
BOARD NOTICES • RAADSKENNISGEWINGS

BOARD NOTICE 543 OF 2024**SOUTH AFRICAN PHARMACY COUNCIL****CRITERIA FOR THE REGISTRATION OF A RESPONSIBLE PHARMACIST**

The South African Pharmacy Council intends to publish in terms of Sections 22(4), 22(5) and 35A of the Pharmacy Act, 53 of 1974, read together with the *Regulations relating to the practice of pharmacy* the **CRITERIA FOR THE REGISTRATION OF A RESPONSIBLE PHARMACIST**.

The *Criteria for the registration of a Responsible Pharmacist* must be read together with Board Notice 514/2023 published on 24 November 2023, in relation to the *Criteria to accredit a generic short course for a pharmacist who wishes to apply for registration as a Responsible Pharmacist*.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the proposed criteria. Comments must be addressed to the Registrar, South African Pharmacy Council by email BN@sapc.za.org (for the attention of the Company Secretary and Head of Legal Services).

SCHEDULE

1. Criteria for registration of a responsible pharmacist



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To obtain the full content of this Board Notice please visit the 'Proposed Legislation' section on the South African Pharmacy Council's website:
https://www.sapc.za.org/Legislation_Proposed



South African
Pharmacy Council

SOUTH AFRICAN PHARMACY COUNCIL

CRITERIA FOR THE REGISTRATION OF A RESPONSIBLE PHARMACIST

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1. DEFINITIONS

“**Act**” means the Pharmacy Act, 53 of 1974.

“**Continuing professional development**” means the process by which registered persons maintain and enhance their competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training.

“**Non-practising**” means the designation on the applicable register indicating that the registered person is currently not providing one or more of the services or performing one or more of the acts pertaining to the scope of practice of the category in which he or she is registered, or does not intend to provide such services or perform such acts.

“**Practising**” means the designation on the applicable register indicating that the registered person is currently providing one or more of the services or performing one or more of the acts pertaining to the scope of practice of the category in which he or she is registered, or intends to provide such services or perform such acts.

“**Responsible pharmacist**” means a natural person who is a pharmacist and who shall be responsible to Council for complying with all the provisions of the Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision and who is registered as such in terms of the Act.

2. ABBREVIATIONS

CPD	Continuing Professional Development
GPP	Good Pharmacy Practice
RP	Responsible Pharmacist
SAPC	South African Pharmacy Council

3. BACKGROUND

The South African Pharmacy Council (hereafter “Council”) registers a Responsible Pharmacist in terms of Section 22(4) and 22(5) of the Pharmacy Act, 53 of 1974, as a pharmacy must be conducted under the continuous personal supervision of a pharmacist, who shall be responsible to Council for any acts performed, and omission of any act required to be performed in that pharmacy. In terms of Section 35A of the Pharmacy Act, Council has the legislative mandate to control pharmacy practice in South Africa.

Regulation 28(b) of the *Regulations relating to the practice of pharmacy* states that “a Responsible Pharmacist must have appropriate qualifications and experience in the services being rendered by such pharmacy” and the criteria seeks to clarify this requirement.

In this regard, Council has published Good Pharmacy Practice minimum standards as contained in the *Rules relating to Good Pharmacy Practice (GPP)* published in Board Notice 129/2004 on 17 December 2004 (as amended).

4. LEGISLATIVE FRAMEWORK

4.1 Pharmacy Act

Council has a statutory obligation in terms of Section 35A of the Pharmacy Act, 53 of 1974, to control the practice of pharmacy, to prescribe the scope of practice of persons registered in terms of the Act, the services or acts which shall for purposes of the Act be deemed to be services or acts specially pertaining to pharmacists and pharmacy support personnel, and the conditions under which those services may be provided or the acts which may be performed.

4.2 Regulations relating to the practice of pharmacy

Regulation 28 of the *Regulations relating to the practice of pharmacy* stipulates:

The Responsible Pharmacist contemplated in Regulation 25(3) must—

- (1) ensure that he or she in fact continuously supervises the pharmacy in which he or she has been appointed;
- (2) have appropriate qualifications and experience in the services being rendered by such pharmacy;
- (3) 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;
- (4) notify Council immediately upon receiving knowledge that his/her services as Responsible Pharmacist have been or will be terminated;
- (5) take corrective measures in respect of deficiencies with regard to inspection reports of Council or in terms of the Medicines Act, 101 of 1965; and
- (6) in addition to the general responsibilities also-
 - (a) ensure that unauthorised persons do not obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;
 - (b) establish policies and procedures for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;
 - (c) ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and
 - (d) ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.

4.3 Regulations relating to Continuing Professional Development

- (a) In terms of the *Regulations relating to Continuing Professional Development* (GNR. 668, published on 17 May 2019), and in particular Regulation 4(3), a Responsible Pharmacist must be designated as practising.
- (b) In terms of Board Notice 201/2019, published on 10 December 2019:
 - (i) All registered pharmacists (including Responsible Pharmacists) shall be required to comply with the requirements for Continuing Professional Development effective from 1 January 2020; and
 - (ii) All registered pharmacists shall submit a minimum of six (6) Continuing Professional Development activities by 31 December annually.

4.4 Rules relating to Good Pharmacy Practice

Rule 3.7.3 and 3.7.3.1 of the *Rules relating to Good Pharmacy Practice*

3.7.3 Responsible Pharmacist

- (a) The Responsible Pharmacist of a wholesale and manufacturing pharmacy must have expert knowledge with regard to the wholesale distribution of medicine and scheduled substances.
- (b) The Responsible Pharmacist is responsible for safeguarding product users against potential hazards arising from poor distribution practices as a result of, for example, purchasing suspect products, poor storage or failure to establish the *bona fides* of purchasers.
- (c) The Responsible Pharmacist must ensure that the conditions of the wholesale and manufacturing pharmacy's licence are met and that there is compliance with the standards and guidelines on pharmacy practice.

3.7.3.1 Duties and responsibilities of the Responsible Pharmacist

In addition, the Responsible Pharmacist of a wholesale or distribution pharmacy must:

- (a) have a direct line of communication with and be part of management;
- (b) have access to all areas, sites, stores and records which relate to the activities being performed;
- (c) regularly review and monitor all such areas, sites, etc., or have delegated arrangements whereby he/she receives written reports that such actions have been carried out on his/her behalf;
- (d) keep appropriate records relating to the discharge of his/her responsibilities;
- (e) ensure the physical security of the stock or have written assurance from the manager responsible for security that administrative and physical security systems are in place and are adhered to by all personnel.

5. REQUIREMENTS FOR THE REGISTRATION OF A RESPONSIBLE PHARMACIST

Council shall apply the following criteria for the registration of a Responsible Pharmacist:

- (a) must be designated as a practising pharmacist and compliant with CPD requirements according to *Regulations relating to Continuing Professional Development*;
- (b) must be registered with Council for three (3) years post pharmacy internship;
- (c) must have completed the Responsible Pharmacist short course or submit proof of registration with an accredited provider;
- (d) must, on completion of the course, record the certificate of completion with the Council;
- (e) in the case of a pharmacy where a pharmacist has been registered for less than three (3) years, the following must be submitted:
 - (i) a motivation;

- (ii) support/mentoring programme; and
 - (iii) certificate of completion of the course or proof of registration with an accredited provider;
- (f) must not be a Responsible Pharmacist of another pharmacy and must have submitted a letter of resignation as RP in the other pharmacy or indicate they are serving a notice of cessation of their services as RP in the other pharmacy; and
- (g) if a pharmacist has been designated as non-practising and has completed the short course five (5) or more years (60+ months) ago, they must complete the short course again.

6. IMPLEMENTATION OF THE CRITERIA

The criteria shall be implemented and enforced when the implementation board notice is published by Council. The following provisions shall be made:

- (a) Persons registered for more than three (3) years as pharmacists and are Responsible Pharmacists at the time of implementation shall be deemed as compliant with the registration requirements of a Responsible Pharmacist.
- (b) Persons registered for less than three (3) years as pharmacists and are Responsible Pharmacists at the time of implementation, must enrol for and complete the course within twelve (12) months.
- (c) Persons registered for more than three (3) years as pharmacists but not registered as Responsible Pharmacists at the time of implementation must comply with these criteria.

7. RP DECLARATION

The Responsible Pharmacist must sign the declaration as shown below:

As the Responsible Pharmacist, I hereby confirm that I am aware of my responsibilities, as outlined below.

1. I am responsible for all the acts performed by or on behalf of the body corporate in question, including any omission to perform an act required to be performed by or on behalf of the body corporate, which may involve disciplinary action by Council.
2. I shall ensure compliance with all the provisions of the Pharmacy Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under my personal supervision.
3. The general security of the premises, including control of the keys or other entry devices.
4. Ensuring the correct supervision of pharmacy personnel (incl. pharmacy support personnel and interns).
5. Ensuring that in my absence, another pharmacist assumes these responsibilities for the period of absence (signed delegation of responsibility).
6. Ensuring that an inspection officer appointed in terms of the Act has access to perform an inspection at all reasonable times.
7. The maintenance of the premises to <i>Rules relating to Good Pharmacy Practice</i> .
8. Ensuring correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.
9. Holding registration as a pharmacist with Council, designated as practising, with no conditions that would impact my ability to fulfil the responsibilities detailed here.
10. Upon registration as a Responsible Pharmacist of (Y.....), I am no longer employed in another pharmacy.

I declare that the above information is true and correct and disciplinary action may be taken against me in terms of Chapter V of the Pharmacy Act, 53 of 1974, if any information is false.