

**Background document to support the  
development of draft Governance and  
Accountability Standards for Retail  
Pharmacy Businesses**

## Contents

About the PSI .....	4
Our Role .....	4
Executive Summary.....	5
Chapter 1 – Introduction.....	7
1.1    Background .....	7
1.2    Methodology.....	8
1.3    Standards Development Process .....	9
1.4    Structure of this report .....	10
Chapter 2 –Summary of pharmacy specific international standards, guidelines and guidance documents .....	11
2.1    Australia .....	11
2.1.1 Guidelines for proprietor pharmacists .....	11
2.2    Canada .....	11
2.2.1 Professional Supervision of Pharmacy Personnel Policy .....	11
2.3    The United Kingdom .....	12
2.3.1 GPhC Standards for registered pharmacies.....	12
2.3.2 GPhC Guidance for responsible pharmacists .....	13
2.2.3 GPhC Guidance for owners and superintendent pharmacists who employ responsible pharmacists.....	13
2.3.4 GPhC Guidance to ensure a safe and effective pharmacy team .....	14
2.3.5 PSNI Standards and Guidance on the Responsible Pharmacist Regulations.....	14
2.3.6 RPS Professional Standards for Hospital Pharmacy Services .....	15
2.3.7 Supervision in Community pharmacy final report to Pharmacy Research UK .....	15
2.3.8 UK: Rebalancing Medicines Legislation and Pharmacy Regulation .....	16
2.4    Summary .....	16
Chapter 3 - Summary of non-pharmacy specific international standards, guidelines and guidance documents .....	19
3.1    Australia .....	19
3.1.1 National Safety and Quality Health Service Standard .....	19
3.1.2 National Model Clinical Governance framework .....	19
3.1.3 Enrolled Nurse Standards for Practice/Midwife Standards for Practice .....	20
3.2    Canada .....	21
3.2.1 Raising the Bar for Healthcare Governance and Leadership in Canada .....	21
3.2.2 <i>Qmentum</i> Programme Governance Standards .....	21

3.3	The United Kingdom .....	22
3.3.1	The NHS Foundation Trust Code of Governance.....	22
3.3.2	Well-led framework for governance reviews: Guidance for NHS foundation trusts	22
3.4	Summary .....	23
Chapter 4 - Summary of non- pharmacy specific national standards, guidelines and guidance documents .....		26
4.1	Health Information and Quality Authority (HIQA).....	26
4.1.1	National Standards for Safer Better Healthcare.....	26
4.1.2	National Standards for Special Care Units / National Standards for Residential Care Settings for Older People in Ireland / National Standards for Residential Services for Children and Adults with Disabilities.....	27
4.2	Health Service Executive (HSE) .....	28
4.3	Mental Health Commission.....	29
4.3.1	Quality Framework .....	29
4.4	TUSLA .....	29
4.4.1	Good Governance Framework.....	29
4.5	Summary .....	30
Chapter 5 – Conclusion .....		31
Appendix 1 – Criteria used to determine eligibility of evidence for inclusion .....		32
References .....		33

## About the PSI

The Pharmaceutical Society of Ireland (PSI) is a public body established in law to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland.

As the pharmacy regulator we set the standard for pharmacists' education and training in Ireland and create the standards and supports to promote good professional practice in pharmacy. We register pharmacists, pharmaceutical assistants and pharmacies, carry out inspections of pharmacies, and take action when there is a concern about a pharmacist or a pharmacy, including when we receive a complaint from a member of the public.

The PSI is an independent body and an agency of the Department of Health. We are governed by a 21 member [Council](#), with each of the members appointed by the Minister for Health.

## Our Role

### *Commitment to the Public*

Our principal function is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically and transparently.

The [Pharmacy Act 2007](#) (as amended) established the role and responsibilities of the PSI, which include:

- **Registration** of pharmacists, pharmaceutical assistants and pharmacies;
- **Setting standards for pharmacy education and training** at undergraduate and postgraduate level;
- Ensuring all registered pharmacists are undertaking appropriate **continuing professional development (CPD)**;
- **Promoting good professional practice** by pharmacists through raising standards and sharing information for the benefit of patients and the wider health system;
- **Assessing compliance and taking actions to address poor performance, practices and behaviours** through our inspection and enforcement functions, by **considering complaints** made against a pharmacist or a pharmacy, and through the imposition of sanctions;
- **Providing advice, support and guidance** to the public, pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.

## Executive Summary

The PSI's Corporate Strategy 2018-2020 sets out the PSI's intention to review whether governance and management structures within retail pharmacy businesses are working to protect the public, and defining, with stakeholders, the high standards of leadership and accountability that must be practised by those holding key governance positions. As part of this review, PSI Council approved a proposal to develop a standards-based approach to guideline development for retail pharmacy businesses.

This document sets out the findings of a review undertaken to inform the development of Draft Governance and Accountability Standards for Retail Pharmacy Businesses. The purpose of the standards is to develop a framework for best practice in providing person-centred, safe and effective care in Irish pharmacies, through clear governance and accountability mechanisms. The documents reviewed in this background document focus on international standards, guidelines and any guidance that specifically address governance and accountability in pharmacy services, healthcare services and other relevant areas.

The document is divided into five chapters. Chapter 2 provides an overview of pharmacy specific international standards, guidelines and guidance documents. Countries such as Australia, Canada and UK were looked at in detail. Chapter 3 looks at international documentation more broadly, examining non-pharmacy related areas. Publications by the National Safety and Quality Health Service in Australia, the Canadian College of Health Leaders and the NHS Foundation Trust in the UK were considered. The work of Irish organisations such as HIQA, HSE, Mental Health Commission as well as TUSLA are also reviewed in Chapter 4 to provide a holistic view of best practice in the area of good governance and accountability.

The findings across all the chapters were broadly similar and will be used to help inform the draft standards. Where information was not readily available, or deficiencies within specific sections were identified, the opinion and advice of pharmacists and patients was sought during focus group meetings.

Overall a consistent approach to governance and accountability was presented. The review found that for pharmacies to demonstrate effective governance arrangements with clear leadership and lines of accountability, standards should:

- Ensure pharmacies perform their functions as outlined in the relevant legislation, regulations and national policies and standards to protect the health safety and well-being of people using pharmacy services
- Ensure pharmacies have effective leadership, governance and management arrangements in place with clear lines of accountability
- Ensure the safe delegation of tasks to appropriately trained staff
- Encourage communication between all those in leadership positions in the pharmacy, so that all reasonable steps to clarify any ambiguities or uncertainties between pharmacy owners, superintendent pharmacist, supervising pharmacists or other pharmacists regarding their roles are taken
- Encourage the development of clinical governance frameworks in pharmacies at a local level so that local needs, local values and the local context are considered when pharmacies develop and implement their governance systems
- Encourage partnership between, patients, clinicians and pharmacists in implementing effective clinical governance systems in a pharmacy
- Foster a culture of safety and ensure that decisions made in the pharmacy are based on research, evidence and ongoing quality improvement
- Ensure that formal and transparent arrangements are in place in pharmacies for reporting errors and managing risk
- Ensure that high standards of behaviour are demonstrated in pharmacies towards patients
- Encourage the implementation of good practices in transparency, reporting, communications, audit and scrutiny so that effective accountability is delivered.

## Chapter 1 – Introduction

### 1.1 Background

One of the roles of the PSI is to promote good professional practice by pharmacists through raising standards. One of the ways the PSI fulfils this role is by producing guidelines<sup>1</sup> to support pharmacists and pharmacy owners in complying with pharmacy and medicines legislation and to provide a safe and effective service to patients. All guidelines produced by the PSI are available on the PSI's [website](#).

At the June 2018 Council meeting, PSI Council approved a proposal to develop a standards-based approach to guideline development for retail pharmacy businesses. This is in line with commitments set out in the PSI Corporate Strategy 2018-2020<sup>2</sup> and follows positive discussions about this approach to regulation with superintendent pharmacists at 11 regional seminars held during springtime 2018<sup>3</sup>. In particular, the proposed standards-based guidelines will enable pharmacists to comply with Regulation 5 of S.I. 488 of 2008; *Management and Supervision of a Retail Pharmacy Business*.

A standards-based approach to guideline development will differ from the format of PSI guidelines issued to date, in that they will provide concise, outcome-focused statements against which a service provider will establish and deliver their service. This new approach can be used to monitor and improve practice and will provide a framework to enable the provision of safe, effective and consistent services and high-quality care to patients and members of the public.

As standards are focused on the outcomes achieved, they enable the service provider, in this case the healthcare setting of a Retail Pharmacy Business, to meet the requirements of the standards in a range of different ways.

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<sup>1</sup> [Regulation 14](#) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) (SI 488/2008) provides that the PSI Council may publish detailed guidelines for the purpose of facilitating compliance with these Regulations.

<sup>2</sup> Strategic Results Area 1 - Action 7 of the [PSI's Corporate Strategy 2018-2020](#) sets out the PSI's intention to review whether governance and management structures within retail pharmacy businesses are working to protect the public, and defining, with stakeholders, the high standards of leadership and accountability that must be practised by those holding key governance positions. This accountability framework will apply to supervising and superintendent pharmacists as well as those responsible for the overall governance of pharmacy businesses, for example the boards of corporate entities.

<sup>3</sup> A [Report on the Seminars for Superintendent Pharmacists](#) is available on the PSI website.

Outcome focused standards are particularly suited to the setting of Retail Pharmacy Businesses which vary in size, have differing management structures (e.g. independent or chain), as well as providing differing types of services depending on their location and patient/customer needs. Standards also provide assurance for patients and members of the public about what they can expect when they engage with the healthcare setting of a retail pharmacy business. It is expected that this new approach to guideline development will avoid a prescriptive, one-size-fits-all approach and ensures that the standards do not stifle innovation.

## 1.2 Methodology

As part of the process of developing these draft standards, the PSI Project Team carried out a comprehensive desktop review. The purpose of carrying out this research was to identify relevant published international and national literature on standards and on the topic of governance and accountability in Retail Pharmacy Businesses (RPBs). The search approach focussed on an in-depth review of the available literature<sup>4</sup> and grey literature<sup>5</sup> on the topic. This included analysis of relevant standards, guidance, reports, audits, reviews, relevant studies, government guidance and regulatory and professional body publications, from both national and international sources. All search results produced had inclusion and exclusion criteria applied to them to determine their suitability to be included in the review. These are documented in Appendix 1.

A targeted search of evidence-based databases was undertaken. To ensure that the most relevant sources and related documents were found, a series of keywords and phrases, both general topic-related and setting-specific, were used for the searches. Where appropriate, a series of filters such as evidence type and/or date of publication were also used to ensure that the most relevant material on governance and accountability standards in pharmacies was found. Although the searches yielded a large number of results, only appropriate and relevant literature was included in this review. The majority of the literature that was used in the review was identified through hand searching relevant and authoritative international and national websites.

All of the information obtained will be analysed and used to inform the content of the standards.

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<sup>4</sup> Literature in this context refers to peer reviewed and published research and articles.

<sup>5</sup> Grey literature in this context refers to information and research that is not commercially published, for example newsletters, government reports and policy statements.



### 1.3 Standards Development Process

This section sets out the process to be followed when developing PSI standards. It was created following engagement with the Health Information and Quality Authority (HIQA) and closely aligns with their established process to develop national standards for health and social care<sup>6</sup>.

Best practice would indicate that standards are most successful if they are created through a collaborative approach involving different stakeholders, including:

- (i) The regulating body developing the standards,
- (ii) The service providers,
- (iii) Users of the service and
- (iv) Relevant independent experts.

To enable the stakeholders to feed into the development process from an early stage, a Standards Advisory Group comprising key stakeholders, including those from the pharmacy sector and patient groups, together with independent experts, has been convened. The Standards Advisory Group will use their expertise to guide and inform the work of the PSI project team in the development of standards to ensure that they are useful, practical and meet their objective.

A scoping consultation is also carried out at an early stage of the process to provide an opportunity for stakeholders to:

- (i) Identify the key issues that should be addressed by the standards,
- (ii) Provide experiences of using related services and examples of best practice, and
- (iii) Raise awareness of the development of standards in this area.

Focus groups, 1:1 interviews and public consultations are used at relevant points throughout the process to gather insight and comments from a wide audience and test the standards before publication. Further information on the standards development process as well as the Standards Advisory Group, is available on the [PSI website](#).

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<sup>6</sup> [HIQA's process for development of national standards](#) was developed following a review of national and international evidence, engagement with national and international experts and applying HIQA's knowledge and experience of the health and social care context.

## 1.4 Structure of this report

This document sets out the findings of the literature review conducted to inform the development of the standards. An overview of the content of each chapter is provided below:

- Chapter 2: focuses on international standards and any associated guidelines or guidance on governance and accountability specifically in the pharmacy setting
- Chapter 3: focuses on international standards and any associated guidelines or guidance on governance and accountability in healthcare and other settings
- Chapter 4: focuses on Irish non-pharmacy specific standards and any associated guidelines or guidance on governance and accountability in healthcare and other settings

## Chapter 2 –Summary of pharmacy specific international standards, guidelines and guidance documents

### 2.1 Australia

#### 2.1.1 Guidelines for proprietor pharmacists

The Pharmacy Board of Australia is the registering and regulating body for the profession of pharmacy in Australia. The functions of the Pharmacy Board of Australia amongst others include developing standards, codes and guidelines for the pharmacy profession. In 2015 they published The Guidelines for Proprietor Pharmacists<sup>1</sup>. These guidelines have been developed to provide guidance to pharmacists in relation to the professional responsibilities of pharmacy proprietors, not set out in the legislation or a registration standard. They focus on the professional responsibilities of proprietor pharmacists that impact on the safe, effective delivery of services to the public. They must maintain, and be able to demonstrate an awareness of, the manner in which that pharmacy business is being conducted, and where necessary, intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines. The guidelines state that if the proprietor is not the pharmacist usually in charge of that pharmacy, he or she must vigilantly maintain an active interest in how the practice of pharmacy is being conducted and cannot delegate their professional responsibilities. Part three of the guidelines lists the responsibilities to ensure the pharmacy business is conducted properly. It outlines how proprietors can do this by ensuring that the pharmacists they employ are complying with and adhering to legislation, appropriate risk management procedures are in place, confidential patient information is secure, and that the pharmacy is suitably resourced. Successful implementation of this is supported by the development, by each pharmacy, of policies and procedures for all services provided by the pharmacy, as well as those relating to occupational health and safety. All such policies are documented and available within the pharmacy for all staff to access and follow.

### 2.2 Canada

#### 2.2.1 Professional Supervision of Pharmacy Personnel Policy

The Ontario College of Pharmacists (OCP) is the registering and regulating body for the profession of pharmacy in Ontario. Its directive is to serve and protect the public and hold Ontario's pharmacists and pharmacy technicians accountable to the established legislation, standards, code of ethics and guidelines. In 2011 they released a policy paper titled Professional Supervision of Pharmacy

Personnel<sup>2</sup>. This policy was produced to clearly explain the responsibilities of the designated manager (DM) with respect to pharmacy personnel supervision. The DM is the pharmacist designated by the owner of the pharmacy as the practitioner responsible for managing the pharmacy.

The DM has the same professional practice obligations as all registered pharmacists, and in addition to these, the DM has authority and accountability over decisions affecting the operation of a pharmacy. It is the responsibility of the DM to effectively oversee the day-to-day management of the pharmacy. The DM's human resources responsibilities are both functional and strategic. For example, not only must the DM establish job descriptions and a performance measurement and improvement system for pharmacy employees, but the DM must also ensure that, at all times, staffing in the pharmacy supports the pharmacist(s) in their cognitive and patient care functions. As inter-professional care expands, this responsibility includes ensuring that the pharmacist has sufficient support to collaborate as needed with other health professionals.

## 2.3 The United Kingdom

### 2.3.1 GPhC Standards for registered pharmacies

The Standards for Registered Pharmacies<sup>3</sup> were revised by the General Pharmaceutical Council (GPhC) in June 2018. The GPhC registers and regulates pharmacists, pharmacy technicians and pharmacy premises in Great Britain. The standards for registered pharmacies were developed to create and maintain an environment, both organisational and physical, for the safe and effective practice of pharmacy. The purpose of the standards is to ensure pharmacy owners are responsible and accountable for making sure the standards are met to ensure the safe provision of pharmacy services irrespective of the ownership structure in place. How these standards can be met depends on the individual pharmacy and all staff must be aware of them. All the standards are grouped under five principles, these are;

- The governance arrangements safeguard the health, safety and wellbeing of patients and the public.
- Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.
- The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

- The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.
- The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

### 2.3.2 GPhC Guidance for responsible pharmacists

The Guidance for Responsible Pharmacists<sup>4</sup> is designed to provide guidance to pharmacists who are designated as the “responsible pharmacist” in charge of a registered pharmacy. The document outlines the legal and professional responsibilities of a responsible pharmacist to ensure that the pharmacy does not present a risk to the level of care provided to patients. It is divided into five main sections;

- Securing the safe and effective running of the registered pharmacy,
- Displaying the notice,
- The pharmacy record,
- Pharmacy procedures, and
- Absence

Each section is explained clearly, and a list is provided of what must be done by the responsible pharmacist in relation to the section in question. For example under the “securing the safe and effective running of the registered pharmacy” responsible pharmacists are reminded that they must establish the scope of the role and responsibilities they have as the responsible pharmacist and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacy owner, superintendent pharmacist or other delegated person.

### 2.3.3 GPhC Guidance for owners and superintendent pharmacists who employ responsible pharmacists

This guidance<sup>5</sup> published by the GPhC recognises the need to provide guidance to owners and superintendent pharmacists on what they need to do when they employ a responsible pharmacist. It specifically only relates to responsibilities in relation to the responsible pharmacist regulations and does not cover other duties and obligations. The focus of this document is on what must be done when appointing and supporting the responsible pharmacist including their competency and the need to support them in complying with legal and professional duties. The second part of this

document examines the pharmacy record which records the responsible pharmacist who is working at a specific date and time.

#### 2.3.4 GPhC Guidance to ensure a safe and effective pharmacy team

More recent guidance published by the GPhC provides Guidance to Ensure a Safe and Effective Pharmacy Team<sup>6</sup>. This guidance is aimed at pharmacy owners and outlines what they should do to ensure a safe and effective pharmacy team, (where team refers to staff both registered and unregistered with the GPhC). Unregistered staff do not have the same responsibilities as registered pharmacists/technicians but the GPhC expects them to meet training requirements specific to their role to help ensure safe and effective care for patients. It is designed to be read in conjunction with the GPhC Standards for Registered Pharmacies and the GPhC Inspection Decision Making Framework. It clearly states that the pharmacy owner is responsible for ensuring the guidance is followed by staff. The guidance sets out the responsibilities of pharmacy owners when it comes to accountability, leadership and management of the pharmacy team. The guidance recognises that each pharmacy is unique in its service provision and patient profiles, however puts an onus on the pharmacy owner to ensure that staffing numbers and staffing skill mix are appropriate to ensure that all customers receive safe and effective care from the pharmacy. Ways to do this that are suggested in this guidance include risk assessments, contingency plans, training, recording and learning from errors. It also sets out the responsibility of the pharmacy owner to make sure that the personnel in leadership and management positions meet all professional and legal obligations so that safe and effective pharmacy services are maintained.

#### 2.3.5 PSNI Standards and Guidance on the Responsible Pharmacist Regulations

The Pharmaceutical Society of Northern Ireland (PSNI) is the regulatory body for pharmacists in Northern Ireland. The PSNI does not regulate the pharmacy premises. In 2016 the PSNI published standards and guidance on the responsible pharmacist regulations<sup>7</sup>. The Health Act 2006 requires each registered pharmacist premises to have a responsible pharmacist in charge in order to operate lawfully (the one pharmacy/one pharmacist rule). The Act requires the responsible pharmacist to secure the safe and effective running of the pharmacy at all times. This document covers three areas for responsible pharmacists:

- Their legal obligations,
- Mandatory Professional Standards
- Their Good Practice Guidance

The standards state that the pharmacist must ensure there is clarity around roles and responsibilities of all staff and to make sure everybody works under the correct supervision within their competency. This guidance looks at the role of the responsible pharmacist in establishing, maintaining and reviewing the procedures in place, which forms part of the quality framework of the pharmacy.

### 2.3.6 RPS Professional Standards for Hospital Pharmacy Services

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain, representing all sectors of pharmacy in Great Britain. The Professional Standards for Hospital Pharmacy<sup>8</sup> were revised in December 2017 to provide a broad framework to help support pharmacists and pharmacy teams to continually improve services, shape future services and roles, and deliver high quality patient care within hospital pharmacies. The document is structured into eight overarching standards grouped into three domains, each standard is defined by dimensions and statements that describe what a quality service should deliver. The third domain is composed of standards examining leadership, systems governance, financial management and workforce. The leadership standard is further subdivided into four dimensions. The first dimension looks at the professional aspect of pharmacy leadership, linking pharmacists' actions and positive patient outcomes. The second dimension of the leadership standard focuses on the strategic element of leadership, demonstrating approaches pharmacists can adopt to ensure a clear vision of pharmacy services and medicine management. The final two aspects of leadership examined are operational and clinical leadership. These four dimensions are supported by example statements providing a clear explanation on how different elements of leadership can contribute to a safe and effective pharmacy service. The seventh standard advocates for the establishment of systems of work that are safe, productive, support continuous quality improvement, are regularly audited and comply with relevant regulations.

### 2.3.7 Supervision in Community pharmacy final report to Pharmacy Research UK

The Supervision in Community Pharmacy report<sup>9</sup> was produced by Manchester University and published in 2013. One of its aims was to investigate arrangements for supervision, role delegation and skill mix in community pharmacy. It also looked at investigating potential future arrangements and perceived requirements for pharmacy team composition and role delegation with varying levels of supervision. The study compared and contrasted insights from four groups of pharmacy personnel, pharmacists and pharmacy support staff working in community and hospital pharmacy using both qualitative and quantitative methods. It was found that respondents felt that if the

requirements for supervision are to be reviewed, it is important that it is clear which activities can/cannot safely be performed by different staff members. The study identified activities which respondents felt could be carried out in a pharmacist's absence when assessed against the risk associated with that activity. These activities were broken down into three categories; safe, borderline and unsafe. The various components of the dispensing process and over the counter medication sales were examined in detail to identify these activities and then categorise them. A key finding from this study was that if an alternative supervision model is to be developed in pharmacies, there will need to be clarity on which pharmacy support staff can perform an activity which is not under the control of a pharmacist.

### 2.3.8 UK: Rebalancing Medicines Legislation and Pharmacy Regulation

In 2017, as part of an ongoing UK project overseen by a governmental programme board, a consultation was issued on behalf of the four UK health departments looking at potentially rebalancing medicines legislation and pharmacy regulation<sup>10</sup>. The consultation focussed on the organisational governance arrangements for registered pharmacies specifically looking at the roles of superintendent pharmacists and responsible pharmacists (categories of pharmacists as defined in UK legislation). UK legislation currently frames these two roles as being distinct, with differing levels of responsibilities attributed to each, however both roles can be performed by the same person. It was suggested that this was giving rise to confusion. The proposals in this consultation aimed to address this issue and to define and clarify the scope and core purpose of both roles. The consultation also examined the responsibility and accountability of both sets of roles from both an organisational and professional standpoint. One of the main areas where clarification was sought was the relationship in place between pharmacy owners, responsible pharmacists and superintendent pharmacists and the associated accountability framework in place, to ensure a safe and effective pharmacy service is delivered to patients. At the end of the consultation document opinions were sought from respondents on whether there was merit in increasing the involvement of the UK pharmacy regulators in defining both roles and responsibilities of the various people in leadership positions in RPBs. As of March 2019 the board was still considering the responses to the public consultation.

## 2.4 Summary

The review of *pharmacy specific* international standards guidelines and guidance documents demonstrates that many jurisdictions have addressed or are endeavouring to address the



governance arrangements in place in retail pharmacy businesses. The core tenet to each of the documents is that the health safety and wellbeing of the public is protected at all times. In Australia, the Guidelines for Proprietor Pharmacists focuses on the professional responsibilities of proprietor pharmacists and outlines that pharmacists must be able to demonstrate an awareness of the way in which that pharmacy business is being conducted, and where necessary, intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines. More detailed descriptors of the governance arrangements needed to be in place to safeguard the health and safety of the public, is described in the GPhC Standards for Registered Pharmacies. These standards outline the responsibilities of pharmacy owners to ensure pharmacy staff are competent and empowered so that they can meet the needs of patients, as well as their responsibilities in safeguarding the health environment and premises of the pharmacy. Further detail is provided for pharmacy owners, regarding the systems that need to be developed for the general operation and management of the pharmacy and for risk mitigation. The importance of an appropriately trained workforce in the pharmacy is highlighted in the GPhC's Guidance to Ensure a Safe and Effective Pharmacy Team. This guidance acknowledges that unregulated staff do not have the same responsibilities as registered staff (i.e. pharmacists) but the guidance puts an onus on the pharmacy owner to ensure that staffing numbers and staffing skill mix are appropriate to ensure that all customers receive safe and effective care from the pharmacy. Ways to do this that are suggested in this guidance include risk assessments, contingency plans, training, recording and learning from errors.

Focussing on hospital pharmacy, the RPS's Professional Standards for Hospital Pharmacy examine the leadership arrangements, governance systems, financial management and workforce planning that need to be in place to support a safe healthcare environment. Safe delegation of tasks to appropriately trained staff was highlighted by both community and hospital pharmacists in the qualitative analysis provided in the Supervision in Community Pharmacy report.

Of particular relevance to the Irish context, where pharmacy legislation refers to pharmacy owners, superintendent pharmacists and supervising pharmacists, the UK-wide Rebalancing Medicines Legislation and Pharmacy Regulation project, focussed on the organisational governance arrangements for registered pharmacies, specifically looking at the roles of superintendent pharmacists and responsible pharmacists. UK legislation currently frames these two roles as being distinct, with differing levels of responsibilities attributed to each, however both roles can be performed by the same person. This project aims to clarify the relationship in place between pharmacy owners, responsible pharmacists and superintendent pharmacists. The potential

confusion regarding pharmacists' roles (as defined in legislation) was also examined by the Ontario College of Pharmacists (OCP), who produced a policy titled Professional Supervision of Pharmacy Personnel, which outlined the additional responsibilities of the 'designated (pharmacist) manager', who is appointed by the pharmacy owner as the practitioner responsible for managing the pharmacy. The GPhC Guidance for Responsible Pharmacists also aims to provide guidance to pharmacists who are designated as the "responsible pharmacist" in charge of a registered pharmacy. In addition to their regular responsibilities, responsible pharmacists are reminded that they must establish the scope of the role and responsibilities they have as the responsible pharmacist and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacy owner, superintendent pharmacist or other delegated person.

## Chapter 3 - Summary of non-pharmacy specific international standards, guidelines and guidance documents

### 3.1 Australia

#### 3.1.1 National Safety and Quality Health Service Standard

The National Safety and Quality Health Service (NSQHS) Standards<sup>11</sup> were developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in collaboration with the Australian Government and other stakeholders in 2017. The Commission works in partnership with patients, consumers, clinicians, managers, policy makers and healthcare organisations to achieve a sustainable, safe and high-quality health system. The primary aims of these Standards are to protect the public from harm and to improve the quality of health service provision. There are eight Standards, which describe the patient care journey and are designed to be implemented in an integrated way. The standards aim to provide a nationally consistent statement about the standard of care consumers can expect from their health service organisations. Each standard contains, a description of the standard, a statement of intent, a list of criteria that describe the key areas covered by the standard, explanatory notes on the content of the standard, item headings for groups of actions in each criterion and actions that describe what is required to meet the standard. The first standard describes the clinical governance, and safety and quality systems that are required to maintain and improve the reliability, safety and quality of health care, and improve health outcomes for patients. It ensures that everyone is accountable to patients and the community for assuring the delivery of health services that are safe, effective, integrated, high quality and continuously improving. This standard outlines the importance of establishing and using clinical governance systems within organisations to improve the safety and quality of health care for patients.

#### 3.1.2 National Model Clinical Governance framework

The National Model Clinical Governance Framework<sup>12</sup> was published by the Commission in 2017 to ensure that patients receive safe and high-quality health care. The framework describes the elements that are essential for acute health service organisations to achieve integrated corporate and clinical governance systems. Through these systems, organisations and individuals are accountable to patients and aim to continuously improve the safety and quality of their services. This framework builds on the NSQHS Standards (discussed above), looking in more detail at corporate and clinical governance, and roles and responsibilities for people working in a health

service organisation. As with the NSQHS Standards this framework does not specify how a clinical governance system should be developed or implemented. Instead it outlines the mechanisms of a clinical governance framework to enable the development and implementation of governance systems, considering local needs, values and the context in which services are provided. It can be used to support effective clinical governance and improve the safety and quality of care. Even though it is ultimately the responsibility of a managing board/governing body to set up a robust clinical governance system and be accountable for outcomes and performance within this system, contributions by individuals and teams at all levels of the organisation was deemed vital for ensuring successful implementation of such a framework. The five components of the Clinical Governance Framework are:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care
- Partnering with consumers

This document discusses in detail factors which have been identified as being important for sustaining a culture that ensures safe and high-quality care. These include a strong and strategic leadership of clinical services, clear responsibilities for managing the safety and quality of care, and delegation of the necessary management authority for this purpose, reliable processes for ensuring that systems for delivery of care are designed and performing well, effective use of data and information to monitor and report on performance and finally well-designed systems for identifying and managing clinical risk. The framework states that implementation of a successful governance system involves contributions by individuals and teams at all levels of the organisation. The roles and responsibilities of, and essential partnership between, patients and consumers, clinicians, managers, and governing board in implementing effective clinical governance systems is outlined in each of the five components of the framework. By ensuring that people are aware of these roles, everybody is held accountable for their contribution to the safety and quality of care delivered to patients

### 3.1.3 Enrolled Nurse Standards for Practice/Midwife Standards for Practice

The Nursing and Midwifery Board of Australia has published 2 sets of standards for nurses that were analysed as part of the research; the Enrolled Nurse Standards for Practice<sup>13</sup> and Midwife Standards

for Practice<sup>14</sup>. Both sets of standards provide a framework for practice in all contexts. They also inform patients and those who regulate, educate and manage nurses and midwives what to expect from a nurse's practice. Each standard has indicators listed below it which are indicative of how that standard is demonstrated. These are designed to be interpreted in the context of individual practice settings. They are not intended to be exhaustive and are designed to enable, rather than limit the development of practice. These standards encompass all competencies expected of a registered nurse/midwife. Both sets of standards contain a standard dedicated to accountability. The indicators listed are examples of activities that demonstrate accountability resulting in a better standard of patient care.

## 3.2 Canada

### 3.2.1 Raising the Bar for Healthcare Governance and Leadership in Canada

The Canadian College of Health Leaders (CCHL), is an association dedicated to ensuring that Canada's health system benefits from capable, competent and effective leadership. A presentation titled "Raising the Bar for Healthcare Governance and Leadership in Canada"<sup>15</sup> examines a framework that aims to represent the key skills, abilities, and knowledge required to lead at all levels of the health system in Canada. The pillars of the framework are:

- Lead Self
- Engage Others
- Achieve Results
- Develop Coalitions
- System Transformation

It also examined governance and leadership standards and why they are important. The framework recommends that the role and remit of governing board versus senior management should be clearly defined, that a culture of safety should be fostered and that decisions are made based on research, evidence and ongoing quality improvement.

### 3.2.2 *Qmentum* Programme Governance Standards

The *Qmentum* Programme Governance Standards<sup>16</sup> were developed by Accreditation Canada's affiliate, the Health Standards Organisation (HSO). Accreditation Canada work with healthcare providers, policy makers and the public to improve the quality and safety of health services. The standards were developed to assist healthcare organisations in meeting demands for excellence in

governance practice and the increasing need for public accountability. There are thirteen standards listed in the document, grouped into four sections. Like previous standards examined they are not intended to be prescriptive and it is acknowledged that the approach of different organisations will be unique in how they implement the standards. Each standard is followed by a guideline description of it and how the organisation can achieve it. The first section of the standards addresses in detail how organisations can function effectively by having a clear governing structure, with the roles and responsibilities of staff clearly demarcated. They describe how the management team of any organisation must have defined roles and responsibilities and a defined and formal process for decision making. The final grouping of standards outlines how organisations can ensure accountability, drive quality improvement, manage risks and achieve sustainable results.

### 3.3 The United Kingdom

#### 3.3.1 The NHS Foundation Trust Code of Governance

The National Health Service (NHS) published a Code of Governance which was updated in 2014<sup>17</sup>. This Code of Governance aims to provide guidance for healthcare providers in implementing an effective corporate governance structure which will contribute to better organisational performance and ultimately a better service for patients. The Code expects that management boards successfully lead their organisations so that decision-making is effective, and the right outcomes are delivered. The Code expects that healthcare managers ensure a safe, effective services in a caring and compassionate environment in a way that is responsive to the changing needs of patients. The document is divided into five sections. Section A and C look at leadership and accountability respectively. Like other standards examined this code is not intended to be prescriptive, instead it sets out best practice principles, structures and processes which can be adapted by the individual provider. The Leadership section sets out in detail the role and leadership functions of the board of directors, the chairperson, non-executive directors and governors. Section C examines what arrangements should be put in place to allow for effective accountability, decision-making, and risk management and performance assurance. The Code also outlines that formal and transparent arrangements should be in place for reporting, risk management, internal control principles and for maintaining an appropriate relationship with auditors.

#### 3.3.2 Well-led framework for governance reviews: Guidance for NHS foundation trusts

In line with the NHS Code of Governance, the Well-Led Framework for Governance Reviews was updated in 2015<sup>18</sup>. The purpose of conducting a governance review of NHS foundation trust boards

is to ensure the trust is addressing any challenges it faces, assuring the current governance structures are fit for purpose and there is no poor practice occurring. The framework is designed to represent a 'core' reference for NHS foundation trusts to structure reviews of their governance mechanisms. It is designed to be flexible in such a way that individual trusts can tailor the areas for investigation through the self-assessment and initial review team findings at the start of the process. It is intended to be used as a guide and not a prescriptive "box-ticking" exercise to review governance within the organisation. The framework has four domains, ten high level questions followed by 'good practice' outcomes and evidence base. These can be used to assess governance.

The four domains are;

- Strategy and planning
- Capability and culture
- Process and structures
- Measurement

The strategy and planning domain challenges the trust board to examine how effectively it is setting the overall strategic direction for the trust, while being cognisant of any potential risks. The second domain addresses the board's experience and ability to positively shape the working culture in the trust to deliver care in a safe and sustainable way. Accountability and reporting lines are examined in the third domain by questioning the effectiveness of the board's processes and the structures that are in place. Finally, the governance review asks the board to question their mechanisms for collating information and data and to interrogate such data if appropriate to support the leadership of the trust in making decisions. Annex one of the document sets out examples of good practice for each domain and the associated questions that should be asked by board members when undertaking a governance review. This document also provides practical advice on how to conduct a governance review, from how often they should be carried out to the steps involved. To further aid boards in using this document to its full potential the document provides an indicative scoring criteria and examples of evidence types that can be used to assist with overall judgements.

### 3.4 Summary

The review of non-pharmacy specific international standards guidelines and guidance documents highlights the ongoing work in the area of governance in other healthcare settings. The Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service (NSQHS) Standards provide a nationally consistent statement about the standard of care consumers

can expect from their health service organisations. These standards describe the clinical governance, and safety and quality systems that are required to maintain and improve the reliability, safety and quality of health care, and improve health outcomes for patients. The standards aim to ensure that everyone working in a healthcare provider is accountable to patients and the community for assuring the delivery of health services that are safe, effective, integrated, high quality and continuously improving. This standard document outlines the importance of establishing and using clinical governance systems within organisations to improve the safety and quality of health care for patients. Integration of safety and quality systems with governance processes enables organisations to actively manage and improve the safety and quality of health care for patients. It is compulsory for all hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented these Standards.

The Australian National Model Clinical Governance Framework looks in more detail at corporate and clinical governance, and roles and responsibilities for people within a health service organisation. It outlines the mechanisms of a clinical governance framework to enable the development and implementation of governance systems, considering local needs, values and the context in which services are provided. This document discusses in detail factors which have been identified as being important for sustaining a culture that ensures safe and high-quality care. These include a strong and strategic leadership of clinical services, clear responsibilities for managing the safety and quality of care, and delegation of the necessary management authority for this purpose, reliable processes for ensuring that systems for delivery of care are designed and performing well. The framework states that implementation of a successful governance system involves contributions by individuals and teams at all levels of the organisation. The roles and responsibilities of, and essential partnership between, patients and consumers, clinicians, managers, and governing bodies in implementing effective clinical governance systems is outlined in each of the five components of the framework. By ensuring that people are aware of these roles, everybody is held accountable for their contribution to the safety and quality of care delivered to patients.

The Canadian College of Health Leaders (CCHL's) presentation titled "Raising the Bar for Healthcare Governance and Leadership in Canada" looks at a framework to represent the key skills, abilities, and knowledge required to lead at all levels of the health system in Canada. The framework recommends that the role and remit of governing boards versus senior management should be clearly defined, that a culture of safety should be fostered and that decisions are made based on research, evidence and ongoing quality improvement. The *Qmentum* Programme Governance Standards were developed by Accreditation Canada's affiliate, the Health Standards Organisation



(HSO) describes how the management team of any organisation must have defined roles and responsibilities and a defined and formal process for decision making. The final grouping of standards outlines how organisations can ensure accountability, drive quality improvement, manage risks and achieve sustainable results

The National Health Service (NHS) published a Code of Governance which aims to provide guidance for healthcare providers in implementing an effective corporate governance structure which will contribute to better organisational performance and ultimately a better service for patients. Of note, the leadership section sets out in detail the role and leadership functions of the board of directors, the chairperson, non-executive directors and governors. Section C examines what arrangements should be put in place to allow for effective accountability, decision-making, and risk management and performance assurance. The Code also outlines that formal and transparent arrangements should be in place for reporting, risk management, internal control principles and for maintaining an appropriate relationship with auditors. In line with the NHS Code of Governance discussed previously, the Well-Led Framework for Governance Reviews was updated in 2015. Accountability and reporting lines are examined in the third domain by questioning the effectiveness of the board's process and the structures that are in place. Finally, the governance review asks the board to question their mechanisms for collating information and data and to interrogate such data if appropriate to support the leadership of the trust in making decisions.

## Chapter 4 - Summary of non-pharmacy specific national standards, guidelines and guidance documents

### 4.1 Health Information and Quality Authority (HIQA)

#### 4.1.1 National Standards for Safer Better Healthcare

HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered. Their aim is to safeguard people and improve the quality and safety of the services that it monitors. In 2012 HIQA published the National Standards for Safer Better Healthcare<sup>19</sup> which set out the key principles of quality and safety that should be applied in any healthcare service setting. These standards have been designed so that they can be implemented in all healthcare services, settings and locations and can be used by both the public, service users and service providers. The Standards are broken into eight themes which collectively describe how a service provides high quality, safe and reliable care centred on the service user. The eight themes are:

- Person-Centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Better Health and Wellbeing
- Leadership Governance and Management
- Workforce
- Use of Resources
- Use of Information

Theme five is of particular relevance when drafting Governance and Accountability Standards for Retail Pharmacy Businesses. Theme five focusses on leadership, governance and management, where the implementation of clear governance arrangements helps assure the delivery of high quality, safe and reliable healthcare. This is supported by setting clear objectives and having clear accountability arrangements in place. The management arrangements and leadership in a service facilitate the delivery of a quality service by providing support to the workforce, helping build a culture of safety and continuous monitoring of the service provided. The theme calls for continuous monitoring to help identify and act on opportunities and to drive improvement. This theme enables the delivery of high quality and safe care by facilitating workers and leaders to exercise their

personal and professional responsibilities, maintain and improve their skills, knowledge and competencies.

#### 4.1.2 National Standards for Special Care Units / National Standards for Residential Care Settings for Older People in Ireland / National Standards for Residential Services for Children and Adults with Disabilities

The National Standards for Special Care Units<sup>20</sup> were developed by HIQA to ensure that children who are living away from home in special care units are provided with privacy, dignity, respect, and their civil and legal rights are promoted and safeguarded. The outcomes-based Standards are intended to provide a framework for providers and also provide children and their families or representatives with a guide as to what they can expect from special care units. When inspecting a special care unit, HIQA assess the unit against the standards to determine if they are providing a high quality, safe and effective service and support to children. There are eight themes/domains listed, each one followed by several standards. Theme number five is based on the care unit providing effective governance arrangements with clear leadership, management and lines of accountability. The four standards used to illustrate this principle are:

- The special care unit performs its functions as outlined in relevant legislation, regulations, national policies and standards to protect each child and promote their welfare
- The special care unit has effective leadership, governance and management arrangements in place with clear lines of accountability
- The special care unit has a publicly available statement of purpose that accurately and clearly describes the services provided
- Appropriate service level agreements, contracts and/or other similar arrangements are in place with the funding body or bodies

Meeting these standards can be accomplished by having an effective governance structure in place and at a service level having overall accountability defined. At individual and team levels the standards call for clear lines of accountability so that everybody working in the care unit are aware of their responsibilities and who they are accountable to. Both the National Standards for Residential Services for Children and Adults with Disabilities<sup>21</sup> and the National Standards for Residential Care Settings for Older People in Ireland<sup>22</sup> highlight the importance of having good governance structures in place to ensure the provision of high-quality, safe and effective services for the people living

there. Both Standards promote person-centred care, uphold the rights of people, respect privacy and dignity and protect people living in residential care from abuse and neglect. The same standards are applicable for residential services for children and adults with disabilities. The standards aim to empower and enable adults and children with disabilities to achieve these rights through the delivery of high quality, safe and effective care and supports to people with different abilities.

## 4.2 Health Service Executive (HSE)

The HSE is required under the Health Act 2004<sup>23</sup> to have a Code of Governance in place. The most recent Code of Governance<sup>24</sup> was published in 2015. The HSE's Code of Governance reflects the current standards, policies and procedures that must be applied by both the HSE and any agencies it funds to provide services on its behalf. It describes all aspects of governance including the structures and organisational processes together with the policies, procedures, protocols and guidelines that are in place in the HSE. The Code details the roles and responsibilities of the directorate as the governing body of the HSE including corporate values, membership and delegation of functions. This document explains the leadership team who support the directorate of the HSE and who are responsible for the delivery of services to the public. These national service divisions are supported by a number of supporting functions such as human resources and quality improvement. It also details the seven hospital groups that form the acute hospital system in Ireland and how they should be organised to make sure patients access suitable treatment in the right setting, receive the best clinical outcome possible and provide sustainability for services for the future. Other organisations detailed in this code are community healthcare organisations and non-statutory service providers. The code also examines the importance of having a strategic and co-ordinated approach to the development of integrated programmes of care to deliver improved patient care, improved access and better use of resources. The delivery of high quality, evidence based, safe, effective and person-centred care is made possible by implementing a culture of safety from the corporate level, having effective risk management procedures and in having in place a wide range of written policies, procedures, protocols and guidelines which provide a standardised and comprehensive framework to staff. A good governance structure is supported by a robust accountability framework which detail accountability levels, processes and an escalation and intervention framework.

## 4.3 Mental Health Commission

### 4.3.1 Quality Framework

The Mental Health Commission (MHC) is an independent body that was set up to promote, encourage and foster high standards and good practices in the delivery of mental health services and to protect the interests of patients who are involuntarily admitted. Their responsibilities include registration of centres, development of codes of practice and inspection. In 2007 the Quality Framework for Mental Health Services in Ireland<sup>25</sup> was published. This framework is designed to provide a mechanism for service providers to continuously assess, measure and improve the quality of their services. Like other frameworks it is flexible to allow for the diverse needs of the service users and the inherent difference in organisations to be accommodated. The framework is divided into eight themes. Each theme is further broken down into standards with each standard explained and then followed by a list of criteria of how to meet that standard. Each standard is broad and enabling. Theme 8.3 examines how corporate governance underpins the management and effective delivery of mental health services. This includes each service having a documented organisational structure that identifies lines of accountability and authority.

## 4.4 TUSLA

### 4.4.1 Good Governance Framework

TUSLA (the Child and Family Agency) was established to support and promote the development, welfare and protection of children and the effective functioning of families. To ensure these services can be carried out a governance reform programme was undertaken. The outcome of this is the Good Governance Framework<sup>26</sup>. Seven principles are outlined in this framework;

- TUSLA and the Service Provider Relationship
- Board and Management
- Organisation Structure and Operations
- Ethics and Integrity
- People
- Finance and Accountability
- Risk Management

Each principle has listed what is required to achieve the appropriate level of organisational performance and accountability, examples of how it is achieved and monitored. Principles two, three and five examine how effective organisation and leadership can help achieve good systems and

structures for governance. Use of this framework is designed to help promote consistency across services, help improve awareness of the benefits of good governance and help services comply with the requirements and regulations that are in place.

#### 4.5 Summary

The review of non-pharmacy specific national standards guidelines and guidance documents examined the publications of Irish bodies such as the HSE, the Mental Health Commission (MHC), TUSLA. The MHC's Quality Framework for Mental Health Services in Ireland provides a mechanism for service providers to continuously assess, measure and improve the quality of their services. Like other frameworks it is flexible to allow for the diverse needs of the service users and the inherent difference in organisations to be accommodated. TUSLA's Good Governance Framework lists what is required of healthcare providers to achieve the appropriate level of organisational performance and accountability. Principles two, three and five examine how effective organisation and leadership can help achieve good systems and structures for governance. Use of this framework is designed to help promote consistency across services, help improve awareness of the benefits of good governance and help services comply with the requirements and regulations that are in place.

HIQA's Standards for Safer Better Healthcare sets out the key principles of quality and safety that should be applied in any healthcare setting. They are aimed at protecting patients and to help drive improvements in the quality and safety of healthcare services in Ireland. The standards are broken into eight themes with theme five focussing on leadership, governance and management. This theme details how a well-governed service is clear about what it does, how it does it and is accountable to its stakeholders. Effective management and leadership helps to achieve this. Use of these standards will help the people in charge identify what they are doing well, and what needs to be improved.

The HSE's Code of Governance was also examined. This Code provides an overview of the principles, policies, procedures and guidelines by which the HSE directs and controls its functions. It was developed to guide those working the HSE and the agencies funded by the HSE, in carrying out their duties to the highest standards of accountability and integrity. The governance, structures and organisational processes together with the policies, procedures, protocols and guidelines described in the code must be in place when providing a service to the public.

## Chapter 5 – Conclusion

This background document outlines the literature that was reviewed by the PSI Project Team to inform the development of Draft Governance and Accountability Standards for Retail Pharmacy Businesses. This included a review of:

- international standards, guidelines and guidance documents relating to pharmacy
- international standards, guidelines and guidance documents not related to pharmacy
- Irish standards, guidelines and guidance documents not related to pharmacy

This literature review was conducted in conjunction with pharmacist focus groups, patient focus groups and a public consultation to inform the scope of the standards. A separate scoping consultation report is available, detailing the results of this engagement.

This desktop research conducted by PSI is intended to inform an initial draft of the standards, which will then be refined at different stages of the standards development process, as follows:

- detailed discussions at meetings of the Advisory Group
- individual meetings with relevant informed and interested parties
- focus groups with people who use pharmacy services.

Each of these steps, in conjunction with the desktop research documented in this report, will form the evidence base for the development of the draft standards. It is intended that the draft standards will be released for public consultation later in 2019.

## Appendix 1 — Criteria used to determine eligibility of evidence for inclusion

### Inclusion criteria:

- international standards (developed or revised since 2009)
- relevant international guidelines that:
  - define best practice in governance and accountability
  - provide context for best practice in the management and/or supervision of different primary and community care settings
  - inform the development of more detailed technical guidance such as policies, procedures and protocols
- national audits and key performance indicators
- national reports and recommendations
- national policies

### Exclusion criteria:

- detailed clinical and technical guidelines
- local policies, procedures, protocols
- local quality improvement tools



## References

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- <sup>3</sup> General Pharmaceutical Council. *Standards for registered pharmacies*; June 2018
- <sup>4</sup> General Pharmaceutical Council. *Guidance for Responsible Pharmacist*. September 2010
- <sup>5</sup> General Pharmaceutical Council. *Guidance for owners and superintendent pharmacists who employ responsible pharmacists* September 2010
- <sup>6</sup> General Pharmaceutical Council. *Guidance to Ensure a Safe and Effective Pharmacy Team*. June 2018
- <sup>7</sup> The Pharmaceutical Society of Northern Ireland. *Standards and guidance on the responsible pharmacist regulations*; March 2016
- <sup>8</sup> The Royal Pharmaceutical Society. *Professional Standards for Hospital Pharmacy*; December 2017
- <sup>9</sup> University of Manchester. *Supervision in Community pharmacy final report to Pharmacy Research UK*; July 2013
- <sup>10</sup> Department of Health and Social Care; *Rebalancing medicines legislation and pharmacy regulation*; June 2018
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- <sup>12</sup> Australian Commission on Safety and Quality in Health Care. *National Model Clinical Governance Framework*; 2017.
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- <sup>15</sup> Canadian College of Health Leaders. *Raising the bar for healthcare governance and leadership in Canada*
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- <sup>17</sup> The National Health Service. *The NHS Foundation Trust Code of Governance*; July 2014
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<sup>20</sup> Health Information and Quality Authority (HIQA). *National Standards for Special Care Units*; November 2014

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<sup>22</sup> Health Information and Quality Authority (HIQA). *The National Standards for Residential Care Settings for Older People in Ireland*; July 2016

<sup>23</sup> *Health Act 2004*. Available at <http://www.irishstatutebook.ie/eli/2004/act/42/enacted/en/html> (Accessed: 3 April 2019).

<sup>24</sup> Health Services Executive (HSE). *Code of Governance*; October 2015

<sup>25</sup> Mental Health Commission. *Quality framework for mental health services in Ireland*; 2007

<sup>26</sup> TUSLA (The Child and Family agency). *The Good Governance Framework*