

## BOARD NOTICE 63 OF 2020

## THE SOUTH AFRICAN PHARMACY COUNCIL

**GUIDELINE FOR THE REMOVAL OF PHARMACY REGISTRATION/ RECORDING AS A RESULT OF NON-COMPLIANCE WITH GOOD PHARMACY PRACTICE AND OTHER PHARMACY LEGISLATION**

Chapter XI of the *Regulations relating to the registration of persons and the maintenance of registers* (GNR.1160 published on 20 November 2000) provides for the registration and removal of the registration of pharmacies. The South African Pharmacy Council hereby publishes for implementation the **Guideline for the removal of pharmacy registration/recording as a result of non-compliance with Good Pharmacy Practice and other pharmacy legislation.**

**SCHEDULE**

1. Guideline for the removal of pharmacy registration/recording as a result of non-compliance with Good Pharmacy Practice and other pharmacy legislation.

In this notice "the Act" shall mean the Pharmacy Act, 53 of 1974 (as amended), and any expression to which a meaning has been assigned in the Act shall bear such meaning.



**TA MASANGO  
REGISTRAR**

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083, Private Bag X40040, Arcadia, 0007.  
Telephone: 0861 7272 00. Facsimile 012-321 1479/92

## Table of Contents

1. Title .....	3
2. Background.....	3
3. Purpose of the guideline.....	3
4. Definitions and abbreviations.....	4
5. Legal framework .....	5
6. Criteria for the removal of the registration/recording of a pharmacy .....	8
7. Process for the removal of the registration/recording of a pharmacy .....	9
8. Restoration of the registration/recording of a pharmacy .....	10
9. Appeal process .....	11
10. Annexures.....	11

## **GUIDELINE FOR THE REMOVAL OF PHARMACY REGISTRATION/ RECORDING AS A RESULT OF NON-COMPLIANCE WITH GOOD PHARMACY PRACTICE AND OTHER PHARMACY LEGISLATION**

### **1. TITLE**

Guideline for the removal of pharmacy registration/recording as a result of non-compliance with good pharmacy practice and other pharmacy legislation.

### **2. BACKGROUND**

The South African Pharmacy Council (the Council) in terms of Section 35A of the Pharmacy Act, 53 of 1974 has the legislative mandate to control pharmacy practice within South Africa. In this regard the Council has published good pharmacy practice standards as contained in the *Rules relating to good pharmacy practice* (GPP). In doing so the Council requires that all responsible pharmacists, pharmacists, pharmacy support personnel and pharmacy owners ensure that the pharmaceutical services they provide are of the highest quality and comply with such good pharmacy practice standards.

The Council has, in terms of Section 38A of the Pharmacy Act, appointed inspection officers to inspect pharmacies for the purpose of monitoring compliance with GPP, the approval of pharmacy premises for the training of pharmacy support personnel and pharmacist interns and for purposes of investigation of complaints received alleging misconduct or unprofessional conduct.

Applications for pharmacy premises licences are made to the Director-General: Health (DG), in line with Section 22 of the Pharmacy Act. The Council conducts a desktop evaluation for compliance with GPP and then informs the DG whether the application is deemed to be compliant or non-compliant to GPP. It has been established that some pharmacies, at the first inspection after the recording of a new pharmacy licence, are non-compliant to critical non-negotiable questions and/or have critical GPP deficiencies. There are also pharmacies which continuously fail to comply with GPP and/or fail to comply with the requirement that, in terms of Section 22 of the Pharmacy Act, the pharmacy must have a registered responsible pharmacist and must be under the continuous supervision of a pharmacist.

In such cases the public is exposed to the risk of compromised, and/or poor-quality pharmaceutical services. It is the duty of the Council to protect, promote and maintain the health, safety and wellbeing of patients and the public and to ensure that where such services are compromised, such pharmacies are restricted from providing pharmaceutical services.

### **3. PURPOSE OF THE GUIDELINE**

The purpose of this guideline is to outline the conditions under which the Council may remove the registration/recording of the pharmacy, in terms of the *Regulations relating to the registration of persons and the maintenance of registers* and restoration of registration/recording process.

This guideline therefore provides-

- (a) the process for the identification of pharmacies that are registered/recorded with Council, or alternatively pharmacies that are deemed to be registered/recorded, that no longer meet the registration/recording requirements;
- (b) the criteria for removal of the registration/recording of a pharmacy, under certain circumstances, when such a pharmacy no longer meets the requirements for registration/recording;
- (c) the process for the removal of the registration/recording of a pharmacy;
- (d) the circumstances and criteria under which the registration/recording of the pharmacy may be restored; and
- (e) the criteria and process to request the DG to cancel or suspend the pharmacy licence in terms of Section 22 (7) of the Pharmacy Act.

The guideline is developed to ensure that the removal of the registration/recording of the pharmacy is for the sole purpose of protecting the public of South Africa, and the actions of Council are consistent with the criteria for administrative action as prescribed in the Promotion of Administrative Justice Act, 3 of 2000.

Removal of the registration/recording of a pharmacy will mean the pharmacy may not continue to operate and must be closed for business.

#### 4. DEFINITIONS AND ABBREVIATIONS

Term	Meaning
BHF	Board of Healthcare Funders
Council	South African Pharmacy Council referred to in terms of Section 2 of the Pharmacy Act, 53 of 1974.
Critical GPP deficiencies	A pharmacy premises which does not comply with the GPP standards, resulting in a Grade C, as defined in the <i>Review of the pharmacy inspection grading methodology 2020</i> (Annexure C).

Desktop evaluation	A process of reviewing compliance to GPP making use of documentation provided by the applicant for the purpose of applying for a pharmacy licence in terms of Section 22 of the Pharmacy Act.
GPP	The Rules relating to good pharmacy practice as published by the Council in terms of section 35A of the Pharmacy Act, 53 of 1974.
NDOH	National Department of Health
Office of the Registrar	The various units established by the Registrar to assist the Registrar with implementing acts and functions delegated to the Registrar in terms of the Pharmacy Act.
SAHPRA	South African Health Products Regulatory Authority established in terms of the Medicine and Related Substances Act, 101 of 1965.

## 5. LEGAL FRAMEWORK

This guideline has been developed taking the following applicable legislation into consideration-

- (a) the Constitution of the Republic of South Africa Act, 108 of 1996 and with particular reference to Chapter 2, being the Bill of Rights;
- (b) the Promotion of Administrative Justice Act, 3 of 2000;
- (c) the Pharmacy Act, 53 of 1974;
- (d) the *Regulations relating to the practice of pharmacy* (GNR.1158 of 20 November 2000);
- (e) the *Regulations relating to the registration of persons and the maintenance of registers* (GNR. 1160 of 20 November 2000);
- (f) the *Regulations relating to the ownership and licencing of pharmacies* (GNR. 553 of 25 April 2003);
- (g) the *Rules relating to good pharmacy practice* (GG 27112 Board Notice 129 of 2004 published on 17 December 2004, as amended);

- (h) the Medicines and Related Substances Act, 101 of 1965; and
- (i) the *General Regulations* published under the Medicines Act (GNR. 856 of 25 August 2017).

## 5.1 The Pharmacy Act

5.1.1 Section 3 of the Pharmacy Act, 53 of 1974 provides for the objects of Council, which includes *inter alia* -

- (a) to assist in the promotion of health of the population of the country [s3(a)];
- (b) to advise the Minister of Health or any other person on any matter relating to pharmacy [s3(b)];
- (c) to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and private sector [s3(d)];
- (d) to establish, develop, maintain and control universally acceptable standards for the registration of a person who provides one or more or all the services which form part of the scope of practice of the category in which such person is registered, of professional conduct required of persons to be registered and control over persons registered in terms of the Pharmacy Act[s3(e)(ii)(iv)]; and
- (e) to maintain and enhance the dignity of the pharmacy profession and the integrity of the persons practicing the profession [s3(g)].

5.1.2 Section 4 of the Pharmacy Act provides for the general powers of Council, which includes *inter alia* -

- (a) in such circumstances that may be prescribed, or where otherwise authorised by the Pharmacy Act, Council may remove any name from the register [s4(d)];
- (b) subject to the provisions of the Pharmacy Act, Council may investigate the activities at a pharmacy [s4(i)]; and
- (c) Council may consider any matter affecting the pharmacy profession and to make representations or take such action in connection therewith as Council may deem advisable [s4(k)].

5.1.3 Section 14 of the Pharmacy Act provides *inter alia* for the recording of pharmacies-

- (a) the various categories of pharmacies which may be recorded [s14(a)];

- (b) Council may in the prescribed manner refuse to record any pharmacy which does not comply with the prescribed conditions [s14(h)]; and
- (c) Council may require in the prescribed manner, persons authorised in terms of Section 22A of the Pharmacy Act to record the prescribed information with Council [s14(i)].

5.1.4 Section 22 of the Pharmacy Act read together with the *Regulations relating to the ownership and licencing of pharmacies* (GNR. 553 of 25 April 2003), provides for the requirements of licencing of a pharmacy-

- (a) a person who wishes to own a pharmacy must apply to the DG for a licence for the premises wherein or from which such pharmacy business is to be conducted. The DG has the discretion to grant or refuse to issue such licence [s22(1)];
- (b) the DG in determining whether an applicant complies with the conditions for ownership of a pharmacy may request the assistance of Council [regulation 8(2)];
- (c) a person issued with a licence must record with Council, the name, address, date of the licence, licence number and any other particulars as prescribed [s22(2)].
- (d) the recording of such licence must be within 30 days from the date of issue of the licence by the DG [regulation 8(4) and 8(5)] of the ownership regulations;
- (e) a pharmacy must be conducted under the continuous personal supervision of a pharmacist in accordance with good pharmacy practice as determined by the Council [s22(4)]. This pharmacist shall be responsible to Council for any acts performed on behalf of the owner, including any acts or omissions by the owner which may involve disciplinary action by Council [s22(5)], unless the Responsible Pharmacist satisfies Council that the responsibility for such act rests upon another pharmacist employed by the owner;
- (f) Council has the right to inspect the pharmacy premises. The Registrar shall provide the DG and the person who made the application with a written report of the findings of the inspection if it is found that the inspected premises are not suitable for the business of a pharmacy [s22(6)];
- (g) the DG may cancel or suspend a licence which does not comply with the licencing conditions [s22(7)]. If the licence is cancelled or suspended, the premises shall from the date of such cancellation or suspension be considered unsuitable for the carrying on of the business of a pharmacy [s22(8) and regulation 9(a)]; and
- (h) the DG may withdraw a licence where the owner of the licence is a pharmacist, and such pharmacist has been suspended from practicing as a pharmacist or has been removed from practicing as a pharmacist in terms of section 45(1) of the Pharmacy Act [regulation 9(g)].

5.1.5 Section 35A of the Pharmacy Act, read together with the *Rules relating to good pharmacy practice* (GG 27112, BN 129 of 2004 published on 17 December 2004) prescribes that all practicing pharmacists are obliged to ensure that the pharmaceutical services they provide are of a high quality and comply with Good Pharmacy Practice Standards as published by Council.

## 5.2 Regulations relating to the registration of persons and the maintenance of registers

The *Regulations relating to the registration of persons and maintenance of registers* (GNR. 1160 published on 20 November 2000) provides for the categories of persons that may be registered with the Council, the requirements for registration and the removal of registration.

5.2.1 Regulation 2 provides, for purposes of registration, *inter alia* the following categories of persons:

- (a) a company entitled to carry on the business of a pharmacy;
- (b) a close corporation entitled to carry on the business of a pharmacy;
- (c) a pharmacy owner; and
- (d) a responsible pharmacist.

5.2.2 Regulation 67 provides for the role of the Council in the registration of a pharmacy. Regulation 67(1) provides that in order to register a pharmacy, the person must apply to Council, identifying the category of pharmacy, the responsible pharmacist for the premises wherein or from which the applicant wishes to carry on the business of a pharmacy, and the owner of the pharmacy;

5.2.3 Regulation 68 provides that if the Registrar is satisfied that the applicant complies with the requirements for registration, then the pharmacy must be registered. However, if the Registrar is not satisfied that the applicant meets all the requirements for registration, the Registrar may refuse to register the pharmacy;

5.2.4 Regulation 72 makes provision for the removal of the registration of a pharmacy:

- (a) if the pharmacy does not comply with any of the conditions of registration;
- (b) if the responsible pharmacist fails to perform the duties of a responsible pharmacist; and
- (c) if the pharmacy fails to comply with good pharmacy practice.

5.2.5 In terms of Regulation 75, the pharmacy may be restored to the register of pharmacies provided it can show that the pharmacy once again complies with the conditions of registration.

## 6. CRITERIA FOR THE REMOVAL OF THE REGISTRATION/RECORDING OF A PHARMACY

A pharmacy registration/recording may be removed from the register if any one or more of the following non-compliance to GPP or any relevant legislation is/are found:

- (a) on the first inspection after the recording of a pharmacy (GPP, Annexure A, Rule 2.1.1):
  - (i) there is no pharmacist present in the pharmacy; or
  - (ii) there is no registered responsible pharmacist; or
  - (iii) there are critical GPP deficiencies resulting in a pharmacy being allocated Grade C score; or



- (iv) the layout of the pharmacy is not in accordance with the floor plans and/or site plans as approved by Council and the actual layout is not compliant to GPP;
- (b) the pharmacy has no registered responsible pharmacist for a period exceeding 3 (three) months;
- (c) the pharmacy has obtained a Grade C score for more than two consecutive inspections;
- (d) the pharmacy has been conducted without a pharmacist present (subject to Rule 2.1.1 of the GPP), which leaves pharmacy support personnel and/or unregistered persons to practice acts specifically relating to the scope of practice of a pharmacist without being a pharmacist, which is a criminal offence in terms of Section 29 of the Pharmacy Act;
- (e) the pharmacy is operating from a facility/location without a valid licence;
- (f) in terms of Regulation 8(4) and (5) of the *Regulations relating to the ownership and licencing of pharmacies*, a pharmacy licence has been issued by the DG, but such licence has not been recorded with the Council, and the pharmacy is operational;
- (g) the pharmacy has failed to pay their annual fees for period exceeding 12 months; or
- (h) the pharmacy has not been in operation for a period exceeding 6 (six) months, and the owner has failed to communicate the reason why the pharmacy is not operational to Council.

## 7. PROCESS FOR THE REMOVAL OF THE REGISTRATION/RECORDING OF A PHARMACY

In terms of this guideline, and taking into consideration Regulation 72 of the *Regulations relating to the registration of persons and the maintenance of registers*:

- (a) the Council may direct the Registrar to give written notice to the owner and the responsible pharmacist (if there is one registered) of the Council's intention to remove the registration of the pharmacy. The pharmacy owner shall be the person identified as the owner as per the register of owners held by the Registrar in terms of Section 14 of the Pharmacy Act, unless it can be shown that an application for the change of ownership of the pharmacy has been lodged with the DG, which application has not yet been approved;
- (b) the pharmacy owner, or a person acting on behalf of the owner, must be afforded the opportunity to furnish the Council with written reasons, within 21 working days, as to why the pharmacy registration should not be removed;
- (c) once the Council is in receipt of the written reasons submitted by the owner or a person acting on behalf of the owner, as to why the pharmacy registration should not be removed, the Council shall review such reasons and make a decision whether to remove the registration of the pharmacy, alternatively to allow the pharmacy to remain registered subject to terms and conditions the Council may deem appropriate;

- (d) once the removal of the registration/recording of the pharmacy has been approved by Council:
- (i) the owner, or person acting on behalf of the owner shall be notified of the removal of the registration/recording and shall be required to cease operations of the pharmacy as of the date of such notification;
  - (ii) the registration/recording certificate of the pharmacy shall be cancelled as from the date of the abovementioned notification, and the owner shall be required to return such certificate to the Council;
  - (iii) the Board of Healthcare Funders (BHF), or any alternative body, that is authorised and responsible for the issuing of practice code numbers in terms of the Medical Schemes Act, 131 of 1998, shall be notified by Council that the registration/recording of the pharmacy has been removed;
  - (iv) in the event that the pharmacy in question is a manufacturing pharmacy or a wholesale pharmacy, the South African Health Products Regulatory Authority (SAHPRA) shall be notified, by the Registrar, that the registration/recording of the pharmacy has been removed;
  - (v) other relevant stakeholders, such as suppliers and distributors of medicines shall be notified, by the Registrar, that the registration/recording of the pharmacy has been removed;
  - (vi) the pharmacy owner and/or the responsible pharmacist shall be handed over to the Professional Conduct Unit of the Office of the Registrar for investigation in terms of Chapter V of the Pharmacy Act, should this process not already have commenced;
  - (vii) the Registrar shall notify the DG of the removal of the registration/recording of the pharmacy and shall request that the DG withdraw the pharmacy licence in terms of Regulation 9 of the *Regulations relating to the ownership and licencing of pharmacies*; and
  - (viii) Council shall conduct an inspection within 3 months of the removal of the registration/recording of the pharmacy.
- (e) in the event of the pharmacy continuing to operate as a pharmacy, despite such removal of the registration/recording of the pharmacy, the Registrar shall inform SAHPRA and the necessary law enforcement agencies for possible investigation and criminal prosecution where necessary.

## 8. RESTORATION OF THE REGISTRATION/RECORDING OF A PHARMACY

- (a) the Registrar shall consider an application for restoration of the registration/recording of the pharmacy should the pharmacy owner, or a person acting on behalf of the owner, be able to demonstrate that:

- (i) there is a responsible pharmacist registered with the Council and that the pharmacy is being operated under the continuous supervision of such pharmacist;
  - (ii) the critical GPP deficiencies as previously identified by way of inspections have been rectified to the satisfaction of the Registrar;
  - (iii) only in the event of a removal following a new pharmacy inspection, the owner, or a person acting on behalf of the owner can provide an improvement plan showing how such critical GPP deficiencies shall be rectified within 21 working days; and
  - (iv) all outstanding pharmacy fees and restoration fees are paid.
- (b) should the Registrar be of the opinion that the registration/recording of the pharmacy be restored, the Registrar shall restore such registration/recording subject to:
- (i) the licence not having been withdrawn by the DG; and
  - (ii) whatever terms and conditions the Registrar deems appropriate for such restoration.
- (c) on restoration of the registration/recording of the pharmacy, the Registrar shall provide the relevant certificate of registration/recording of the pharmacy.
- (d) provided that if the Registrar is not satisfied that the registration/recording of the pharmacy, should be restored to the relevant register, the Registrar must submit the application to the council for a decision.

## 9. APPEAL PROCESS

The pharmacy owner may, in terms of Section 24 of the Pharmacy Act read together with Chapter XII of the *Regulations relating to the registration of persons and the maintenance of registers*, appeal the decision of the Council to remove the registration/recording of the pharmacy as a result of non-compliance with GPP and other pharmacy legislation as per this guideline.

In terms of Regulation 89 of the *Regulations relating to the registration of persons and the maintenance of registers*, if an appeal has been properly noted, the decision appealed against and any execution thereof shall be suspended pending the outcome of the appeal, unless the appeal committee, upon the urgent motion of the Council or the Registrar, is, on the strength of *prima facie* proof, of the opinion that it is in the public interest that a temporary suspension order should be granted and imposed pending the outcome of the appeal.

## 10. ANNEXURES

The Annexures to the guideline are available on the Council website [www.sapc.za.org](http://www.sapc.za.org)

- (a) **Annexure A:** a copy of the **Pharmacy inspections and guide to compliance.**
- (b) **Annexure B:** a copy of the **Application for restoration.**
- (c) **Annexure C:** a copy of the **Review of the pharmacy inspection grading methodology 2020.**