


What to expect when being inspected – An overview of the processes involved in the inspecting of community pharmacies

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Introduction

Pharmacy council inspectors play a crucial role in ensuring the quality, safety, and compliance of pharmacies with established regulations and standards. These inspectors are typically appointed by pharmacy regulatory bodies in South Africa, the South African Pharmacy Council (SAPC). It is important for both the responsible pharmacists and other pharmacists to be aware of the functions of these inspectors and what would be expected of them. Pharmacists have the right to expect that any sensitive patient information or confidential business information observed or discussed during the inspection will be kept confidential. It is important for pharmacists to be informed of any specific standards or requirements being assessed during the inspection. After the inspection, pharmacists have the right to receive a written report (provided in a timely manner) that details the findings of the inspection, including any deficiencies or areas of non-compliance. In many cases, pharmacists have the opportunity to correct any deficiencies or violations identified during the inspection. If pharmacists disagree with the findings or actions taken by the regulatory council as a result of the inspection, they may have the right to appeal the decision. Pharmacists should conduct themselves professionally and cooperatively during the inspection process. Additionally, open communication and cooperation with the SAPC can help ensure a smooth and productive inspection process. If pharmacists have concerns or questions about an inspection, they should consider seeking guidance from the SAPC or their professional organisation.

The pharmacy council inspector needs to regularly visit and inspect pharmacies, to make sure that:

- 1. Patient safety and quality assurance:** Inspections help to ensure that pharmacies are providing safe and effective medications to patients. By evaluating the storage conditions, dispensing practices, and overall quality of medicines, inspectors help prevent errors that could harm patients.
- 2. Compliance with regulations:** Regulations are put in place to safeguard public health. Inspectors ensure that pharmacies

adhere to these regulations, which include requirements for the storage, handling, dispensing, and labelling of medications. This ensures that pharmacies are operating within the legal framework and maintaining ethical practices.

- 3. Preventing counterfeit medicines:** Inspectors can verify the authenticity of medications and track their sources, which is essential in preventing the distribution of counterfeit drugs. Counterfeit medicines can pose serious risks to patients' health.
- 4. Controlled substances and drug abuse prevention:** Inspections help to monitor the proper handling and dispensing of controlled substances, such as opioids and other potent medications. This oversight is critical in preventing drug abuse, diversion, and illicit distribution.
- 5. Pharmacist competence:** Inspectors assess the qualifications and competence of pharmacists and pharmacist's assistants. Ensuring that staff are adequately trained and knowledgeable contributes to the safe and effective delivery of pharmaceutical care.
- 6. Proper documentation:** Inspections verify that pharmacies maintain accurate records of prescription orders, dispensing activities, and patient interactions. Proper documentation is essential for tracking patient history, ensuring accountability, and addressing any potential issues that arise.
- 7. Facility conditions:** Inspectors evaluate the physical infrastructure of the pharmacy to ensure that it meets standards for cleanliness, organisation, and appropriate storage conditions. This helps prevent contamination and degradation of medications.
- 8. Adverse event reporting:** Inspections contribute to pharmacovigilance efforts by identifying adverse events or incidents related to medications. This information can be used to take appropriate measures to prevent similar incidents in the future.
- 9. Continual improvement:** Inspectors provide feedback and recommendations for improvement to pharmacy owners

and managers. This encourages pharmacies to continuously enhance their practices and maintain a high standard of care.

10. Public trust: Regular inspections enhance public trust in the healthcare system by demonstrating that pharmacies are being held accountable for their practices. When patients have confidence in the safety and quality of their medications, they are more likely to adhere to prescribed treatments.

The Pharmacy Act, No.53 of 1974, directs our statutory body, the South African Pharmacy Council (SAPC), to perform inspections of our premises in order to uphold and regulate the laws of the industry.

Monitoring, training, and disciplinary inspections in all categories of pharmacies (new and existing) are conducted by inspection officers. These officers, whose identities are disclosed on the Council website in the Inspection Officers Catalogue (available from [https://www.pharmcouncil.co.za/Media/Default/Documents/Inspectors%20Catalogue%2022-1.pdf](https://www.pharmcouncil.co.za/Media/Default/Documents/Inspectors%20Catalogue%202022-1.pdf)), are tasked to assist Council in the maintenance and control of standards of pharmacy practice in both the public and the private sector. These inspections can be classified as follows:

- Training facility inspection
- Monitoring or routine inspection
- New premises inspection
- Follow-up inspection
- Disciplinary inspections

In order to become an inspection officer, the individual must be a registered pharmacist in good standing with Council and who honours the policies and objectives of Council and abides thereby in the execution of his or her tasks. The Council trains the appointed inspection officers during an annual Lekgotla and several ad-hoc meetings to strive towards a uniform standard of inspection practice.

Appointments are scheduled for inspections regarding Training Facility or New Premises applications, but all other inspections could be unannounced visits.

There are two types of Council inspection officers:

- Routine
- Disciplinary

However, some inspectors can be tasked to undertake both roles.

Community pharmacies can also be inspected by the South African Health Products Regulatory Authority (SAHPRA). SAHPRA have their own inspectorate and may be accompanied by the South African Police Services (SAPS) during certain visits. These types of inspection are not routine and could include search and seizure warrants.

A pharmacist may NOT prevent an inspection officer from Council or SAHPRA from entering the pharmacy and conducting an inspection. Any person who fails to give or refuses access to

inspection officers appointed by Council when they request entrance to any pharmacy, who obstructs or hinders them in the execution of their duties under the Act, who fails or refuses to give information that they may lawfully be required to give to such an officer, or who gives false or misleading information to such an officer knowing it to be false or misleading will be investigated in terms of Chapter 5 of the Act.

It is important that all professionals understand the intention and mandate of inspection officers as they should serve the public and the pharmacy profession in an unbiased and impartial manner in order to create confidence in the Council and the profession. It is expected that inspection officers should treat members of the profession and the public as customers who are entitled to receive a high standard of service and may not discriminate unfairly against any member of the profession or the public on whatever basis.

Role of Council

The role of the inspection officers is to assist Council in achieving two of its primary objects in terms of the Pharmacy Act 53 of 1974:

- 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.

The inspection officers are responsible for conducting inspections at manufacturing, wholesale, community, and institutional pharmacies in order to assist in the maintenance and control of standards of pharmacy practice in both the public and the private sector.

Council utilises the services and expertise of 37 inspection officers. Pharmacists should note that the inspection officers are not obligated to make an appointment and that they can arrive unannounced at any time. To be ready for an inspection, ensure that you comply with the rules pertaining to good pharmacy practice (GPP) and other applicable legislation. Complete the Self-Inspection Questionnaire for the relevant category of pharmacy. These are available online via the Council website.

All inspection officers must at all times behave in a way that upholds the Council's values, integrity, and good reputation. They are obliged to advise the Council as soon as possible as they become aware of any actual or possible conflict of interest, financial or otherwise. Examples of this include that an inspection officer may not inspect his/her own pharmacy, or that of a family member or close friend, nor pharmacies where they have a financial benefit (shareholding) or that of a competitor (if they own a pharmacy).

Powers of Council to achieve its mandate

- To inspect the records and accounts of or investigate the activities at a pharmacy carried on by a person so registered.

These powers are delegated to inspection officers appointed by Council.

- Powers of inspection officers:
 - An inspection officer may enter any pharmacy at any time reasonable in order to conduct an inspection as requested by Council.
 - They will have a document confirming their appointment as a Council Inspection Officer signed by the Registrar of Council. This is renewed on an annual basis.
 - This document must be shown to the pharmacist on entering the pharmacy.
- Any person who refuses access, obstructs, hinders, fails to supply requested information, or furnishes false information to an inspector, is guilty of an offence
- The Council may obtain a warrant authorising an inspection officer, alone or with assistance from the SAPS, to close a pharmacy for not more than 90 days pending an investigation into possible contraventions of the Medicines Act deemed to be a risk to public health.
- Inspection officers have the obligation to report to Council any act which constitutes an offence, or which is prejudicial to the public's, the Council's, or the profession's, interest.

In the performance of their duties, an inspection officer should always strive to achieve the objectives of Council in a cost-effective manner and in the public's interest. Officers should be punctual and should execute their duties in a professional and competent manner. Although inspection officers should always promote sound, efficient, effective, transparent, and accountable administration, they are under no obligation to inform pharmacies of the intended inspection, prior to such inspection, and may arrive unannounced. Ultimately, inspection officers should be committed to the development and upliftment of the profession, respecting, and protecting every person's dignity and his or her right as contained in the Constitution of the Republic of South Africa. Under no circumstances should an inspection officer ever use their official position to obtain private gifts or benefits for themselves during the performance of his or her official duties nor does he or she accept any gifts or benefits when offered as these may be construed as bribes. Similarly, inspection officers should also not abuse their position to promote or prejudice the interest of any member of the profession.

In turn, pharmacists should treat the inspection officer with respect and in a cooperative manner. If at any time a pharmacist feels that an inspection officer has violated the code of conduct, then the pharmacist has the right to lay a complaint against the inspection officer with the Council.

Routine inspections

After conducting a routine inspection, a pharmacy would be graded as follows:

- Grade A Pharmacy: minor shortcomings identified; cycle for

inspection three years

- Grade B Pharmacy: major shortcomings identified; cycle for inspection two years
- Grade C Pharmacy: critical shortcomings identified; cycle for inspection one year

The costs of a routine inspection of Grade A and Grade B Pharmacies are included in the pharmacy annual fee. Grade C pharmacy inspections attract an inspection fee each time the pharmacy is inspected.

Please note that the inspection report, shortcomings document and Grading Certificate will be available on the Council website for the Responsible Pharmacist [RP] to access after the inspection. The process and timelines for the inspection report are managed by Council and the inspectors are not involved post the submission of the report. Ask the inspector to assist you to access the website and show you where to find the reports before he/she leaves. The RP must reply to Council within 21 days of receiving the Shortcomings Letter with a written response or explanation. Grading certificates will also be posted to the pharmacy and the original must be displayed in the pharmacy.

Rights of the pharmacists when being inspected

Pharmacists in South Africa, like in many other countries, have rights and responsibilities when they undergo inspections by regulatory authorities (e.g. Council or SAPHRA). These inspections are typically conducted to ensure that pharmacists and pharmacy practices comply with the above-mentioned laws, regulations, and professional standards. Embedded in this article is a [hyperlink](#) to a SOP, to provide guidance to pharmacy owners and Responsible Pharmacists (RPs) on the self-inspection, pharmacy inspection processes and preparations ahead of an inspection. Here are some general rights and considerations for pharmacists during inspections:

- Fair treatment with no favour or abuse.
- Polite and helpful dealings with the inspection officer who undertakes a coaching role.
- Entitled to receive a high standard of service. The inspection officer is an ambassador of Council.
- No discrimination with respect to race, gender, ethnic or social origin, colour, sexual orientation, age, disability, religion, political persuasion, belief, culture or language.
- Right of access to information. The pharmacist has a right to read through the inspection report, has a right to comment on the report; if they do not agree with any comment they may state so in the report. Pharmacists have a right to a copy of the inspection report.
- The inspection officer does not have to schedule or give notice of an intention to perform an inspection except for new premises and training facility inspections.
- Confidentiality.

- The inspection should not interfere with the normal running of the pharmacy and the pharmacist can ask the inspection officer to wait while patients are attended to.

Conclusion

Council inspection officers are legislated to ensure that pharmacists are upholding the regulatory requirements, maintaining professionalism, and most importantly providing health care that is of the highest standards. To ensure that the pharmacy profession maintains high standards, establishing

a good rapport between pharmacist and inspection officer remains key. Pharmacy Council inspectors play a vital role in safeguarding patient health, ensuring regulatory compliance, preventing drug-related problems, and maintaining the overall integrity of the pharmaceutical industry. Their work contributes to a safer and more reliable healthcare system.

Reference

1. Pharmacy Council. Code of conduct of the inspectors of the South African Pharmacy Council. 2023. Available from: <https://www.mm3admin.co.za/documents/docmanager/0C43CA52-121E-4F58-B8F6-81F656F2FD17/00020013.pdf>.