

Unpacking the role of the pharmacy owner and superintendent pharmacist

Jackie Maimin

Chair of Practice Committee

PHARMACY

SHAPING THE FUTURE



Objectives of SA Pharmacy Council

Two of the primary objects of the South African Pharmacy Council in terms of the Pharmacy Act 53 of 1974 are;

- to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the private and public sector
- to establish, develop, maintain and control universally acceptable standards of practice of the various categories of persons required to be registered

Regulatory Environment

The rapidly evolving pharmaceutical environment presents unique challenges to Pharmacy Council as the regulatory body.

Some of these challenges arose from;

- Opening of pharmacy ownership to lay owners
- Juristic persons as pharmacy owners
- Formation of large pharmacy groups
- Phases of dispensing happening at multiple locations by different pharmacists and pharmacy support personnel

The General Pharmaceutical Council

The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales.

Part of their role is to set the standards which govern the practice of pharmacists and pharmacy technicians.



MANAGEMENT AND LEADERSHIP RESPONSIBILITIES THE UK EXPERIENCE

- Owners and superintendent pharmacists(SP) have overall responsibility for setting out the standards and policies for the provision of pharmacy services by their organisations.
- Where a body corporate owns a pharmacy business, a superintendent pharmacist must be appointed to manage the pharmaceutical aspects of the business.
- Superintendent pharmacists and responsible pharmacists have legal obligations under the Medicines Act 1968.
- The role of superintendent pharmacist is a key position carrying full time responsibility and accountability within a company

MANAGEMENT AND LEADERSHIP RESPONSIBILITIES

As a member of a board of a body corporate you must;

- **Consider and act on the advice of the superintendent pharmacist** when dealing with the requirements of the **pharmaceutical parts of the business**
- Provide the superintendent pharmacist with the necessary **support and resources** to carry out their **legal and professional obligations**
- **Notify** the General Pharmaceutical Council, in writing, of **any changes** of superintendent pharmacist or to the address or ownership of a registered pharmacy premises

RESPONSIBILITIES OF AN OWNER OR A SUPERINTENDENT PHARMACIST IN UK

As an owner or a superintendent pharmacist you must

- **Identify and manage risks** to patients, the public and those you employ
- **Set the overarching standards and policies** for the pharmaceutical aspects of the business.
- **Manage** the keeping, preparing, dispensing and sale or supply of medicinal products by a registered retail pharmacy business
- **Ensure that all legal and professional requirements are adhered to**
- **Respond** appropriately to any systems failures or concerns that may arise
- Make sure that the **responsible pharmacist is supported** to fulfil their legal and professional responsibilities and appropriate systems are in place to deal with concerns raised by the responsible pharmacist
- Make **sure clear lines of accountability** exist and that a retrievable audit trail of the health professional taking responsibility for the provision of each pharmacy service is maintained
- Be satisfied that there are **appropriate policies** setting out the **number of staff** and their required experience

RESPONSIBILITIES OF AN OWNER OR A SUPERINTENDENT PHARMACIST IN UK

As an owner or a superintendent pharmacist you must

- Make sure all professional activities undertaken by you or under your control are covered by **adequate professional indemnity cover**
- **Declare** to the relevant person or **authority any interests that could be perceived to influence your judgement** in financial or commercial dealings which impact on patient care or public safety
- Be satisfied that any **advertising and promotional activity** for professional services or medicines is **legal, decent and truthful** and complies with appropriate advertising codes of practice
- Make sure **products that may be injurious** to a person's health, for example tobacco products, alcoholic beverages and products intended to mask the signs of alcohol or drug consumption **are not sold or supplied** from registered pharmacy premises

RESPONSIBILITIES OF A SUPERINTENDENT PHARMACIST IN UK

As a superintendent pharmacist you must

- Be satisfied that you have **sufficient resources, authority and influence** within your organisation to comply with your legal and professional responsibilities
- **Make sure that the members of the board of the body corporate are aware of and understand your responsibilities**
- **Retain overall professional accountability** for the pharmaceutical aspects of the business even if you are employed for fewer hours than the pharmacy business operates

RESPONSIBILITIES OF A SUPERINTENDENT PHARMACIST IN UK

- Policies, procedures and records – Superintendent Pharmacist must ensure that all legal and professional requirements are met in relation to the pharmacy services he/she manages.
 - ➔ Record keeping
 - ➔ Standard operating procedures
 - ➔ Incident Reporting Mechanisms
 - ➔ Handling complaints and managing concerns
 - ➔ Operating an internet pharmacy service

RESPONSIBILITIES OF A SUPERINTENDENT PHARMACIST IN UK

- Pharmacy Staff - SP must make sure that staff are employed, managed and trained appropriately.
 - ➔ **Employing, managing or leading others**
 - ➔ **Training staff**
- Pharmacy premises - SP must ensure that the premises he/she manages is appropriate for the professional services being provided
 - ➔ **The conditions of the premises**
 - ➔ **The availability of facilities and equipment at the premises**
 - ➔ **The conditions in which medicinal products are to be stored**
 - ➔ **Arrangements for the obtaining, handling, use and security of medicinal products or medical devices**
 - ➔ **Operating an internet pharmacy service**

RESPONSIBILITIES OF A RESPONSIBLE PHARMACIST IN UK

As a responsible pharmacist you must

- **establish the scope of the role and responsibilities** you will have as the responsible pharmacist and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacy owner, superintendent pharmacist or other delegated person.
- only take on the role of the responsible pharmacist if this is **within your professional competence**.
- only be **the responsible pharmacist in charge of one registered pharmacy** at any given time.
- **secure the safe and effective running** of the of the pharmacy business at the registered pharmacy in question **before the pharmacy can undertake operational activities**.
- Only after you are personally satisfied that you have secured the safe and effective running of the pharmacy can any operational activities begin to take place
- **conspicuously display** a notice in the registered pharmacy- allows patients and the public to **identify the pharmacist who is responsible** for the safe and effective running of the registered pharmacy.

RESPONSIBILITIES OF A RESPONSIBLE PHARMACIST IN UK

As a responsible pharmacist you must

- **Conspicuously display a notice** in the registered pharmacy which allows patients and the public to identify the pharmacist who is responsible for the safe and effective running of the registered pharmacy.
- **Keep pharmacy record** - ensure the pharmacy record is accurate and reflects who the responsible pharmacist is, and was, at any given date and time (including whether or not the responsible pharmacist is, or was, absent from the registered pharmacy).
- **Main pharmacy procedures** - establish, maintain and review pharmacy procedures.

Proposed Nominee Pharmacist in SA

nominee pharmacist

“means a natural person registered as a pharmacist in terms of the Act, employed and registered as a nominee pharmacist by the owner of a pharmacy and who shall be responsible for performing the duties as prescribed in regulations 24 and 25 of these regulations;”

Proposed Regulations - Appointment of a Nominee Pharmacist

- A natural person, who is not registered as a pharmacist and who owns a pharmacy or multiple pharmacies shall employ a nominee pharmacist who shall have the duties and responsibilities as set out in regulation 24 of these regulations relating to his or her pharmacy business
- In the event of a pharmacy owner being a juristic person, such owner shall appoint and register a person as a nominee pharmacist;
- In the case pharmacies owned by the state or an organ of the state, such nominee pharmacists shall be the most senior person in respect of pharmaceutical services employed by each provincial department of health

Proposed Authority, Duties and Responsibilities of a Nominee Pharmacist in SA

A nominee pharmacist must—

- complete and submit the licence and recording application forms provided by council in respect of the registration of the owner of the pharmacy;
- ensure payments of the applicable fees as determined by council in respect of the pharmacy;
 - furnish the information as required by the Registrar from time to time; and
 - ensure that there is compliance at all relevant times with—
 - the requirements which entitled such owner to own a pharmacy; and the conditions of registration of the pharmacy.”

Responsibilities of Responsible Pharmacist in SA

- ensure that he or she in fact **continuously supervises** the pharmacy in which he or she has been appointed;
- have **appropriate qualifications and experience** in the services being rendered by such pharmacy;
- ensure that persons employed in such pharmacy and who provide services forming part of the **scope of practice** of a pharmacist are appropriately registered with council;
- **notify council** immediately upon receiving knowledge that his/her services as responsible pharmacist have been or will be terminated;
- take **corrective measures** in respect of deficiencies with regard **to inspection reports** of council or in terms of the Medicines Act;

Responsibilities of RP in SA (Cont)

in addition to the general responsibilities also:-

- ensure that unauthorised persons do not **obtain access to medicines** or scheduled substances or the pharmacy premises outside of normal trading hours;
- **establish policies and procedures for the employees** of the pharmacy with regard to the acts performed and services provided in the pharmacy;
- ensure the **safe and effective storage** and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and
- ensure **correct and effective record keeping** of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.

Thank You

Jackie Maimin
Chair of Practice Committee

PHARMACY

SHAPING THE FUTURE

