

Superintendent Pharmacists – Responsibilities and Accountabilities

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PSI/ICCPE taskforce on initiative on Superintendents

In November 2010, the PSI/ICCPE 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.

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 prerequisite 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

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.

Succession Planning

An element of reflection and effective planning is required in all businesses and pharmacy is no exception, particularly as it involves ensuring the continuity of patient care. A company for example, cannot lawfully trade in medicinal products or conduct a pharmacy without a superintendent, therefore it follows that due consideration must be given to succession planning within the business.

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 Regulator; 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

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.

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, CD5s, products with abuse potential, etc.), including a process for effective vetting of all promotional material. All personnel within that pharmacy, both in the pharmacy itself as well as relevant office personnel, 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 fail 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.

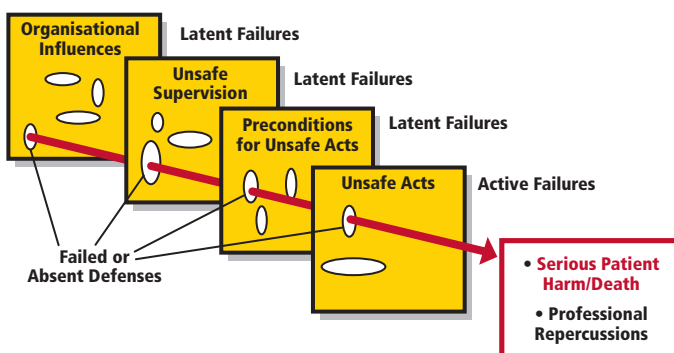


Fig 1: Reason's Swiss Cheese Model; paradigm for error analysis and prevention

Identifying Latent Failures and Active Failures

A common latent failure in pharmacy practice is the lack of regularly reviewed dispensing procedures. If, for example, a superintendent has not introduced a procedure for the systematic checking of expiry dates and removal of expired medicines from stock, this is one latent failure (or hole in the cheese). To compound the risk, if the superintendent has not introduced a dispensing procedure with a provision for date-checking of all medicines at the point of dispensing, another latent failure is permitted. If on top of this, you add an active failure such as pharmacist tiredness, an out-of-date medicine may be dispensed, resulting in an ineffective treatment and/or serious patient harm.

A second example of a latent failure would be lack of a policy reflecting the necessity for having a registered pharmacist present at all times and engaging in effective supervision of the pharmacy. If a staff member opens a pharmacy and medicinal products are subsequently sold or supplied, the superintendent can be held accountable. A superintendent must be able to demonstrate that they have an effective and robust policy in place to ensure full-time supervision and control of that pharmacy, and that all pharmacy staff are made aware of, trained in and are in compliance with this policy. All pharmacy staff should be formally made aware of the procedure to follow should, for example, a locum not present themselves to conduct the pharmacy. Such a procedure should outline what to do to (pharmacy not to open) and what not to do (e.g. no sale of non-prescription medicinal products), and who to contact (e.g. superintendent pharmacist, locum agency).

For the most part, latent failures are preventable. It is the duty of the superintendent pharmacist to reflect on their particular practice, to proactively identify the preconditions and endeavour to minimise, and where possible eliminate, risks and incident occurrence.

A third example of a preventable latent failure is the failure to incorporate guidance of the Regulator into the pharmacy's systems and procedures. An example with potentially serious repercussions is failure to action the points of guidance provided in the PSI's Methotrexate Practice Notice. If the superintendent has no policy or specific training in place for the safe dispensing of high-risk medicines, the risk is compounded and another weakness is introduced in the system. If a superintendent also fails to introduce a policy to reflect the requirement for therapeutic review and patient counselling by the registered pharmacist (to comply with Regulation 9 of S.I. No. 488 of 2008), an inappropriate label may be printed, the patient may not be adequately counselled and a daily dose of methotrexate taken by the patient, which could result in serious side effects, hospitalisation or even death.

Many active failures can also be predicted and prevented, for example introducing a minimum break period for a certain number of hours worked; or identifying busy periods within the practice and organising sufficient support and cover accordingly.

Error Review and Root-Cause Analysis

All errors that do occur must be systematically recorded in the pharmacy and be subjected to a regular review and root-cause analysis by the superintendent pharmacist. Learnings made from such a review must then be incorporated into the policies and procedures of the pharmacy in order to prevent recurrence.



Fig. 2: Superintendent pharmacist's error prevention cycle

When a superintendent reviews and analyses the errors for example, they may find that some medicinal products have a higher risk of being dispensed incorrectly, within one individual pharmacy or across numerous pharmacies. When the cause is examined it may be due to storage proximity to another product with a similar name, brand, ingredient or packaging - a Sound-Alike Look-Alike-Drug (SALAD) error. Such errors or near misses should be routinely reported to manufacturers and the Irish Medicines Board so that any necessary changes to the product can be examined.

If a superintendent is in control of one pharmacy, they should communicate both the cause of the error as well as their updated or new procedure to all staff engaged within that pharmacy and maintain a record of any re-training completed. If a superintendent is in control of numerous pharmacies, they must ensure that learnings made from incidents occurring in the originating pharmacy are communicated to all pharmacies and that the overarching policies for the organisation are updated.

The appropriate process to follow when an error is reported must be outlined, including, for example, how to deal with errors reported by patients over the telephone. Under no circumstances should a patient be left with incorrect medicine(s) at home, nor should the onus be on the patient to return the incorrect medicine to the pharmacy, or the error left for the next pharmacist to address. When an error is reported, the pharmacist on duty must act immediately to retrieve any incorrect medicine, assess any risks to the patient's health, give the

appropriate advice and follow-up and furnish the patient with their correct treatment, as appropriate.

To take effective ownership of the situation does not necessarily mean accepting 'responsibility' for making the error. According to a defined procedure, the pharmacist on duty must communicate what has occurred to the supervising pharmacist and/or the superintendent pharmacist and the error is appropriately documented, along with any remedial actions taken.

For an error-reporting system to be truly effective, the superintendent should foster a no-blame culture and encourage transparency within the pharmacy. Such reflective practice and incorporation of learning into review of procedures are equally important both for superintendents that are in personal control of one pharmacy and those in control of many.

An Effective Complaints System

In parallel with an effective Error Review process, every pharmacy must have a robust complaints system in place in the interest of patients and the public. A patient or member of the public may be dissatisfied or concerned with the treatment they have received in a pharmacy, or with the behaviour, conduct, practice or health of a particular pharmacist. If there is no effective complaints process in place within that pharmacy, the person may feel it necessary to escalate their grievances to the PSI.

Although the possibility of such an escalation is a vital mechanism which must exist to enable patients to report serious concerns and complaints, or for the Regulator to detect real and immediate public risk, many complaints are escalated simply because the patient feels they have not been treated appropriately when they raised their concerns within the pharmacy.

Many complaints can be easily resolved within the pharmacy itself if a simple, standardised procedure is in place to facilitate local action. This documented procedure should have clearly outlined responsibilities and give explicit instructions on how complaints are to be dealt with, from the point of reporting by the patient until full resolution. The procedure must specify any person(s) to be notified of the complaint (i.e. supervising pharmacist and superintendent pharmacist) and give details of what procedures and timelines they themselves will adhere to and in what instances, for example, reporting to the prescriber where necessary.

Soft skills and communication training are vital elements here for pharmacy staff. A defensive tone or attitude, or failure to take ownership over the complaint, may lead to escalation of even the simplest of grievances. The complaints policy of a pharmacy should remind pharmacists to be mindful of their Code of Conduct which necessitates professionalism and accountability. Pharmacy staff must be trained to deal with concerns respectfully and with understanding and to ensure the patient's experience of

pharmacy is a professional and positive one. A patient will feel compelled to escalate their complaint if they feel that their concern is not being taken seriously or if they sense apathy or fear a recurrence.

Patients should be given appropriate reassurance, such as explaining how the pharmacy procedures have been updated as a result of the error and the nature of any re-training carried out. All complaints and errors must be followed up thoroughly until a satisfactory conclusion is reached.

Professional Guidance of the Regulator

All superintendents undertake to comply with professional guidelines of the Regulator. Official formal guidelines are being published by the PSI in order to facilitate compliance with the Act and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). All pharmacists and pharmacies are expected to comply in full with these formal guidelines. In 2010, for example, guidelines were published in relation to Patient Consultation Areas and Safe Supply of non-prescription Codeine Medicines (accessible via PSI website). Guidelines for the safe and appropriate Sourcing, Storage and Disposal of medicinal products will be published early in 2011, with guidelines relating to Premises and Equipment, Record-keeping, Management and Supervision, and Supply and Counselling of Prescription and Non-prescription Medicines Regulation (Regulations 9 and 10) to be published later.

PSI Practice Notices and Guidance – example of implementation process

As various guidance documents are published and disseminated by the PSI, it is the superintendent's responsibility to reflect on how they apply to their pharmacy and ensure the recommendations are implemented. An example is the recent Practice Notice on Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes. This should be reviewed along with HIQA's National Quality Standards for Residential Care Settings for Older People which set out what a quality, safe service for an older person living in a residential care setting should be.

When implementing the recommendations of the Practice Notice, superintendent pharmacists must review their current processes to ensure patients in such care settings receive the same level of professional care as those who attend the pharmacy in person.

How is this achieved?

Firstly, it is important to identify where pharmacist intervention is required (example see fig. 3) and then decide on the exact procedures to be implemented in order for the individual pharmacy to provide an appropriate, standardised system for pharmaceutical care to the residential setting – one which facilitates counselling by the pharmacist of each individual patient. It is essential that the pharmacist personally and physically attends to the patient in the home, on a frequency appropriate to the individual patient's needs. Records of these visits to patients by the pharmacist should be retained and be available for review in the pharmacy and in the care setting itself.

There must be regular, and frequently as required, contact with medical personnel responsible for the patients in the care setting, particularly in relation to new patients, to establish any needs or requirements specific to that patient. Such contact and all resulting actions should be systematically documented and maintained for reference and inspection.

The delivery process must incorporate provision for a registered pharmacist's supervision and intervention. No queries must be answered or advice given by a person who is not qualified to provide such information. All healthcare professionals involved in deliveries to the care setting, including all pharmacy employees, must be readily identifiable to receiving patients and their carers. A demonstrable mechanism must be in place whereby the patients are made aware that there is ready and ongoing access to a pharmacist.

All pharmacists involved in the care of a patient within a residential

care setting must actively participate in the development of appropriate policies governing medicines safety and management, in co-operation with other named healthcare professionals involved in patient care within the organisation. Going forward, in line with the HIQA National Quality Standards for Residential Care Settings for Older People in Ireland, all pharmacists will be required to participate in an Interdisciplinary Medication Review of each patient on long-term medication, at least on a three-monthly basis. These reviews should give special consideration to the specific medicinal products referred to in the HIQA standards, including antipsychotic medication, sleeping tablets and other sedating medication and analgesics.

With all guidance documents issued by the PSI, the superintendent must decide whether any new procedures or amendments to current procedures are required. They must ensure that all pharmacy employees involved in provision of specific pharmaceutical services are appropriately trained to carry out the clearly defined role(s) for which they are responsible. Competency assessment sheets must be signed and a record of associated training maintained.



Fig. 3: Reflection on Practice Notice for Patients in Residential Care. Identification of pharmacist intervention requirements.

Other tools for improvement of standards and professional guidance have been provided by the PSI; for example, many superintendent pharmacists and owners have found the the Security Assessment Template, developed jointly by the PSI and An Garda Síochána, and the PSI's Pharmacy Practice Guidance Manual valuable mechanisms for the facilitation of self-audit.

As policies and procedures should be in place to govern all processes within a pharmacy that may impact on patients, the superintendent should determine their own practice-specific requirements in this regard. All guidance and support documentation are accessible on the PSI website, www.thePSI.ie, under the Pharmacy Practice section.

The PSI welcomes queries from superintendents in relation to guidance issued by the PSI or any matters of concern relating to their role and responsibilities. Such queries should be sent in writing, preferably by email, to info@thepsi.ie.