

SUPERINTENDENT PHARMACISTS

Responsibilities & Accountabilities

PSI/ICCPE Joint Initiative

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Nov 2010 – March 2011

Agenda

- Introduction/Scene setting – Kate O’Flaherty
- Presentation on legal requirements, responsibilities and accountabilities of superintendent pharmacists and their role in driving professional development – Leonora O’Brien
- Facilitation of Q and A – Cicely Roche / Noel Stenson

Setting the Scene

- Now 2 years on from introduction of Retail Pharmacy Businesses Regulations and other significant changes from Pharmacy Act 2007
- 1 year on from introduction of formal complaints and disciplinary system
- Learnings from implementation and transition: key issues emerging through variety of sources:
 - Inspections/Investigations/Surveillance
 - Complaints
 - Queries/Consultation/Engagements
 - Baseline Study (thanks to those of you here who may have participated in this)
- Currently focus is on implementation of mandatory CPD for pharmacists, establishment of Institute of Pharmacy and facilitate development of pharmacy practice in Ireland

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- New regulatory system, new responsibilities and new expectations have required adjustment by profession
 - Variation in terms of how well some are adjusting and varying levels of support/clarification required
 - Recognise much good, some excellent practice in pharmacy in Ireland and many have made significant efforts to engage in change process in a challenging external environment

Role of the superintendent

- One key issue emerging is level of confusion about role of superintendent - among pharmacy owners, among pharmacists holding role, among profession generally
- The role of superintendent pharmacist is one of the key elements of successful implementation of fundamental objectives of legislation:
- Appropriate professional management, administration and control of pharmacy
- Assurance of safe, quality care for patients from pharmacists and in pharmacies and
- Pursuit of excellence in pharmacy practice, supported by reform of pharmacy education and training regime

- Superintendent pharmacists are identified as an important group among the profession for the regulator to inform/support/develop
- Therefore, PSI and ICCPE have decided to prioritise an initiative to clarify issues and requirements (building on last year's joint meetings) and to develop dialogue with superintendents to see where the barriers and enablers are to facilitating superintendents discharging their full functions and roles
- And to inform the further development of continuing professional development resources for superintendent pharmacists (training needs assessment to assist this process)

Pharmacy – part of wider healthcare reform

Development of a patient safety and quality framework in Ireland

- It is also important to note that the changes in pharmacy are not confined to this profession alone - all professions getting new legislation with similar regulatory systems
- Patient Safety Commission - agreed that the vision or framework around which the Irish health system should be based is as follows:

Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes

New legal and regulation requirements for all healthcare professions

- Many of the main principles of the patient safety agenda are already in place in pharmacy from Pharmacy Act 2007, e.g.:
- registration/licensing of facilities (pharmacies)
- management, leadership and accountability (superintendents)
- standards (RPB regulations)

Patient-centered approach

HIQA Themes for Quality & Safety

- HIQA standards for safe, better healthcare – will underpin licensing system for healthcare facilities and service generally
- HIQA standards provide framework for implementation of other standards across healthcare system e.g.
 - ✓ management of patient safety incidents
 - ✓ minimising risks
 - ✓ learning from incidents
 - ✓ making service delivery more patient-centred
 - ✓ evidence based care (including national clinical guidelines)
 - ✓ more co-ordinated and integrated care; health promotion



PSI

Role in Pharmacy Practice Development

- Pharmacy Practice Development: PSI Corporate Strategy 2010-2012 one of strategic objectives is to support more active involvement of pharmacists in delivery of integrated, patient-centred, cost-effective health services
- In the past, lack of a robust regulatory system for pharmacy was argument against expansion of role of pharmacist and development of new pharmacy services - successful implementation (and demonstration) of regulatory system will facilitate these developments, underpinned by CPD.

- There has been a lot of change in past 3 years and more significant changes in the near future
- PSI recognises that the main objectives of the regulator - in terms of high standards of patient care and good pharmacy practice and developing the profession to contribute to patient safety agenda and integrated health services - are shared by individual members of the profession and the profession as a whole
- Purpose of tonight's meeting and future initiatives is to clarify to you how we seek to achieve these goals and to emphasise to you the important part that you play by virtue of the role you hold

Meeting aims

- ✓ The Legal Requirement for a superintendent pharmacist understood
- ✓ Legal Responsibilities & Accountabilities of a superintendent pharmacist understood

Recent Advertisements

Spot the errors?

1. *'Part-time supervising pharmacist required'.*
2. *'Supervising pharmacist – no management of staff required'*

Superintendent Pharmacists – Responsibilities and Accountabilities

Leonora O'Brien M.P.S.I.
Pharmacy Governance and Professional Development Consultant, PSI

PSI/ICPE taskforce on initiative on Superintendents

In November 2010, the PSI/ICPE taskforce organised an initial series of meetings for superintendent pharmacists. The aim of these meetings was to provide an understanding of the legal requirement for a superintendent pharmacist and the responsibilities of superintendent pharmacists, as well as the leadership, governance and accountability aspects of the role. Some of the main aspects of the PSI presentation given at the meetings are summarised here.

The introduction of the role of the superintendent pharmacist is a significant driver for the implementation of the Pharmacy Act 2007 (the Act) and the development of pharmacy in Ireland, establishing a framework for achievement of a high quality, safe and consistent service for the benefit of patients and public as well as facilitating the development of the professional role of the pharmacist.

understand and facilitate the management and professional obligations of the superintendent. They must consider and act on the advice of the superintendent pharmacist when dealing with the management of medicinal products within the business and provide the superintendent pharmacist with the necessary support and resources to fulfil their legal and professional obligations and in turn, those of all registered pharmacists engaged within that business.

the capacity as both the superintendent and supervising pharmacist, for example a Sole Trader, identifying a successor to include in a succession plan may prove more difficult. In these cases, the superintendent pharmacist should simply communicate to those who may be tasked with carrying on the business in unforeseen circumstances (such as sudden death of a superintendent), that the appointment of a new superintendent, with a minimum of three years' post-registration experience, is a condition of the operation of and maintenance of the registration of that pharmacy. The name of the nominated superintendent must be submitted to the Registrar. Those who may be tasked with carrying on the business should be informed that in such unforeseen circumstances they may contact the PSI for support and advice as necessary.

In cases where a particular superintendent is appointed only for an interim period until a long-term superintendent has been recruited, they must nonetheless undertake to be fully responsible and officially accountable for that pharmacy business during this time.

The Legal Requirement for a Superintendent Pharmacist

The role of the superintendent pharmacist, established by the Act, ensures that the management and administration of the sale and supply of medicinal products in retail pharmacy businesses (pharmacies) in Ireland, is firmly under the control of a senior pharmacist with a defined minimum level of experience. The superintendent pharmacist position is one of management and leadership and in company terms is equivalent to a 'Chief Officer' role, carrying full-time responsibility and accountability within a company.

Prior to the Act, pharmacy in Ireland was largely unregulated in terms of openings and practice. It was possible for non-healthcare professionals to form a company and operate a pharmacy without having a robust or defined relationship between that pharmacy owner and the responsible pharmacist(s). The responsibilities and accountabilities for that pharmacy practice and most importantly, for the patient, were not clearly defined.

Now the role of the pharmacist and owner are inextricably linked. Since the Act, engaging a superintendent pharmacist is a legal pre-requisite for a company to open or operate a registered pharmacy. Companies must formally enter into agreement with a named superintendent by signing the 'Statement by Pharmacist And On Behalf Of A Corporate Body' provided for in section 28(a) of the Act. By signing this statement, the corporate body officially recognises that all decisions and processes pertaining to medicinal products must be under the personal control of the superintendent, that the pharmacist is accountable and that both accept this responsibility.

Pharmacy owners now have a legal duty to

For superintendents in control of two or more pharmacies, drafting a succession plan normally involves identifying a supervising pharmacist within the organisation with the right knowledge, skills and attitudes required to discharge the duties of superintendent; a pharmacist who would be committed to driving the professional performance and legal compliance of the pharmacy and who, on assuming the role, would accept the accompanying responsibilities and accountability. The name of this appropriate successor is then agreed internally and documented in a contingency plan.

If the supervising pharmacist nominated in this succession plan subsequently leaves the organisation or changes their mind for whatever reason, another potential successor is identified and the contingency plan is updated accordingly. Succession planning is not an officially binding process necessitating communication to the Registrar; it is, however, an example of good organisational practice which demonstrates a superintendent's attention to risk-assessment, continuity of patient care and legislative compliance.

It is advisable for a superintendent to arrange for their successor to shadow them for a period of time before the date they are to be solely and officially in personal control.

In situations where a pharmacist is acting in

Key Legal and Professional Responsibilities of a Superintendent

All superintendent pharmacists declare in law that they are aware of their legal responsibilities under the Act and that they undertake to use the best of their endeavours "to ensure compliance therewith and with any Regulations, Code of Conduct, Statutory Rules and professional guidelines as may be in force". Superintendents have overall responsibility for ensuring that ethical and appropriate policies and procedures are in place and implemented within their organisation in order to achieve full compliance with such legislation and to govern every aspect of the sale and supply of medicinal products. They must promote the rational and safe use of medicines in the interests of patients and the public and ensure that the appropriate assessment, information and advice are made available for each individual patient.

Policies and Procedures – why are they required?

The requirement for a superintendent to have policies and procedures in place should not

be viewed as a redundant administrative burden but as a responsible and demonstrable approach to risk management within a pharmacy. Robust policies and procedures are now required across most sectors and businesses, e.g. Aviation, Manufacturing, Service Industry, Retail, Telecommunications, Energy, Hospitality, etc. It's now common practice for many hotels for example, to have SOPs in place for simple tasks such as answering the reception telephone, in order to guarantee a standardised level of service. Within healthcare facilities such as a pharmacy, it is understandable that documented procedures are essential, given the potential that exists for irreversible harm to patients.

Policies and procedures are simply a mechanism used by superintendents to ensure that their pharmacy's processes and services are performed in a consistent way according to pre-defined standards. Superintendents must maintain a reporting relationship with their supervising pharmacists and ensure that all registered pharmacists engaged within that pharmacy are free to raise professional or ethical concerns or queries they may have about any policy or procedure, without fear of reprisal.

Having policies and procedures in place promotes safe practice regardless of whether the superintendent is physically present or not, enabling the superintendent to demonstrate full-time control and governance over all pharmacy operations. By clearly defining exactly what is to be carried out, how and by whom, documented procedures also help the superintendent communicate and underpin the responsibilities and accountability of all their staff. All persons engaged within the pharmacy, including all supervising and registered pharmacists, must be compliant with the superintendent's policies and procedures. If an incident occurs, the superintendent is able to track and demonstrate that they have communicated the correct procedure and facilitated appropriate training for staff and that a procedural violation has occurred for which that staff member may subsequently be held responsible. It is the superintendent's responsibility to analyse the cause of the violation or error and endeavour to prevent recurrence.

All organisational policies must be in line with the Code of Conduct for Pharmacists and must not impair or compromise the ability of any registered pharmacist to adhere to this, their statutory professional code. This has particular relevance in larger organisations where certain tasks may be delegated to functional departments, for example HR, Marketing, or Finance. It remains the superintendent's responsibility, and not that of other staff employed in such departments, to ensure the legal compliance of all policies that impact on the operations of the individual pharmacies. The law is clear about where this accountability lies.

In relation to HR for example, it is the superintendent pharmacist in co-operation with the pharmacy owner that must, *inter alia*, ensure that they are satisfied that all staff "have the requisite knowledge, skills, including language skills, and fitness to perform the work for which they are, or are to be, responsible". For example, if an error occurs due to a language competency issue, the superintendent can be held accountable if they do not have a robust policy or mechanism in place to govern the process of recruitment and selection, including provision for a thorough screening process and reference checks to facilitate appropriate and safe engagement within that pharmacy. For locums, measures taken by a superintendent may include development of a Service Level Agreement with their locum agency, or a policy of using known locums only or those which have passed a standard vetting procedure which has been pre-defined by the superintendent.

In relation to a marketing or advertising function, again it is the superintendent who is legally responsible for the pharmacy's compliance with all legislation pertaining to the advertising and promotion of medicinal products. A superintendent must have robust policies and procedures in place to govern fundamental aspects such as the rational and safe use of medicines and accessibility of medicines (for POMs, non-prescription medicines, CDs, products with abuse potential, etc.), including a process for effective vetting of all promotional material. All relevant office that pharmacy, both in the pharmacy itself as well as separate within that pharmacy, must have read, understood and signed off on such policy.

All persons holding positions of responsibility, including pharmacy owners and members of the board of a corporate body, as well as all departments and centralised management functions, must be aware of the superintendent's formal training in pharmacy law and ethics, understand

their responsibility for legal compliance within that pharmacy and must not thwart the superintendent's professional judgement or decisions.

'Full-time Accountability'

To err is human; to analyse, learn and prevent is superintendent policy

Is a superintendent directly and solely responsible for every human error made by others within a pharmacy? And if not, how can they assume full-time accountability for that pharmacy?

As autonomous professionals, registered pharmacists are responsible and professionally accountable in their day-to-day practice. They are required to possess, maintain, update and display competence in respect of the management of the health of a patient and the delivery of an appropriate standard of pharmaceutical care.

However, it is the superintendent who has overall responsibility and accountability for the maintenance and adherence to a sound system of controls in order to manage risk and promote patient safety within the pharmacy. This is assured by, for example, having appropriate policies and procedures in place within that pharmacy. This is a mandatory practice requirement which is the responsibility of the superintendent. If mandatory requirements are not met by the superintendent, they fall in this responsibility and may be held accountable for any negative repercussions. Accountability is simply the acknowledgment and assumption of a set of responsibilities. It is not unique to pharmacy; it is the backbone of any effective healthcare system. Having an effective system of accountability simply means someone is answerable for deficiencies found within our professional practice or for any resulting consequences for our patients.

In the words of Alexander Pope, "to err is human" – a fact which necessitates this structure of defined responsibility and accountability within a pharmacy. Without a system of accountability, no one is tasked with taking responsibility for analysing errors and experiences and incorporating any learnings into our systems and processes in order to facilitate continuous improvement and development.

Error Management Within a Pharmacy

To further understand the nature of the responsibility and accountability structure within a pharmacy, it is important to consider the many types of error which can occur in practice. Reason's Swiss Cheese Model, (see fig. 1) is a particular method of illustrating Risk-Cause analysis and is useful for superintendents to reflect on error management within their individual healthcare facilities. Simply put, the holes in the Swiss Cheese represent weaknesses within our systems or standards of practice and they vary in size and position. When these individual weaknesses align, an error can occur resulting in patient harm. The holes, or weaknesses within our practice, can be caused by 'active failures', i.e. unsafe acts directly linked to the error such as staff carelessness or aberrant mental processes; or 'latent failures', i.e. contributory factors within the system which may have lain dormant for a long time but have finally contributed to an error.

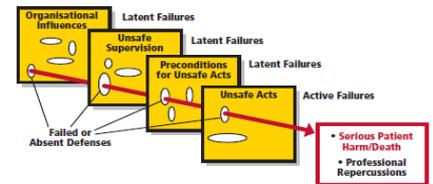


Fig 1: Reason's Swiss Cheese Model: paradigm for error analysis and prevention

Also accessed via new website: www.thePSI.ie

The screenshot shows a web browser window displaying the website for the Pharmaceutical Society of Ireland (PSI). The browser's address bar shows the URL: www.thepsi.ie/gns/pharmacy-practice/current-developments/superintendent-pharmacists.aspx. The website header includes navigation links such as 'Skip to Content', 'Contact Us', 'News', 'Publications', 'Consultations', 'Links', and 'Irish Language Content'. The PSI logo and name are prominently displayed, along with the tagline 'THE PHARMACY REGULATOR'. A search bar is located in the top right corner. Below the header, a main navigation menu includes 'Home', 'About PSI', 'Registration', 'Education', 'Pharmacy Practice', 'Inspection & Enforcement', and 'Making a Complaint'. A breadcrumb trail indicates the current location: 'You are here: Home > Pharmacy Practice > Current developments > Superintendent Pharmacists'. The main content area features a section titled 'Superintendent Pharmacists' with a sub-section 'In this section' containing links to 'Overview', 'Practice Guidance', 'Code of Conduct', 'Current developments', 'Baseline Study', 'Documents for Consultation', and 'PSI-CCPE Taskforce'. The 'Current developments' section contains the following text: 'In November 2010 the PSI/CCPE taskforce organised an initial series of meetings for superintendent pharmacists. The aims of these meetings were to provide an understanding of the legal requirement for a superintendent pharmacist and the responsibilities of superintendent pharmacists, as well as the leadership, governance and accountability aspects of the role. The aim was also to provide an opportunity for superintendent pharmacists to give feedback with a view to informing the development of future resources for the CPD of pharmacists holding this important role. The presentation given by the PSI at these meetings is [available in article form to download here.](#) PSI/CCPE Meetings for Superintendent Pharmacists The PSI and ICCPE held two joint education meetings aimed at superintendent pharmacists late last year, and a further two meetings had to be cancelled due to the weather. These two meetings, in Galway and Dublin North, have now been re-scheduled for mid-February and a further three meetings will also be held in the first half of March – in Sligo, Limerick and Waterford – following requests from

Background of Superintendent Pharmacist Role

The Pharmacy Act 2007 established the role of the superintendent pharmacist and places the management and administration of the sale and supply of medicines, including its professional and clinical management and accountability for a retail pharmacy business (RPB), firmly in their hands. Equivalent to a 'Chief Officer' role.

What is a superintendent pharmacist? (*secn. 27(b), 28(a) and 29(b)*).

Individual responsible for the overall professional policy and clinical management of the pharmacy practice...*'in personal control of the management and administration of the sale and supply of medicines...has a minimum of 3 years' post-registration experience'*

Superintendent & Supervising pharmacist roles – very different

Supervising pharmacist

Supervising pharmacist 27c,28b,29c

'3 year minimum post-registration experience; in whole time charge of the pharmacy (individual premises). Responsible for all operations of the pharmacy, even when absent; may operate in this capacity for one pharmacy only at a given time'

- 'consistent, continuous, significant proportion of hours'
- SOPs are in place & consistently operated – demonstrate how exercise control when not there
- Appropriate supervision of non-Rx medicines
- Ensure that all medicinal products are sourced from an authorised supplier
- Out-of-date products are appropriately segregated and disposed of
- Pharmacy staff training
- Awareness of circumstances necessitating referral to a pharmacist (particularly non-Rx meds liable to misuse e.g. CD5s)
- Ensure Duty Log is accurately maintained
- Policies and procedures of the superintendent are implemented
- Ensure adherence to PSI Standards and guidance

Superintendent pharmacist

Superintendent Pharmacist 27b, 28a and 29b.

'...in personal control of the management and administration of the sale and supply of medicines.. 3 years' post-registration experience' ...responsible for professional policy and clinical management of the pharmacy practice

- In **personal control** of the management and administration of the sale and supply of medicines **AT ALL TIMES**. This must be demonstrable.
- Superintendent must develop and maintain all the policies governing the RPB and the supervising pharmacist must implement these
- Can you demonstrate that you :
 - A) Have reflected on all aspects of the practice involving medicinal products
 - B) Have Policies and Procedures in place to govern these
 - C) Are ensuring all relevant employees are appropriately trained in or have read and understood these policies

Before and after the Pharmacy Act 2007

Prior to the Act

- Unregulated in terms of openings and practice
- No defined relationship between the pharmacy owner and the responsible pharmacist(s)

Ownership structures provided for in the Act, e.g.:

- Natural persons – i.e. a registered pharmacist, '**Sole Trader**' (> 1000 superintendents act in this capacity for one RPB)
- Natural persons – acting as a **Partnership**; made up of 2 or more registered pharmacists
- **Corporate body** – e.g. limited companies
- **Representative** – e.g. executor or nominated representative if a pharmacist dies/bankruptcy

Statement on behalf of a corporate body (section 28(a))

Role of superintendent pharmacist and owner inextricably linked

- Legal prerequisite for a company to open or operate a RPB
- Companies **must** enter into agreement with a named superintendent and declare **in law** that they have appointed that pharmacist to discharge the responsibility for the management and administration, sale and supply of medicinal products, and pharmacist accepts this responsibility

PART 3

DECLARATION ON BEHALF OF A CORPORATE BODY

(if Pharmacy Owner is not a Corporate Body, proceed to Part 4)

I/We, being authorised to complete this Statement on behalf of the corporate body specified in Part 1 of this Form, hereby **DECLARE** that:

1. Name: _____ Reg. No. _____
[Insert name and registration number of pharmacist]

has been appointed by the said corporate body for the purposes of Section 28(a) of the Pharmacy Act 2007 in respect of the retail pharmacy business(es) to which this Statement relates.

2. The said pharmacist is aware that the part of the business of the corporate body that consists of the management and administration of the sale and supply of medicinal products will be under his or her personal control, and he or she has undertaken to discharge that responsibility, and the corporate body in turn recognises this position as established by Section 28(a) of the said Act.

3. The said pharmacist is a registered pharmacist with a minimum of 3 years' post-registration experience as set out in Section 25(2) of the Pharmacy Act 2007 and as required by such a pharmacist under the said Act *(See footnote 2)*.

| | |
|------------------------------|---|
| Signed: | [Signature(s) of person or persons signing for or on behalf of the Corporate Body] ³ |
| (Print name under signature) | 1. |
| (Print name under signature) | 2. |
| Date: | |
| Capacity of Signatory(ies): | |

Statement on behalf of a corporate body

What it means for the company

- Enshrines the agreement between the superintendent and owner and ensures that the superintendent's **responsibilities are both conveyed and understood**.
- By signing this mandate, the corporate body officially recognises that the sale and supply of medicinal products, and all **decisions pertaining to medicinal products**, must be under the **personal control** of the superintendent.
- Roles of the **pharmacist and owner are inextricably linked**.
- Pharmacy owner now has a **legal duty to understand and facilitate** the professional obligations of the superintendent.
- Act hands the profession of pharmacy back to the pharmacist and in turn ensures a **patient-centred focus** is maintained.

9th July 2010 Letter Re:

‘Superintendent Pharmacists and Companies Conducting Retail Pharmacy Businesses’

- Without a superintendent, the company cannot lawfully trade in medicinal products or conduct a RPB
- must cease its activities in respect of medicinal products (or close) until a replacement has been officially appointed and their nomination accepted by the PSI
- If it continues without a superintendent, owner can be prosecuted for breach of Section 26(2) of the Act and can be subjected to disciplinary proceedings under Part 6.
- **Leaving role without notifying the PSI – superintendent can be referred for investigation under Part 6**
- If any offence is committed by a corporate body during the term of a superintendent’s control, the responsibility and the legal sanctions relating to that superintendent does not end until the matter, in the professional opinion of that superintendent pharmacist and that of both the professional Regulator and legal authorities, has been concluded (i.e. the sanctions follow you).



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9th July 2010

Re: Superintendent Pharmacists and Companies Conducting
Retail Pharmacy Businesses

Dear Pharmacy Owner/Superintendent Pharmacist

It has come to the attention of the Pharmaceutical Society of Ireland (PSI) that there appears to be a serious misunderstanding in relation to the essential link that must exist between the corporate body (i.e. the company) carrying on a retail pharmacy business and the Superintendent Pharmacist (being the pharmacist referred to in section 28(a) of the Pharmacy Act 2007).

The position is that in order for a company to lawfully carry on a retail pharmacy business under the Pharmacy Act 2007, the company must be satisfied that the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a pharmacist who, together with the company, has signed the statement specified in section 28(a) of the Act and which statement has been provided to the Registrar, as required by the Act. Should the pharmacist concerned die or resign his or her position with the company, the company concerned is no longer in a position to lawfully trade in medicinal products or to lawfully conduct a retail pharmacy business.

It is important to note that a Superintendent Pharmacist is not legally in place until the signed statement specified in section 28(a) of the Act has been provided to the Registrar.

If the Superintendent Pharmacist, for whatever reason, ceases to be engaged in that role, the company concerned is no longer in a position to lawfully trade in medicinal products or to conduct a retail pharmacy business. It is imperative, therefore, that both companies and Superintendent Pharmacists understand and appreciate the implications of this situation and that they should both plan their activities and operations in a manner that will ensure that this position will not arise. If such plans (including essential succession planning) are not in place, it is inevitable that a company will be obliged to cease its activities in respect of medicinal products (or to close) until a replacement Superintendent Pharmacist can be installed and is notified to the PSI.

In the event that such an eventuality were to arise due to actions on the part of the pharmacy owner or on the part of the Superintendent Pharmacist, it is possible that the person(s) responsible would be referred for investigation under Part 6 of the Act. This could particularly be the case if some patients were to be denied access to medicines or prescription records due to the unavoidable closure of a pharmacy or pharmacies.

PSI (RPB) Registration Rules 2008

S.I. No. 495 of 2008 (into force on 29 November 2008)

- A pharmacy cannot open or operate without first being registered as a RPB with the PSI
- Nomination of named superintendent legal requirement to be a “registered pharmacy” in register kept by the Council under section 13(1).

Notifications of changes in personnel and premises

(Provided for in PSI (RPB) Registration Rules 2008)

6. (1) The pharmacy owner or, as the case may be, the superintendent pharmacist shall forthwith notify the registrar of—

- any changes of any registered pharmacist or registered pharmaceutical assistant specified in the application for registration...[]
- must notify of **changes of superintendent or supervising pharmacist**
- any **material changes** made or proposed to be made in respect of the registered pharmacy

A change in ownership of a Retail Pharmacy Business (as defined in section 17(6) of the Pharmacy Act) has the effect of **cancelling its registration.**

Succession planning

Purpose: To ensure continuity of patient care

One RPB (e.g.: Sole Trader)

Reflect:

1. Who may be tasked with carrying on the business in unforeseen circumstances?
2. Are they informed of the legal requirement to have a superintendent pharmacist?
3. Are they aware the superintendent must have a minimum of 3 years post-registration experience?
4. Are they aware that the name of a superintendent must be submitted to the Registrar?
5. Are they aware that they can contact the PSI for support and advice where necessary?
6. Has this communication been documented?

Two or more RPBs

Reflect:

1. Is there a pharmacist in the organisation with the right knowledge, skills and attitude to be your successor?
2. Does this superintendent have a minimum of 3 years post-registration experience?
3. Have I agreed this name and hand over process internally?
4. If the answer is 'no' to the above how would you recruit a suitable candidate?
5. Have I documented this plan?

It is good practice for a new superintendent to shadow their predecessor for some time to ensure a professional hand-over.

Succession Planning

Demonstrates a superintendent's attention to risk-assessment, legal compliance and continuity of patient care

Summary of requirement for superintendent

- ✓ Patient-centred approach – Act hands profession back to the Pharmacist
 - ✓ Owner-pharmacist relationship inextricably linked
 - ✓ Pharmacy legislation compliance
 - ✓ Accountability structure in place as required by all health professions
 - ✓ Public registers of professionals and premises as required by all health professions - transparency in public interest
 - ✓ Continuity of service
 - ✓ **Avoid irreversible harm to patients and public**
- ✓ The Legal Requirement for a superintendent pharmacist understood

Meeting aims

- ✓ The Legal Requirement for a superintendent pharmacist understood
- ✓ Legal Responsibilities & Accountabilities of a superintendent pharmacist understood

Declaration By A Pharmacist

What the superintendent agrees in law to do (1)

1. You are the pharmacist for the purposes of Sections 27(b), 28(a) 29(b) of the Pharmacy Act 2007...[]’
2. ‘...Management and administration of the sale and supply of medicinal products will be under your personal control, and you undertake to discharge that responsibility’.
3. ‘...registered pharmacist with a minimum of 3 years’ post-registration experience...’
4. ‘...Director in the corporate body or an office-holder in the corporate body (if applicable)..?’

PART 2
DECLARATION BY A PHARMACIST

I, _____, being a registered pharmacist with Registration Number _____,
[Name as it appears on the Register of Pharmacists]

DECLARE that:

1. I have been appointed by the aforementioned pharmacy owner as the pharmacist for the purposes of Sections 27(b), 28(a) and 29(b) of the Pharmacy Act 2007 in respect of the Retail Pharmacy Business(es) to which this Statement relates.
2. I, as such pharmacist, am aware that the part of the business that consists of the management and administration of the sale and supply of medicinal products will be under my personal control, and I undertake to discharge that responsibility.
3. I am a registered pharmacist with a minimum of 3 years' post-registration experience as set out in Section 25(2)¹ of the Pharmacy Act 2007 and as required by such a pharmacist under the said Act.
4. I am a Director in the corporate body (if applicable) Please Tick: Yes No

OR

I am an office-holder in the corporate body (if applicable) Please Tick: Yes No

If an office-holder, please specify the nature of the office held: _____

5. The Retail Pharmacy Business(es), to which this statement relates, will be conducted in compliance with the provisions of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
6. I am aware of the legal responsibilities of such a pharmacist under the Pharmacy Act 2007 and I undertake to use my best endeavours to ensure compliance therewith and with any Regulations, Codes of Conduct, Statutory Rules and professional guidelines as may, for the time being, be in force.
7. I am aware that if there is any change to the Retail Pharmacy Business or of the list of Retail Pharmacy Businesses listed in this application, in respect of which I act as Superintendent Pharmacist, then I undertake forthwith to notify the PSI in the event of such change.

| | |
|--------------------------------------|--|
| Signed by Superintendent Pharmacist: | |
| Date: | |
| Professional Contact Address: | |
| | |
| | |

Declaration By A Pharmacist

What the superintendent agrees in law to do (2)

5. RPB(s) will be conducted in compliance with the Pharmacy Act 2007 and the Regulation of RPB Regulations 2008 (**S.I. No. 488 of 2008 / 'section 18'**).
6. You are aware of your legal responsibilities under the Act and undertake to ensure compliance and with any Regulations, Codes of Conduct, Statutory Rules and professional guidelines as are in force.
7. '...any change to the Retail Pharmacy Business or of the list of RPB in the application, then you undertake to notify the PSI...[]'.

PART 2
DECLARATION BY A PHARMACIST

I, _____, being a registered pharmacist with Registration Number _____,
[Name as it appears on the Register of Pharmacists]

DECLARE that:

1. I have been appointed by the aforementioned pharmacy owner as the pharmacist for the purposes of Sections 27(b), 28(a) and 29(b) of the Pharmacy Act 2007 in respect of the Retail Pharmacy Business(es) to which this Statement relates.
2. I, as such pharmacist, am aware that the part of the business that consists of the management and administration of the sale and supply of medicinal products will be under my personal control, and I undertake to discharge that responsibility.
3. I am a registered pharmacist with a minimum of 3 years' post-registration experience as set out in Section 25(2)¹ of the Pharmacy Act 2007 and as required by such a pharmacist under the said Act.
4. I am a Director in the corporate body *(if applicable)* Please Tick: Yes No

OR

I am an office-holder in the corporate body *(if applicable)* Please Tick: Yes No

If an office-holder, please specify the nature of the office held: _____

5. The Retail Pharmacy Business(es), to which this statement relates, will be conducted in compliance with the provisions of the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).
6. I am aware of the legal responsibilities of such a pharmacist under the Pharmacy Act 2007 and I undertake to use my best endeavours to ensure compliance therewith and with any Regulations, Codes of Conduct, Statutory Rules and professional guidelines as may, for the time being, be in force.
7. I am aware that if there is any change to the Retail Pharmacy Business or of the list of Retail Pharmacy Businesses listed in this application, in respect of which I act as Superintendent Pharmacist, then I undertake forthwith to notify the PSI in the event of such change.

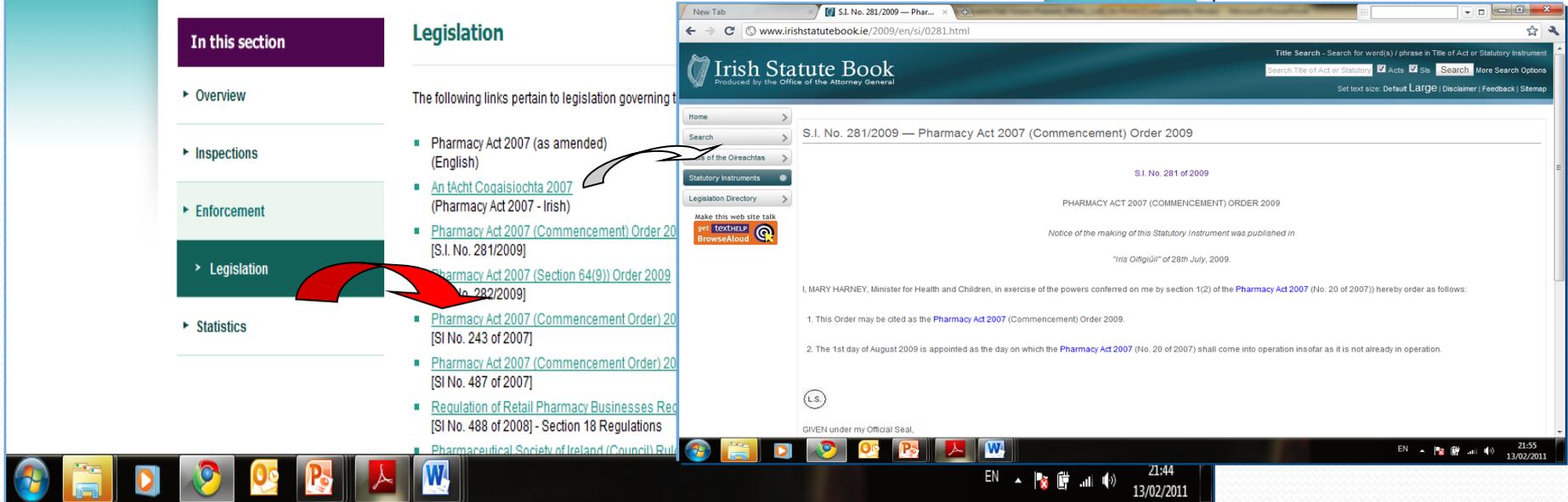
| | |
|--------------------------------------|--|
| Signed by Superintendent Pharmacist: | |
| Date: | |
| Professional Contact Address: | |
| | |
| | |

Key legal responsibilities

- Management and administration of the sale & supply of medicines must be under the **personal control** of a superintendent pharmacist.
- Overall **organisational control of professional & clinical pharmacy policy**.
- All legal and professional standards are met by all pharmacists and staff within the RPB.
- If deficiencies are found, you are **accountable, professionally & legally**.
- Drive high standards of patient care and pharmacy practice.
- **Full-time** Responsibility & Accountability.
- Must **demonstrate** control over the overall operation of the Pharmacy

Source of Pharmacy Legislation www.thePSI.ie

Access to both PSI libraries & Irish Statute Book direct links



Key Legislative Areas

Superintendents must be familiar & in compliance with all Legislation governing practice of pharmacy in Ireland

Pharmacy Act 2007

sets out the fundamental requirements for conduct of RPB, broad principle and policy of law, including any offences

Regulations (S.I. No 488 of 2008)

further legal provisions and detailed requirements necessary for the purposes of the Act. e.g. Section Regs and PSI Guidelines re premises, storage, staff, equipment, records, counselling etc.

Rules

Set out various procedures relating to Registration, RPB Registration, Council, Education & Training, Fees and arrangements for the conduct of the business of Council / PSI

Professional Guidance

Guidance for good pharmacy practice eg PPGM; security assessment template. Best practice sharing. PSI Practice Notices. PSI communications eg: Understanding your role.

Code of Conduct (Statutory)

Section 7(2)(a)(iii) of the Act requires the PSI to draw up a Code of Conduct. a public declaration of the principles and ethical standards which govern pharmacists in the practice of their profession

Section 18 – Regulation of Retail Pharmacy Businesses Regulations

(S.I. No. 488 of 2008 / 'Section 18').

- Superintendents declare their RPB(s) will be conducted in compliance with the Regulation of RPB Regs 2008.
 - 15 Regulations contained therein.
- ✓ *Staff, Premises, Equipment and Procedures;*
 - ✓ *Management and Supervision of RPB;*
 - ✓ *Sourcing, Storage & Disposal;*
 - ✓ *Sale & Supply of medicinal products;*
 - ✓ *Review and Counselling of patients (Rx & non-Rx);*
 - ✓ *Veterinary meds;*
 - ✓ *Record keeping.*



STATUTORY INSTRUMENTS

S.I. No. 488 of 2008

REGULATION OF RETAIL PHARMACY BUSINESSES
REGULATIONS 2008

(Prn. A8/1883)

Section 18 – Regulation of Retail Pharmacy Businesses Regulations (S.I. No. 488 of 2008).

- In accordance with the Act, the PSI provides guidelines to facilitate compliance with the Regulation of RPB Regs 2008.
- Draft guidelines are published for public consultation before final review by Council.
- Publication in line with PSI Service Plan.
- ✓ 2010: *PCAs & Non-Rx Codeine Meds*
- ✓ early 2011: *Sourcing, Storage & Disposal*
- ✓ By 2012: *Premises & Equipment;*
Record Keeping;
Regs 9&10.
Management & supervision
- All superintendents expected to comply in full with all professional guidelines.

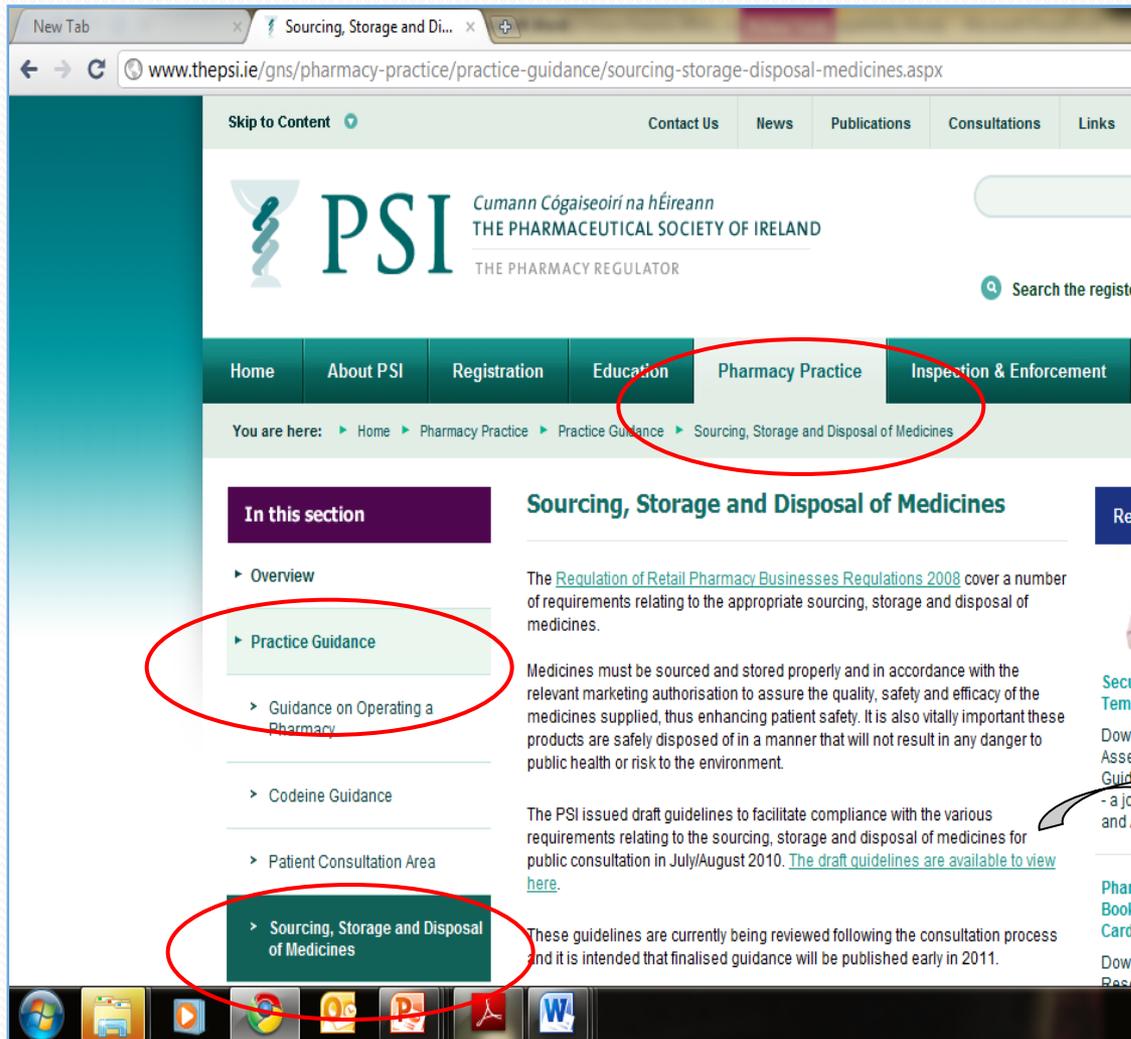


GUIDELINES ON PATIENT CONSULTATION AREAS IN RETAIL PHARMACY BUSINESSES

to facilitate compliance with Regulation 4(3) of the
Regulation of Retail Pharmacy Businesses Regulations 2008
(S.I. No. 488 of 2008)

Guidelines location on PSI website

(Pharmacy Practice – Practice Guidance – (e.g.) Sourcing, Storage & Disposal).



SOURCING, STORAGE AND DISPOSAL OF MEDICINAL PRODUCTS WITHIN A RETAIL PHARMACY BUSINESS:

Draft Guidelines for Public Consultation

PUBLIC CONSULTATION DOCUMENT

Comments are welcome in writing to consultation@pharmaceuticalsociety.ie or to Public Consultation, Pharmaceutical Society of Ireland, 18 Shrewsbury Road, Ballsbridge, Dublin 4

This period of public consultation will end at 5.00pm on Friday, 27 August 2010

PSI Guidance on Inspections (ref: Inspection & Enforcement section)

- PSI's Short Guide to Inspections
- Checklist for pharmacy Inspections
- Checklist for new opening inspections



The Pharmaceutical Society of Ireland Short Guide on What to Expect During the Inspection Process

- PSI Authorised Officers (the formal title of the inspectors) will identify themselves at the start of an inspection. All Authorised Officers carry a PSI identity card and their warrant as Authorised Officer, which is their authority to enter pharmacies and other premises. You can ask to see the warrant to assure yourself the person is an Authorised Officer of the PSI.
- On arrival at a pharmacy for inspection, the inspector will first ask to see the pharmacist or pharmacists who are present.
- Most pharmacists will choose to keep the pharmacy open during an inspection, which means that patients and members of the public will need to be attended to during the inspection. The PSI and its Authorised Officers make it clear that patient needs are everyone's priority. During the inspection, the pharmacist will be asked to source particular records or documents for the inspector, but this will be done while ensuring that patients are being dealt with as the priority, and where necessary, the inspector will wait while the pharmacist attends to patients.

So what will the inspectors look for during an inspection?

The PSI has produced a checklist to assist pharmacy owners and pharmacists in preparing for a future inspection and to inform them what to expect during an inspection.

The following areas should be covered in any self-assessment:

- **Premises:** security arrangements, 'keyholding' policy (including policy around the pharmacy not opening when no pharmacist is present), layout to allow for supervision of professional activities and to restrict access to dispensary and medicinal products, patient consultation area; also storage areas, staff areas, bathroom; housekeeping/cleaning records; clean, uncluttered dispensary and professional areas, including proper paper record-filing arrangements.
- Registration certificates (retail pharmacy business and supervising pharmacist) on conspicuous display.



Checklist for a Pharmacy Inspection by the The Pharmaceutical Society of Ireland



The following is a non-exhaustive list of what may be reviewed by an Authorised Officer of the PSI during an inspection of a retail pharmacy business (RPB). This checklist is intended as a self-assessment tool to assist you in preparing for an inspection.

| 1.0 Registration Certificates | Yes | No |
|---|-----|----|
| 1.1 Has the retail pharmacy business (RPB) the correct certificate of registration and is it prominently displayed to the public? | | |
| 1.2 Has the supervising pharmacist the correct certificate of registration and is it prominently displayed to the public? | | |

| 2.0 Codeine Containing Products | Yes | No |
|---|-----|----|
| 2.1 Are codeine-containing products stored in the dispensary, out of sight of the public? | | |

| 3.0 Policies and Procedures | Yes | No |
|---|-----|----|
| 3.1 Has the RPB a full suite of documented policies and procedures/SOPs? The following are recommended: | | |
| a) Dispensing, including therapeutic review and patient counselling; high-risk/High Tech medicines | | |
| b) Storage of medicines | | |
| c) Sourcing of medicines | | |
| d) Expiry date checking | | |
| e) Sale and supply of medicinal products | | |
| f) Storage and record-keeping for controlled drugs | | |
| g) Disposal and/or destruction of medicines (including controlled drugs) | | |
| h) Management of additional services provided (including supply to residential care homes) | | |
| i) Error and incident management (including error logs) | | |
| j) Locum induction/communication policy | | |
| k) Housekeeping and cleanliness of dispensary and shop floor (inc. cleaning records) | | |
| l) Use of patient consultation area | | |
| m) Policy on use of child resistant containers | | |
| n) Keyholding policy (to premises and CD Safe) | | |
| 3.2 Is there an implementation date on all SOPs? | | |
| 3.3 Is there a review date on all SOPs? | | |
| 3.4 Is there evidence that staff have been trained on SOPs? | | |

| 4.0 Duty Register | Yes | No |
|---|-----|----|
| 4.1 Has the RPB a duty register/log for the current year? | | |
| 4.2 Is the duty register being correctly maintained? | | |
| 4.3 Is there professional cover available for all hours of opening? | | |
| 4.4 Does the supervising pharmacist provide adequate cover? | | |

PSI Practice Guidance - examples

- Security Assessment Template: developed jointly by the PSI and An Garda Síochána
- Letter 9th July 09 – further outline of duties to be discharged.
- Letter 9th July 2010 – underpins the corp. owner & superintendent relationship
- Practice Notices; PPGM



THE PHARMACEUTICAL SOCIETY OF IRELAND
AND
AN GARDA SÍOCHÁNA

SECURITY ASSESSMENT
GUIDANCE DOCUMENT FOR RETAIL PHARMACIES

vs. 2 December 2009


THE PHARMACEUTICAL SOCIETY OF IRELAND
Curiam Cógaitoír na hÉireann
THE PHARMACY REGULATOR

(Individual Name and Address)

9th July 2009

Dear (Name)

Re: Responsibilities of Superintendent Pharmacist
The Pharmacist

I am writing to you in your capacity as superintendent pharmacist under the Pharmacy Act 2007. In appreciation of your assistance and support in the past, I am writing to you to clarify your responsibilities as such a pharmacist under the Pharmacy Act 2007.

As you are aware, that part of the retail pharmacy administration of the sale and supply of medicinal products for which you are responsible, you have undertaken that the retail pharmacy complies with the provisions of the Pharmacy Act 2007, Statutory Rules and professional guidelines.

As the superintendent pharmacist for the retail pharmacy, you are responsible for ensuring that –

- all legal and professional standards are met by the pharmacist (including any supervising pharmacist and/or employed in any of the retail pharmacies) under your supervision;
- the certificates of registration for each of the retail pharmacies for which you are responsible, are conspicuously displayed; and
- the sale and supply of all medicinal products is under the personal supervision of a registered pharmacist and that no such sale or supply is made other than under the personal supervision of a registered pharmacist.

¹ See also the form, provided for in Section 28a of the Pharmacy Act 2007, signed by the pharmacist and on behalf of the corporate owner.


THE PHARMACEUTICAL SOCIETY OF IRELAND
Curiam Cógaitoír na hÉireann
THE PHARMACY REGULATOR

9th July 2010

Re: Superintendent Pharmacist
Retail

Dear Pharmacy Owner/Superintendent Pharmacist

It has come to the attention of the Pharmacy Regulation Unit that there is a serious misunderstanding in relation to the role of the pharmacist (i.e. the company) carrying on a retail pharmacy business (being the pharmacist referred to in section 28(a) of the Pharmacy Act 2007).

The position is that in order for a company to carry on a retail pharmacy business under the Pharmacy Act 2007, the company must be responsible for the management and administration of the sale and supply of medicinal products under the control of a pharmacist who, together with the company, is responsible for section 28(a) of the Act and which states that the company must ensure that the pharmacist concerned does not cease to be a company concerned is no longer in a position to carry on a retail pharmacy business.

It is important to note that a Superintendent Pharmacist statement specified in section 28(a) of the Pharmacy Act 2007 is required for the company to carry on a retail pharmacy business.

If the Superintendent Pharmacist, for whom the company concerned is no longer in a position to carry on a retail pharmacy business, it is imperative that the Superintendent Pharmacist understand and appreciate the importance of such plans (including essential succession plans) and that the Superintendent Pharmacist will be obliged to cease its activities in respect of the retail pharmacy business. A Superintendent Pharmacist can be installed in the event that such an eventuality were to occur or on the part of the Superintendent Pharmacist concerned. The Superintendent Pharmacist may be referred for investigation under Part 6 of the Pharmacy Act 2007 if patients were to be denied access to medicinal products as a result of the closure of a pharmacy or pharmacies.



The Pharmaceutical Society of Ireland
(Standards and Practice Unit)

PHARMACY PRACTICE GUIDANCE MANUAL
A self-audit tool for pharmacists and pharmacy owners

1st edition May 2008



Core legal & professional requirements

Examples:

1. Ensure Sale & Supply of all Med. Products (Rx or non-Rx) is under **personal supervision** of a registered pharmacist.
2. **Duty Register** is accurately maintained
3. Custody and supply and records of **CDs** in full compliance with legislation
4. Supply, ordering, keeping and records of all POMs in full compliance with legislation.
5. Reg 13 complied with for Paracetamol products
6. Procedures and arrangements in place ensuring **Reg. 9** Review and Counseling are met
7. **Reg 10:** Counseling for all non-POMs are met at all times – compliance with related guidance e.g. Codeine
8. Sections 63 to 65 of Act is strictly adhered to – re beneficial interest in a medical practice
9. All owners / persons holding positions of responsibility in corporate body are fully aware of superintendent responsibilities – you must **promote full understanding of the role and obligations.**

pharmacy act implementation

Guidance on the Roles and Responsibilities of Superintendent and Supervising Pharmacists

Introduction

Any registered pharmacist operating in a pharmacy must act in accordance with all legislative requirements, guidance of the Regulator, and the Code of Conduct, and is personally accountable for all professional practices he or she carries out and oversees.

The Pharmacy Act 2007 establishes the roles of 'superintendent' and 'supervising' pharmacists, and places the clinical and professional management and accountability of a retail pharmacy business within these two key roles, in co-operation with the pharmacy owner.

During public consultations on the implementation of the Pharmacy Act 2007, it became apparent that further guidance on the roles and responsibilities of these pharmacist grades was required.

Notwithstanding the fact that the two roles may rest in the one individual, there is a reporting relationship between the supervising pharmacist and his or her clinical manager, the superintendent pharmacist.

Role of a Pharmacist

The role of the pharmacist is essentially that of the expert in the science of medicines, inclusive of development, supply and use. In the exercise of this expertise, a patient has a right to safe and effective pharmacy services operated by a competent, trained professional in a regulated and appropriate environment. Each pharmacist in practice should ensure that, in partnership with colleagues and the patients attending, a measurable quality of pharmacy service is available that is safe, efficient, effective and respectful of the patient's rights and entitlements. Differing levels of accountability will apply in respect of differing roles fulfilled, but all practitioners are required to possess, maintain, update and display competence and accountability in respect of the management of the health of a patient and the delivery of an acceptable standard of pharmaceutical care.

The Pharmacy Act 2007 has provided for an appropriate structure of accountability and governance to ensure the safe delivery of a professional, clinical service. The following is initial guidance on the differing levels of accountability and responsibility as provided for in the Act.

Scope

A Pharmacist is an expert in the science of medicines, inclusive of development, supply and use. A number of basic criteria apply to every pharmacist in their professional practice (see Figure 1); however, the responsibilities underpinning each of the criteria vary depending on the clinical governance position held, in addition to fulfilling the role of pharmacist; each and every action will be governed by demonstrated awareness, application of and adherence to the provisions of the statutory Code of Conduct.

Criteria

Each and every pharmacist in practice will:

1. Produce and distribute/supply medicinal preparations and products
2. Optimise professional performance and contribute to the optimisation of the performance of others.
3. Contribute to the effectiveness of the pharmacy systems and activities
4. Contribute to the effective operation of the practice environment
5. Provide pharmaceutical care including information and services

Legislative basis

Pharmacy Act 2007

- Requirement for pharmacist operation of a pharmacy practice is contained in sections 27(d), 28(c) and 29(d), which state that at "the sale and supply of medicinal products in the premises in which the business is carried on is conducted in those premises... by or under the personal supervision of a registered pharmacist".
- Requirement for a Supervising Pharmacist is contained in sections 27(c), 28(b) and 29(c) which state that at the premises where a retail pharmacy business is carried on, there must be "a registered pharmacist who has a 3 year minimum post-registration experience in whole time charge of the carrying on of the business there".
- Requirement for a Superintendent Pharmacist is contained in sections 27(b), 28(a) and 29(b) which state that in the carrying on of a retail pharmacy business "the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has a 3 year minimum post-registration experience".

The Regulation of Retail Pharmacy Business Regulations 2008 (Section 18 regulations) and the Retail Pharmacy Business Registration Rules 2008 further set out requirements in respect of the roles, and have implications in practice, as do the Code of Conduct, and guidance issued by the PSI.

Figure 1

Criteria that apply to every pharmacist in their professional practice

```
graph TD; A[Pharmacist expert in the science of medicines, inclusive of development, supply and use] --- B[Optimise professional performance (of themselves and those they supervise)]; A --- C[Produce and distribute/supply medicinal preparations and products]; A --- D[Provide pharmaceutical care, including information and services]; A --- E[Contribute to the effective operation of the practice environment]; A --- F[Contribute to the effectiveness of the pharmacy systems and activities];
```

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Responsible for everything that happens within RPB

Superintendent pharmacists must:

Examples:

1. Ensure the maintenance and adherence to a sound system of internal controls and policies to manage risk and promote patient safety
2. Be satisfied that you have **sufficient resources, authority and influence**
3. Make sure that all persons **holding positions of responsibility**, including all members of the board of the corporate body, as well as all departments & centralised management functions **are aware of and understand your responsibilities** & do not thwart your professional judgement or decisions
4. **Not permit** another person(s) to **impair or compromise** your ability to observe your statutory obligations under the Code of Conduct
5. Not put your own or commercial interests of the company before patient safety
6. Retain **overall control** and professional accountability at all times
7. Inform the PSI in writing of changes to the RPB (change of superintendent / ownership etc.)
8. Ensure **active participation** and interaction with the **professional regulator**
9. **Maintain clear lines of accountability – reporting structures**

Practice Policy Requirements

Examples:

- Policies for full compliance with Section 18 regs
- Prescription Dispensing Policy; Reg 9 Therapeutic Review & Counselling; High Risk & High-Tech meds policies
- Sale & Supply of Meds - personal supervision policy (including provision for Consultation Area, appropriate layout; adequate staffing)
- Rational & Safe Usage of Medicines Policy
- Accessibility of Medicines Policy (POMs, P-Meds, CD5s & products of abuse, Hazardous products etc.)
- Supervising & superintendent Pharmacist requirement policy
- On-going Training & Development Policy
- Pharmacy Colleague Recruitment & Vetting Policy
- Appropriate Skills, Knowledge, Competence & Registration Policy
- Locum Induction & on-going Communication Policy
- Local complaints policy and feedback Procedures
- Error Report management; SOPs and Policy (including Review)
- Health & Safety Policy
- Security Policy (key-holding)
- Clinical Service Governance Policy
- I.T. Appropriate Usage Policy
- Review & audit Policy
- Sourcing from Authorised Suppliers Policy (including contingency plans & IMB communication pathway)
- Selection and evaluation of products and services (including appropriate merchandising)

Full organisational policies must be in place to govern RPB

Why are written policies required?

- Demonstrate full-time control & governance over all RPB operations
- Full-time Accountability – policies to ensure safe practice when you are present or not
- Procedural optimisation & Standardised practice from one RPB to the next
- Training mechanism – all procedures explicitly set forth policies read and understood
- Responsibilities clearly defined and delegated
- Improved environment for employees – confidence & professional development
- Audit & Review – on-going improvement of care & service provision

Prevention of irreversible harm to patients / public

Pro-active Implementation of Guidance Documents:

EG: PSI Practice Notices

- *'Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes'*

Reflect & plan:

- How does it apply to services within my RPB?
- How do I implement the recommendations?
- How will I audit new process?

Implement:

- Write new process document / update SOPs?
- Write e.g. new 'residential care policy'
- Regular audit of service & policy review

Communicate:

- All relevant staff trained in new process
- Nursing homes staff and prescribers briefed - interdisciplinary elements agreed and documented
- Competency assessment – 'Read & Understood' sheets signed



Many Organisational Structures - One Superintendent Role

Full-time responsibility & accountability for all pharmacies

1

→ Approx. 1000 superintendent pharmacists are acting in this capacity for one single RPB.

1 RPB

**One pharmacist =
S.I + S.V
(may also be owner)**

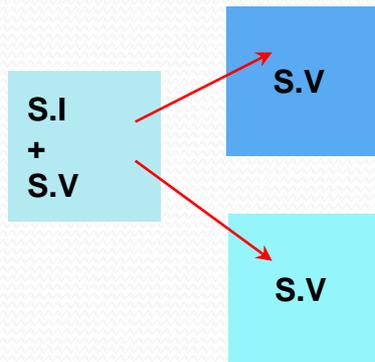
Problems / Challenges

- No written policies or procedures. Presumption that they are not required?
- 'Silo' approach. No best practice sharing. Lack of awareness of current developments and requirements.

Many Organisational Structures - One Superintendent Role

2

- Approx. 200 superintendent pharmacists are acting in this capacity for 2 or more RPBs.



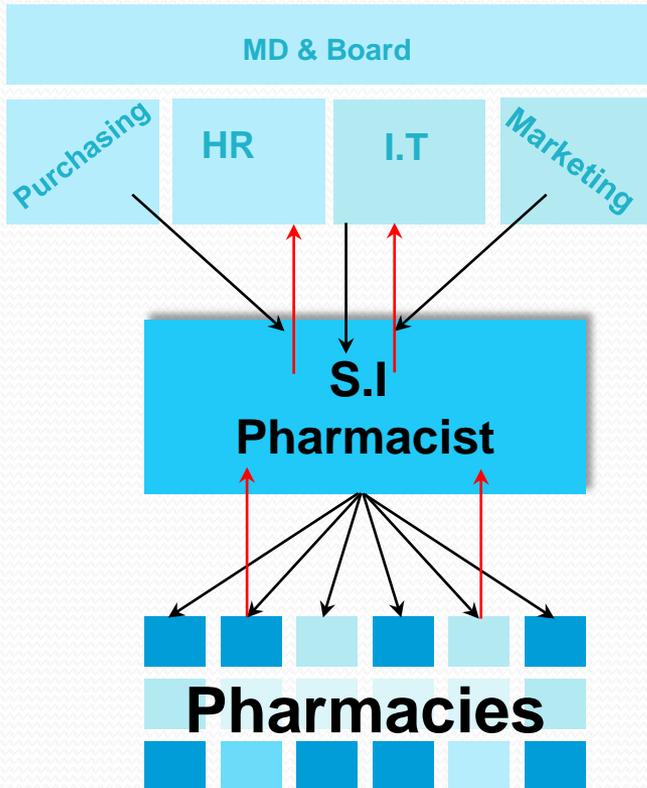
Problems / Challenges

- Superintendent is working full-time in one pharmacy
- Discharging duties of both superintendent & supervising pharmacist
- How can one be in 'whole time charge' of one pharmacy and yet be in 'personal control of management & admin of meds' in other pharmacies?
- Often not in control. How can you satisfy yourself that clinical & professional policies are being adhered to in all pharmacies?
- Sufficient number of pharmacists need to be employed in the organisation to enable the superintendent to direct the running of the all RPBs.

Same level of control required across all RPBs

Many Organisational Structures - One Superintendent Role

3



Problems / Challenges

- 'Power failure' – professional V financial clash
- Lack of awareness of legislative changes and operational impact at office level
- Lack of 'front line' experience & professional knowledge at office level
- Lack of pharmacist confidence in communication with owners
- Inappropriate delegation of duties – e.g. Non-pharmacist managers – superintendents legally accountable
- Misunderstandings at pharmacy and head office level
- Overall responsibility for the implementation of legal, professional and clinical policy. Overall accountability.

Same level of control required across all RPBs

Tasks can be delegated – Accountability can not

- **Sourcing** - securing your supply chain of medicines and ensuring quality & traceability – YOUR responsibility

Robust policies e.g. sourcing from an authorised supplier?

- **Marketing** - legislation governing advertising & promo activity? YOUR responsibility

Robust policies & Vetting procedures for all promo material?

- **HR** – all staff ‘requisite knowledge & skills & are fit to perform..’ – adequate staffing levels - YOUR responsibility
- **IT** - Data Protection Act / appropriate Information Security – YOUR responsibility
- **Finance** – Provision of adequate resources for safe and high standard of patient service - YOUR responsibility

Accountability & Root-cause Analysis

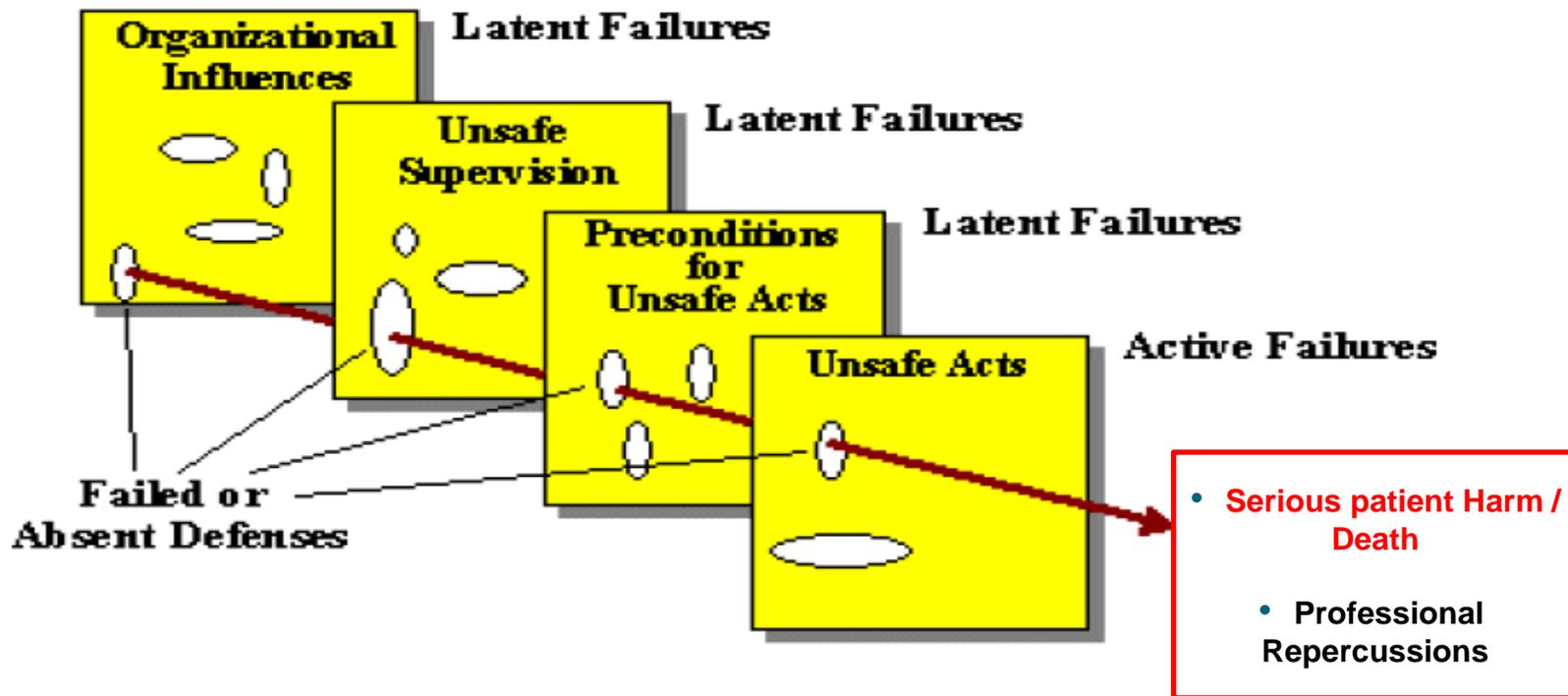
Who is responsible for errors within the pharmacy?

- As autonomous professionals, all registered pharmacists are responsible and professionally accountable in their day-to-day practice.

However, the superintendent is:

- *'The individual responsible for the overall clinical management of the pharmacy practice'*
- Human error will always occur. However, many errors occur due to 'systems' failure, not human error. The superintendent is responsible for implementation and maintenance of safe systems.
- Often errors result from a combination of systems and human error and the responsibility may be shared

To minimise error, superintendents must Reflect, Predict and Prevent Root-Cause Analysis – ‘Swiss Cheese effect’



- Latent failures are **preventable** - superintendent pharmacists must **reflect & identify preconditions**
- Examples of preventable latent failures: lack of appropriate and regularly **reviewed policies and procedures**; **understaffing**; non-compliance with legislation.
- Not unique to Pharmacy - All healthcare facilities must incorporate a Risk Management approach.

How to avoid disciplinary action (1)

Also consider 'Swiss Cheese' model

Reflect; Predict; Prevent.

- Full compliance with section 18
- Demonstrable control – written practice policies (e.g. evaluation and improvement in respect of the delivery of care) & SOPs in place
- When procedural infringements / deficiencies / failures occur in one RPB – establish cause; procedural review and update systems & communicate. On-going improvement.
- Code of conduct; keeping patient safety paramount
- Robust risk assessment
- Good complaints handling at pharmacy level – prevent escalation

How to avoid disciplinary action (2)

Local Conciliation Process

Always report the error!

- Error management & complaints policy in place?
- Simple processes avoid escalation – majority of cases can be resolved at branch level
- Prioritise errors
- Culture of Transparency within organisation & with patients
- Documented staff training – Communication skills vital. All pharmacy staff should treat patients the way they would like to be treated
- Root-cause analysis: procedural review and update systems & communicate/re-train. On-going improvement.
- Never bury problems! Address immediately.

Summary of Legal Responsibilities & Accountabilities

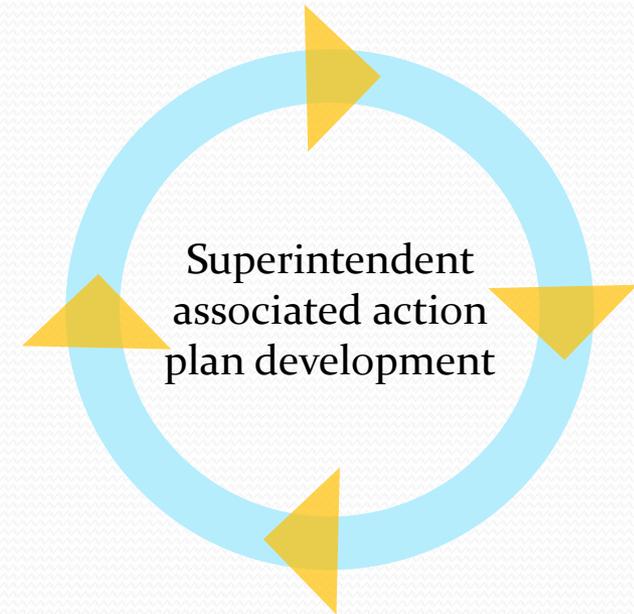
Superintendent Pharmacists

- ✓ Responsible for everything that happens within RPB
- ✓ Must ensure full compliance with all legislation
- ✓ Must have sufficient resources, authority and influence
- ✓ Full documented organisational policies must be in place – not unique to pharmacy
- ✓ Many Organisational Structures – One Superintendent Role
- ✓ Tasks can be delegated – Accountability can not
- ✓ Avoid disciplinary action - Reflect; Predict; Prevent

✓ Legal Responsibilities & Accountabilities of a superintendent pharmacist understood

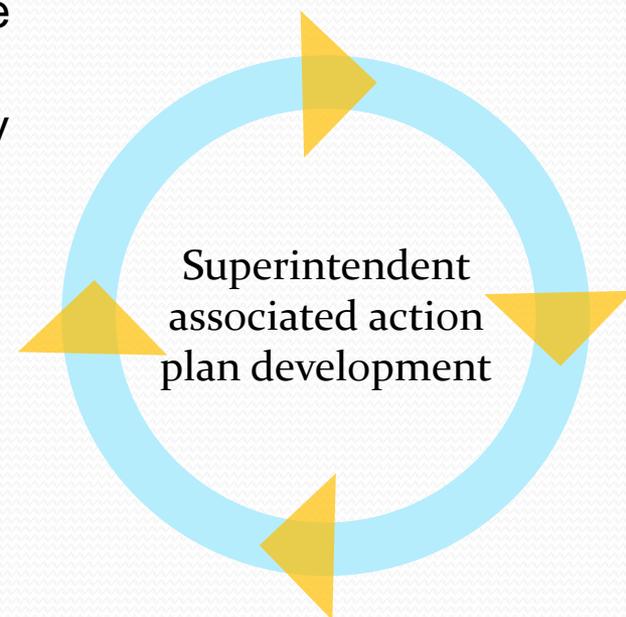
Reflection

- Do I fully understand what is required of me as superintendent? Do I understand the systems I have to implement? Do I understand the accountability of my Role?
- How do I as a superintendent ensure patient safety within my retail pharmacy business(es)? What further initiatives can I take?
- Risk management - Am I pro-actively identifying latent failures?
- How do I facilitate clinical Review and Audit within the practice? What further initiatives can I take?
- Does my pharmacy owner/employer fully understand my Role, what is expected of me and the significance of the new regulations?



Reflection

- How do I ensure all legal and professional standards are met by all pharmacists (including myself) and all other staff that may be engaged and/or employed in any of my retail pharmacy businesses?
- How can I ensure consistency of standards and sustainability of service across the RPB?
- How can I achieve fulfillment of compliance to all legislative requirements?
- How can I achieve high level of adherence to Professional Guidance?
- How can I Increase reflection and understanding of new standards and requirements amongst the colleagues in the RPB for which I am responsible?
- **How can I be a champion for my profession?**





Thank you