, a **risk-based decision** should be made by the pharmacy owner and the superintendent pharmacist as to what level of professional cover is to be provided by the supervising pharmacist. Consideration should be given to the views of the supervising pharmacist, the pharmacy opening hours, and any additional services provided. The decision should clearly support the provision of safe and quality pharmacy services for patients and the public, and the agreement should be documented by those involved.

In summary, whole-time charge entails the supervising pharmacist taking proactive steps to establish clear procedures, ensure safe and patient-centred practices, manage risks effectively, maintain a robust quality management system, and facilitate ongoing staff training and development to uphold high standards of pharmacy services, without requiring their physical presence on-site at all times.



Clear, structured procedures are consistently followed by the pharmacy team.



The day-to-day management of dispensing activity and pharmacy services are safe and patient-centred.



Risk management is an integral part of how pharmacy services are delivered.



Robust Quality Management System is in place.



Support staff training and ensure pharmacy team keep their knowledge and skills up to date.

Figure 1: ‘Whole-time charge’ responsibilities



The Pharmacy Regulator
An Rialtóir Cógaisíochta



Pharmaceutical Society of Ireland

PSI – The Pharmacy Regulator

PSI House, Fenian Street,
Dublin 2, D02 TD72

+353 1 218 4000

info@psi.ie

www.psi.ie