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.

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.

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

Figure 1

Criteria that apply to every pharmacist in their professional practice

- Optimise professional performance (of themselves and those they supervise)
- Contribute to the effectiveness of the pharmacy systems and activities
- Produce and distribute/supply medicinal preparations and products
- Contribute to the effective operation of the practice environment
- Provide pharmaceutical care, including information and services
Role and Responsibilities of a Supervising Pharmacist

The Supervising Pharmacist of a practice is the professional who is in whole-time charge of the operation of the pharmacy, and has three years’ post-registration experience. This individual is responsible for all operations of the pharmacy, even when absent, and has a reporting relationship to the superintendent pharmacist. The pharmacist fulfilling this role may operate in this capacity for one pharmacy practice only at a given time.

In fulfilling the role of a pharmacist, the supervising pharmacist is impacted specifically by the following additional considerations:

1 In respect of the production, distribution and supply of medicinal preparations and products a supervising pharmacist should:
   - Attend for reasonable, regular and ongoing periods of the operating time of the pharmacy at the professional services area of the practice, in order to properly carry out the role of supervising pharmacist.
   - Ensure that clear, structured procedures are in place and consistently operated within the pharmacy, with regard to the management of dispensing activity, including quality-assured safety checking systems and the maintenance of adequate records.
   - Ensure that procedures are in place and consistently operated within the pharmacy to facilitate the supervision of, and intervention by, the pharmacist in the supply of non-prescription controlled medicinal products.
   - Ensure that all medicinal products, including animal remedies, are sourced from an authorised supplier.
   - Ensure that all medicinal products, for both human and animal use, are authorised for supply.
   - Ensure inter-practice transfers of medicinal products occur only with a view to facilitating immediate patient need.
   - Ensure any returned unwanted or out-of-date product is appropriately segregated and located in a designated secure area.
   - Ensure any medicinal product held is maintained in a manner that is in accordance with its authorisation and with provisions to maintain quality of the product.

2 In respect of the optimisation of professional performance and contribution to the optimisation of the performance of others, a supervising pharmacist should:
   - Ensure that all pharmacists, pharmaceutical assistants and other staff in the pharmacy are qualified, trained, competent and fit to perform the functions assigned to them.
   - Ensure that all personnel operating within a retail pharmacy business under his or her charge are aware of the scope of their role and the limits applicable in respect of the management of the professional services provided.
   - Ensure that all personnel are aware of the circumstances necessitating referral to a pharmacist, and that appropriate controls are in place to govern the accessibility of medicines, including prescription medicines, medicines exempt from prescription control and CD 5 classified products, or products liable to misuse.
   - Be responsible for prohibiting any individual or entity from unduly influencing, directing, controlling or supervising in a way that is contrary to the law, Code of Conduct for Registered Pharmacists, or is unethical or inappropriate to the professional activity of the pharmacy for which he or she is responsible.
   - Ensure that compliance with the Code of Conduct, in respect of his or her own professional activity and of those he or she supervises, is expected and facilitated.
   - Ensure that the duty log is properly and accurately maintained in the pharmacy.
   - Ensure that the policies and procedures of the organisation are implemented and raise concerns about those policies and procedures with the superintendent pharmacist or pharmacy owner, if in the reasonable opinion of the supervising pharmacist they are in breach of the law, the Code of Conduct, or are unethical or inappropriate in a pharmacy context.

3 In respect of the contribution to the effectiveness of the pharmacy systems, a supervising pharmacist should:
   - Be accountable for all professional activities occurring there, including the provision of medicines, products and services, and advice and counselling regarding those medicines, products and services.
   - Be responsible for the generation, implementation and application of procedures and systems documents to cover all personnel operating in the particular pharmacy in accordance with current law and best practice.
   - Ensure that standards and guidance issued by the PSI and other bodies are adhered to.
   - Ensure that appropriate records are maintained.
   - Ensure that a practice-specific operations manual is maintained, regularly reviewed and updated, and implemented by all staff, and that staff receive appropriate training on the manual’s procedures.

4 In respect of the contribution to the effective operation of the practice environment, a supervising pharmacist should:
   - Be responsible for personally managing, controlling and supervising the pharmacy
   - Ensure that all personnel employed are adequately and appropriately identified, referencing name and role in a manner which is clear to the patient.
   - Ensure that the appropriate registration certificates are conspicuously displayed, including his or her own certificate.
   - Ensure that full co-operation be provided to the Regulator and all requests for information from the PSI be answered within the appropriate timeframe.
   - Ensure on a day-to-day basis that the pharmacy premises are maintained to a standard that is safe for patients and staff.

5 In respect of the provision of pharmaceutical care, including information and services, a supervising pharmacist should:
   - Ensure that any pharmacist operating while he is absent from the pharmacy is suitably qualified to do so.
   - Ensure that continuing professional development is undertaken by him or her, and by any other pharmacist operating in the retail pharmacy business for which he or she is responsible.
   - Ensure that a registered pharmacist reviews all prescriptions dispensed, to assess the pharmaceutical and therapeutic appropriateness of the product for the patient, in accordance with appropriate parameters thereof.
   - Ensure that any patient receiving a dispensed medicinal product is provided with sufficient information, advice and counselling to facilitate the safe use and handling of the product.
   - Ensure that any supply of a non-prescription, controlled medicinal product is conducted in a manner such that the pharmacist is satisfied it may be safely and appropriately used and is not being sought to intentionally abuse or misuse.
   - Ensure that there is proper clinical management of the delivery of the pharmaceutical care services provided by the pharmacy.
Role and Responsibilities of a Superintendent Pharmacist

The Superintendent Pharmacist of a practice is the individual responsible for the professional policy and clinical management of the pharmacy practice. This individual is in personal control of the management and administration of the sale and supply of medicines, and has overall control of the professional and clinical pharmacy policy. The pharmacist fulfilling this role will have three years’ post-registration experience and may operate in this capacity for more than one pharmacy practice at a given time.

(The roles of superintendent and supervising pharmacist may rest in the one individual; however, such an individual can only act as supervising pharmacist in respect of one retail pharmacy business, but as superintendent in respect of more than one).

In fulfilling their role as a pharmacist, the superintendent pharmacist has the following additional responsibilities:

1 In respect of the production, distribution and supply of medicinal preparations and products, a superintendent pharmacist should:
   • Ensure the pharmacy premises are of appropriate standard to provide for safe storage, preparation, dispensing, compounding, sale and supply of medicinal products, and address this with the pharmacy owner if this is not so.
   • Ensure that an ethical and appropriate policy is in place that provides proper controls to govern the accessibility of medicines, including prescription medicines, pharmacist-supervised medicines, and other products, and that CD 5 classified products and veterinary medicines are not available to the public for self-selection.
   • Ensure that ethical and appropriate policies are in place and implemented within the organisation and pharmacy to ensure the rational and safe use of medicines in the interests of patients.
   • Ensure that co-operation is afforded to the IMB in respect of product recalls and/or withdrawals and procedures are in place to manage this.
   • Ensure that policy is clear to guarantee that all medicinal products, including animal remedies, are sourced from an authorised supplier.
   • Ensure that policy is clear to guarantee that all medicinal products, for both human and animal use, are authorised for supply.
   • Ensure the maintenance of a system to manage the return of unwanted medicines and out-of-date medicines.

2 In respect of the optimisation of professional performance and contribution to the optimisation of the performance of others, a superintendent pharmacist should:
   • Ensure the supervising pharmacist responsible for the operational control and implementation of the pharmacy policy has three years’ post registration experience.
   • Ensure a clearly-defined policy is understood by the individuals employed at the practice as to the necessity for pharmacist supervision of any operation of the practice.
   • Ensure that all pharmacists and other staff employed are in possession of the knowledge, skills and competence to perform, and are identified as being appropriately registered, as applicable.
   • Ensure that policies are in place to support compliance with the Code of Conduct.
   • Ensure a policy is in place to address the requirement for ongoing training and development of all pharmacy staff.
   • Ensure that robust and proper policies and procedures are in place and implemented for the recruitment and vetting of pharmacists and all staff employed or engaged at the pharmacy.

3 In respect of the contribution to the effectiveness of the pharmacy systems, a superintendent pharmacist should:
   • Ensure that a duty log is available and appropriate procedures in place to ensure it is appropriately maintained.
   • Ensure the appropriate policy is in place to comply with disposal of medicinal and other products supplied in the pharmacy.
   • Ensure that the policy in respect of the running of the pharmacy practice and the organisation and governing thereof is in compliance with the legal framework in place.
   • Ensure that policy is in place in accordance with best practice in human resource management and this is applied in the recruitment of individuals operating within the pharmacy practice.
   • Ensure that the supervising pharmacist in each practice maintains a practice-specific operations manual for which policies on record-keeping, error management, ADR reporting, complaints-handling, quality assurance and governance matters are clearly outlined.
   • Ensure there is a policy requirement to ensure a system is in place for inducting all individuals associated with the delivery of pharmacy care and service.
   • Ensure that effective systems of communication exist with the supervising pharmacist and other pharmacists employed or engaged at the pharmacy so that policies are properly communicated and issues in practice can be identified and auctioned.
   • Ensure that a robust complaints system is in place and implemented in the pharmacy in order that complaints are properly addressed in the interests of patients, and that learning from complaints made feed into reviews of policies, systems and procedures.
   • Ensure that the organisation’s policies and decision-making processes take account of the ethos of a pharmacy as location for the provision of healthcare services.

4 In respect of the contribution to the effective operation of the practice environment, a superintendent pharmacist should:
   • Ensure policy is in place to assure that a pharmacist is facilitated in exercising appropriate supervision, in respect of the delivery of professional services.
   • Ensure that the designated area for professional counselling is appropriate and utilised for this purpose only.
   • Ensure and facilitate the pharmacy owner in complying with obligations in respect of the practice premises.
   • Ensure there is a policy requiring the availability of systems for the appropriate use, management and protection of IT resources and electronic data, and that these are utilised.
   • Ensure that an ethical and appropriate policy is in place and implemented for the selection and evaluation of products and services which are offered by the pharmacy as a provider of healthcare services.

5 In respect of the provision of pharmaceutical care, including information and services, a superintendent pharmacist should:
   • Ensure that policy reflects the requirement that a registered pharmacist reviews any prescription dispensed, to assess the pharmaceutical and therapeutic appropriateness of the product for the patient, in accordance with appropriate parameters thereof.
   • Ensure that policy is in place to encourage evaluation and improvement in respect of the delivery of care.
   • Ensure that policy is in place to encourage involvement with local and national health promotion or education initiatives.
   • Ensure that the clinical management policies of the organisation are in place and implemented within the pharmacy, and ensure there are robust systems of review and audit of the delivery of the pharmaceutical care services provided by the pharmacy.