
BOARD NOTICES • RAADSKENNISGEWINGS

BOARD NOTICE 196 OF 2019

THE SOUTH AFRICAN PHARMACY COUNCIL

GUIDELINE FOR THE REMOVAL OF PHARMACY REGISTRATION/ RECORDING AS A RESULT OF NON-COMPLIANCE WITH GPP 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 registration of pharmacies. The South African Pharmacy Council hereby publishes for comment the **Guideline for the removal of pharmacy registration/recording as a result of non-compliance with GPP and other pharmacy legislation**.

SCHEDULE

1. Guideline for the removal of pharmacy registration/recording as a result of non-compliance with GPP 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.

Interested persons are invited to submit within 60 days of publication of this notice, substantiated comments or representations to The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 0865063010 or email: BN@sapc.za.org (for the attention of the Senior Manager: Legal Services and Professional Conduct).



TA MASANGO REGISTRAR

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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.pharmcouncil.co.za/Legislation_Proposed



Guideline No:	
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GUIDELINE FOR THE REMOVAL OF PHARMACY REGISTRATION/RECORDING AS A RESULT OF NON-COMPLIANCE WITH GPP AND OTHER PHARMACY LEGISLATION

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

1. TITLE

Guidelines for the removal of the registration/recording of pharmacies.

2. BACKGROUND

The South African Pharmacy Council (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 ensures that all responsible pharmacists, pharmacists, pharmacy support personnel and pharmacy owners are required to 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.

It has been established through the various inspections conducted at pharmacies that there are 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 which could cause harm. 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 DOCUMENT

The purpose of this document is to outline the conditions under which the Council may remove the registration/recording of the pharmacy licence, the criteria for removal in terms of Section 22 of the Pharmacy Act, read together with the *Regulations relating to the registration of persons and the maintenance of registers* and restoration of registration process.

This Guideline therefore provides-

- (a) the process for the identification of pharmacies that are registered/recorded with Council, alternatively pharmacies that are deemed to be registered/recorded, that do not meet the registration/recording requirements of a pharmacy;

- (b) the criteria for removal of registration/recording of a pharmacy, under certain circumstances, when such pharmacy does not meet the requirements of the registration/recording of such pharmacy;
- (c) for the process for the suspension of the registration/recording of a pharmacy;
- (d) for the circumstances and criteria under which the registration/recording of the pharmacy may be restored; and
- (e) for the criteria and process to inform the Director General: Health to remove the Pharmacy Licence in terms of Section 22 of the Pharmacy Act, 53 of 1974.

This 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.

4. DEFINITIONS AND ABBREVIATIONS

Term	Meaning
BHF	Board of Healthcare Funders
DG	Director General: Health
Chief Executive Officer/Registrar	The person appointed as the Registrar by Council in terms of the Pharmacy Act, 53 of 1974
GPP	The Rules relating to good pharmacy practice as published by the SAPC in terms of section 35A of the Pharmacy Act, 53 of 1974, as published from time to time
Office of the Registrar	The various units established by the Registrar to assist the Registrar with implementing acts and functions delegated to the Registrar
SAHPRA	South African Health Products Regulatory Authority established in terms of the Medicine and Related Substances Act, 101 of 1965
Council	South African Pharmacy Council referred to in terms of Section 2 of the Pharmacy Act, 53 of 1974

5. LEGAL FRAMEWORK

This Guideline has been developed and guided by taking into consideration the following applicable legislation-

- (a) the Constitution of the Republic of South Africa Act, 108 of 1996 and in particular 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;
- (b) to advise the Minister of Health or any other person on any matter relating to pharmacy;
- (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;
- (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; and
- (e) to maintain and enhance the dignity of the pharmacy profession and the integrity of the persons practicing the profession.

5.1.2 Section 4 of the Pharmacy Act (*supra*) 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 (*supra*) 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 Director General: Health for a licence for the premises wherein or from which such pharmacy business is to be conducted. The Director General has the discretion to grant or refuse to issue such licence. [s22(1)];
- (b) the Director General 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)]. The recording of such licence must be within 30 days from the date of issue of the licence [regulation 8(4) and 8(5)];
- (d) a pharmacy must be conducted under the continuous supervision of a pharmacist in accordance with good pharmacy practice as determined by the SAPC [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)];
- (e) Council has the right to inspect the pharmacy premises. The Registrar shall provide the Director General 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)];
- (f) the Director General may cancel or suspend a licence which does not comply with the licencing conditions [s22(7)]. If the licence is suspended or cancelled, the premises shall from the date of such suspension or cancellation be considered unsuitable for the carrying on of the business of a pharmacy [s22(8) and regulation 9(a)]; and
- (g) the Director General may suspend or cancel a licence were 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, as amended) prescribes that all practicing pharmacists are obliged to ensure that the pharmaceutical services they provide are of a high quality and complies 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 SAPC, 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 Council's role 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. IDENTIFICATION OF PHARMACIES WHERE THE PROVISION OF PHARMACEUTICAL SERVICES SHOULD BE REMOVED

In 2013 Council implemented a grading system for inspections, where pharmacies that had gross GPP shortcomings were identified as *Grade C* pharmacies. Over the cycle of inspections, it has been identified that some pharmacies:

- (a) over three inspections, continue to score below the required standards and persist as a *Grade C* pharmacy, showing indications that the responsible pharmacist or owner has continuously failed to make any attempts to rectify the shortcomings;
- (b) have continuously operated without the registered responsible pharmacist and there is evidence that the pharmacy is not being conducted under the continuous supervision of a pharmacist, e.g. the pharmacy has a registered responsible pharmacist according to Councils' register, but the responsible pharmacist is employed elsewhere;
- (c) have not had a registered responsible pharmacist with Council for a period in excess of 12 (twelve) months;
- (d) have been conducted without a pharmacist present, which leaves pharmacy support personnel and/or unregistered persons to practice the scope of practice of a pharmacist, which is a criminal offence in terms of Section 29 of the Pharmacy Act, 53 of 1974;
- (e) are operating as pharmacies at locations which the pharmacy has not been licenced to operate from;
- (f) continue to operate without recording the licence issued by the Director General with Council; and
- (g) operate without paying annual fees.

7. CRITERIA FOR THE REMOVAL OF THE REGISTRATION/RECORDING OF A PHARMACY

A pharmacy registration/recording shall be removed from the register if:

- (a) on the first inspection after the recording of a pharmacy licence,
 - (i) there is no pharmacist present in the pharmacy;
 - (ii) there is no registered responsible pharmacist;
 - (iii) there are gross GPP shortcomings resulting in Grade C scoring; and
 - (iv) the layout of the pharmacy is not in accordance with the approved floor plans and side plans and such plans are not compliant to GPP.
- (b) the pharmacy has no registered responsible pharmacist for a period exceeding 12 (twelve) months;
- (c) the pharmacy has obtained a *Grade C* score for more than two consecutive inspections;

- (d) the owner and/or the responsible pharmacist has been handed over to the Professional Conduct Unit of the Office of the Registrar for investigation and prosecution in terms of Chapter V of the Pharmacy Act, due to shortcomings, no registered responsible pharmacist and/or no pharmacist being present at the pharmacy;
- (e) the pharmacy has been conducted without a pharmacist present, which leaves pharmacy support personnel and unregistered persons to practice the scope of practice of a pharmacist, which is a criminal offence;
- (f) the pharmacy is operating from an unlicensed facility;
- (g) 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 Director General, but such licence has not been recorded with the Council, and the pharmacy is operating the business of a pharmacy; and
- (h) The pharmacy has failed to pay their annual fees for a period in excess of 12 months.

8. PROCESS FOR THE SUSPENSION 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 Registrar shall 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, read with Regulation 2 of the *Regulations relating to the registration of persons and maintenance of registers*, unless it can be shown that an application for the change of ownership of the pharmacy has been lodged with the Director General, 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 Registrar with written reasons, within 14 working days, as to why the pharmacy registration should not be removed;
- (c) once the Registrar 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 Registrar 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 any terms and conditions the Registrar may deem appropriate;
- (d) once the removal of the registration/recording of the pharmacy has been approved by the Registrar:
 - (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 that the registration/recording of the pharmacy has been removed;
- (iv) suppliers and distributors of medicines shall be notified that the registration/recording of the pharmacy has been removed;
- (v) 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 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 have already commenced;
- (vii) the Registrar shall notify the Director General of the removal of the registration/recording of the pharmacy and shall request that the Director General suspend the pharmacy licence in terms of Regulation 9 of the *Regulations relating to the ownership and licencing of pharmacies*;
- (viii) conduct an inspection within 3 months of removal of the registration/recording of the pharmacy licence; and
- (ix) 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.

9. 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 gross GPP shortcomings 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 gross GPP shortcomings shall be rectified within 30 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 should be restored, the Registrar shall restore such registration/recording of the pharmacy subject to whatever terms and conditions the Registrar deems appropriate for such restoration; and
- (c) On restoration of the registration/recording of the pharmacy, the Registrar shall provide the relevant certificate of registration/recording of the pharmacy on restoration of such registration/recording.

10. 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 Registrar to remove the registration/recording of the pharmacy as a result of non-compliance with GPP and other pharmacy legislation as per this Guideline.