



**South African
Pharmacy Council**

PHARMACY INSPECTIONS AND GUIDE TO COMPLIANCE

TABLE OF CONTENT

1.	INTRODUCTION.....	3
2.	PHARMACY INSPECTIONS.....	3
3.	INSPECTION OFFICERS.....	4
4.	DIFFERENT TYPES OF INSPECTIONS.....	5
5.	APPROACH TO INSPECTIONS.....	6
6.	INSPECTION REPORTS AND PHARMACY GRADING.....	8
6.1.	Inspection cycle.....	8
6.2.	Scheduling of pharmacy inspections.....	8
6.3.	Pharmacy grading.....	9
7.	REQUEST FOR A FOLLOW-UP INSPECTION OR TRAINING INSPECTION.....	11
8.	GUIDE TO COMPLIANCE.....	11

1. INTRODUCTION

The mandate of the South African Pharmacy Council (SAPC) in terms of section 3(d) of the Pharmacy Act, 53 of 1974, (the Act) is to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and the private sector. Council fulfils this mandate by conducting pharmacy premises inspections in terms of section 38A of the Act. Inspections are carried out to check compliance with the *Rules relating to good pharmacy practice* (GPP), published in terms of section 35(b)(ii) of the Act and other applicable legislation. In this way, SAPC assures patients and the general public that each category of pharmacy offers quality, patient-centred pharmaceutical services.

This document outlines some of the reasons why Council conducts pharmacy inspections, the types of inspections, who conducts the inspections, when pharmacy owners and RPs (RPs) should expect these inspections to be performed and to provide guidelines for compliance to GPP.

Since this document is only a guide, pharmacy owners and RPs are still required to comply with the *Rules relating to GPP* as well as pharmacy-related legislation.

2. PHARMACY INSPECTIONS

Pharmacies are expected to provide a high standard of pharmaceutical care and excellent pharmaceutical services daily, and not only when expecting an inspection by SAPC.

Council may conduct unannounced inspections at a pharmacy on a regular basis to verify how a pharmacy and its personnel conduct business on a daily basis and to allow SAPC to satisfy itself that the public and patients are offered services that are compliant with standards of practice.

Council conducts inspections in the various categories of pharmacies, primary healthcare clinic dispensaries, remote automated dispensing units (RADU), mobile pharmacies and facilities approved by SAPC. The categories of pharmacies are:

- Community pharmacies
- Consultant pharmacies
- Institutional (public hospital) pharmacies
- Institutional (private hospital) pharmacies
- Manufacturing pharmacies

- Wholesale pharmacies

3. INSPECTION OFFICERS

Inspection officers are persons appointed in terms of sections 38A and 49(1)(l)(v) of the Act to inspect pharmacies. They may enter any pharmacy at any time reasonable for the proper performance of this duty or to make such an inspection.

Any person who fails to give or refuses access to inspection officers appointed by SAPC 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.

The role of inspection officers is to assist SAPC in achieving two of its primary objects in terms of the Act, namely:

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

Inspection officers are responsible for conducting inspections at the various categories of pharmacies, primary healthcare clinics dispensaries, RADU, mobile units and other facilities approved by SAPC in both the public and the private sector. SAPC contracts and uses the services and expertise of inspection officers in all the nine provinces.

The designation of an inspection officer is determined according to the type of inspection being conducted. Training inspections are conducted by training officers. New and monitoring inspections are conducted by monitoring officers. Disciplinary inspections are conducted by compliance officers.

SAPC publishes a list of pharmacies that are due for a monitoring inspection annually. It publishes a list of appointed inspection officers from time to time.

RPs and pharmacy owners should note that inspection officers are not obligated to make an appointment and that they can arrive unannounced at any time.

4. DIFFERENT TYPES OF INSPECTIONS

SAPC fulfils its mandate by conducting different types of pharmacy inspections, as outlined below.

New inspection – this type of inspection is carried out at a new facility either before a pharmacy is granted a licence or shortly after a pharmacy has obtained a licence. In manufacturing and wholesale pharmacies, an inspection is conducted before a pharmacy is granted a licence to ensure compliance with GPP and other applicable standards. In community, institutional (hospital) and consultant pharmacies, inspections are carried out after a pharmacy has recorded its licence. During a new inspection, the monitoring officer also assesses whether the layout of the pharmacy is in line with the pharmacy layout plans approved by SAPC.

Monitoring inspection – this is a routine inspection carried out in all categories of pharmacy including primary healthcare clinics dispensaries, RADU, mobile pharmacies and any other facilities approved by SAPC in both the public and the private sector. The outcome of such an inspection determines the frequency of monitoring inspections to be performed for the pharmacy in future. A pharmacy will be inspected once every three years if the results are excellent (Grade A), once every two years if the results are good (Grade B) and annually if the results are either satisfactory or poor (Grade C). The following inspection will be conducted during the year of expiry of the previous grading, not necessarily at the end of that year. If a pharmacy is inspected during the first half of the year i.e. between January and June, then the applicable term is calculated from the year in which the inspection is conducted. If a pharmacy is inspected during the second half of the year i.e. between July and December, the applicable term is calculated from the following year. Since monitoring officers are required to perform at least three inspections in close proximity per day, planning for conducting inspections are left to the discretion of each officer.

Training inspection – this type of inspection is only carried out by SAPC at the request of the RP who intends to use the pharmacy premises for training pharmacist interns and/or pharmacy support personnel. The results of this inspection will determine when the pharmacy premises will be eligible for approval again i.e. a three-year approval period for Grade A pharmacies, a two-year approval period for Grade B pharmacies and no approval for Grade C pharmacies. Training inspections are conducted by training officers. An appointment with the RP or person delegated by the RP will be made to conduct the inspection.

Disciplinary inspection – this type of inspection is conducted by a compliance officer appointed by SAPC following receipt of a complaint from the profession or the public. Disciplinary inspections are also conducted where a monitoring/training officer could not find a pharmacy at the recorded address during an inspection (Grade D) and, on investigation, it is established that the pharmacy has relocated without informing SAPC. The inspection report and the findings thereof are referred to the professional conduct unit and the related disciplinary committees of SAPC for further processing. As a result of this inspection, the RP may be charged for noncompliance with the standards of GPP and professional misconduct, which may result in a penalty being imposed by SAPC. The penalty may vary depending on the gravity of the non-compliance or misconduct.

Follow-up inspection – this type of inspection is conducted by monitoring officers following a request by the RP or owner of a pharmacy that has obtained a Grade B or C to obtain an excellent grade (Grade A). SAPC also conducts follow-up inspections for pharmacies that were found to be not in operation at the time of inspection and re-opened at a later stage.

SAPC's approach to inspections is to assist pharmacies to maintain high standards of practice i.e. a Grade A pharmacy status.

5. APPROACH TO INSPECTIONS

SAPC's objective in conducting inspections is to monitor the compliance of pharmacies with the *Rules relating to GPP* and to allow owners and RPs to engage with inspection officers to improve future inspection outcomes.

SAPC's approach to inspections is generally educational rather than punitive. RPs together with pharmacy staff should make use of the opportunity during an inspection to learn best practices and ask the inspection officer questions that will help them to attain excellent compliance with rules and legislation governing the practice of pharmacy in the country.

The average time to complete an inspection is 3 hours, except for disciplinary inspections which may take up to 5 hours.

RPs and pharmacy owners are responsible for meeting GPP standards. SAPC recognises that it is not always possible for the RP and pharmacy owner to be available at the time of inspection. In circumstances that both the RP and pharmacy owner are absent during an inspection, the inspection officer will still carry out the inspection, even if the pharmacist in charge is a locum. It is therefore advisable that the locum pharmacist in charge is properly

oriented regarding running the pharmacy, quality management systems and the use of resources in the pharmacy.

During an inspection, the inspection officer interviews the pharmacy personnel as a whole rather than just the owner or RP. Inspection officers conduct inspections using the appropriate inspection questionnaire. They work in collaboration with pharmacy personnel who provides evidence of how they meet the standards of pharmacy practice and other applicable legislation.

Inspection officers gather and record evidence using multiple approaches, including:

- (a) Looking at written or documentary evidence such as standard operating procedures (SOPs), policies, processes, etc.
- (b) Observing interactions between pharmacy personnel and patients
- (c) Testing systems, processes and procedures
- (d) Questioning and posing scenarios to staff

At the end of an inspection, inspection officers review their findings with the RP or pharmacist in charge. The RP or the pharmacist in charge is required to sign the inspection form to indicate that it is a true reflection of the inspection findings on the day of the inspection. The RP or the pharmacist in charge during the inspection also has the opportunity to make additional comments on the electronic feedback form provided at the end of the inspection regarding the conduct of the officer or any areas of improvement regarding inspections. These comments are relayed to the Registrar via the electronic feedback system.

The inspection officer is required to submit an electronic inspection report to SAPC within five working days of the inspection. The report is evaluated and checked for quality assurance by the Office of the Registrar. Once the evaluation is done, the electronic inspection report together with a letter to the RP is made available on SAPC's online platform. An email and SMS notification are send to the RP to respond to the findings. Where the inspection report has minor deficiencies, a letter congratulating the RP for high standards of pharmaceutical services is generated. The RP has 14 days from the date on which the electronic report is made available to respond online to the shortcomings identified.

In their response, RPs can indicate if there are any factual inaccuracies in the report which may have affected the grading status of the pharmacy. RPs can request a follow-up inspection if they are not satisfied with the first inspection report. The cost of a follow-up inspection will be borne by the RP or the pharmacy owner.

A RP who fails to respond to any shortcomings identified, regardless of the grading outcome, will be referred to SAPC's disciplinary committee.

6. INSPECTION REPORTS AND PHARMACY GRADING

6.1 Inspection cycle

In 2009, SAPC reviewed the approach to pharmacy inspections. The purpose of the review was to ensure that there is a classification system of the inspection's findings and a revision of the cycle of inspections.

Until then, the policy on inspections was to inspect a pharmacy every two years irrespective of the inspection findings i.e. a pharmacy found to be compliant with the legislation was inspected within the same period as a non-compliant pharmacy.

To remedy this anomaly, SAPC introduced a system of classifying inspection findings according to the shortcomings identified during inspections. A pharmacy that was found to have minor shortcomings during the inspection would be inspected every three years. A pharmacy that was found to have major shortcomings would be inspected every two years. A pharmacy with critical shortcomings would be inspected annually.

The objective of this classification system is to assist Council to implement a new cycle of inspections based on the outcome of inspection findings to assist pharmacies that were found to be non-compliant to a stage where they can achieve compliance through frequent inspections and where necessary to impose a penalty through disciplinary processes.

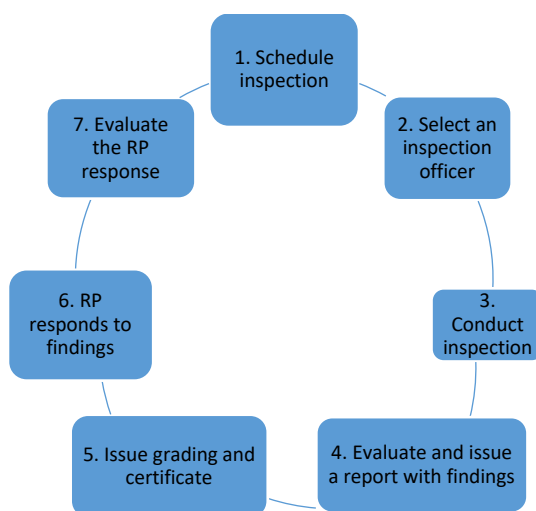
6.2 Scheduling of pharmacy inspections

The Office of the Registrar schedules an inspection under the following circumstances:

- (a) when a new pharmacy is opened;
- (b) when a pharmacy is due for inspection based on the grading obtained in the previous inspection cycle i.e.:
 - (i) Grade A pharmacies are inspected after three years;
 - (ii) Grade B pharmacies are inspected after two years; and
 - (iii) Grade C pharmacies are inspected annually;

- (c) when a complaint is received regarding the conduct of a pharmacy;
- (d) when a GradeD pharmacy is found to be in operation during further investigation;
- (e) when a pharmacy owner or RP applies for their pharmacy to be approved as pharmacy training premises; and
- (f) when a pharmacy owner or RP requests re-inspection and pays for it.

The process flow for inspections are as depicted below:



6.3 Pharmacy grading

After conducting an inspection, a pharmacy is graded as follows:

Table 1: Classification of pharmacy grading

Grading system	Inspection findings	Classification	Percentage score	Inspection cycle	Training approval periods
Grade A	The pharmacy premises comply with most of GPP standards	Excellent – minor deficiencies were observed during inspection	90–100%	3 years	3 years or less
Grade B	The pharmacy premises comply with some of GPP standards	Good – major deficiencies were observed during inspection	80–89%	2 years	2 years or less
Grade C	The pharmacy premises do not comply with most of GPP standards or any of the non-negotiable criteria	Poor - critical deficiencies were observed during inspection	1–79%	1 year	No approval

Grading system	Inspection findings	Classification	Percentage score	Inspection cycle	Training approval periods
Grade D	The pharmacy was found to be not in operation, has closed or relocated without informing SAPC	N/A	0%	N/A	N/A

A pharmacy is classified as Grade C if it is found to be non-compliant with one or more of the non-negotiable criteria. The non-negotiable criteria are:

- (a) The pharmacy name on the registration/recording certificate is not the same as that on the register system;
- (b) The pharmacy registration number on the registration/recording certificate is not the same as that on the register system;
- (c) A valid, original licence issued by the Director-General or a registration certificate issued by SAPC (not applicable for pre-May 2003ⁱ pharmacies) is not displayed visibly in the pharmacy for identification by the public;
- (d) The pharmacy is not recorded with SAPC or a valid original recording certificate signed by the Registrar of the SAPC for the recording of the pharmacy is not displayed visibly in the pharmacy for identification by the public (not applicable for pre-May 2003 pharmacies);
- (e) The pharmacy is operated without a RP or the RP on SAPC's register system is not the same as the one at the time of inspection;
- (f) There is no pharmacist present during the inspection or there was no proof that the person in charge during the inspection is registered with SAPC;
- (g) Illegal or counterfeit medicines are found in the pharmacy during an inspection;
- (h) Schedule 6 medicines or substances are not stored in designated places under lock and key at all times;
- (i) The register of all schedule 6 purchases and sales is not up to date;
- (j) There is no refrigerator in the pharmacy for the storage of thermolabile medicines (if applicable).

All Grade D pharmacies are investigated further by the Office of the Registrar. The investigation leads to one of the following scenarios:

- (a) If the owner has no intention to open the pharmacy, the office will remove the pharmacy from SAPC's register;

- (b) If the owner has relocated the pharmacy without informing SAPC, a disciplinary inspection will be conducted;
- (c) If the pharmacy was not yet in operation at the time of inspection or there are reasons why the pharmacy was closed at the time of inspection, a follow-up inspection will be conducted, and the owner will bear the cost of such an inspection.

7. REQUEST FOR A FOLLOW-UP INSPECTION OR TRAINING INSPECTION

A pharmacy that has obtained Grade B or C can request a follow-up inspection to obtain an improved grade. However, the RP or pharmacy owner is required to correct all shortcomings identified in the previous inspections before requesting a re-inspection.

A pharmacy that requires pharmacy training approval for training pharmacist interns and/or pharmacy support personnel may apply for re-inspection of the pharmacy if:

- (a) the current grading is due to lapse, or the RP requires an extension of the current approval period; and
- (b) the RP believes that the pharmacy can achieve a better grade than the previous grading awarded to them.

8. GUIDE TO COMPLIANCE

8.1 What do inspection officers do when they arrive for inspection?

Inspection officers do the following during inspections:

- (a) Upon entering the pharmacy, they observe the activities of the pharmacy for compliance with the Pharmacy Act and other applicable legislation.
- (b) They request to speak to the RP or the pharmacist in charge.
- (c) They identify themselves to the RP or pharmacist in charge by producing their SAPC officer's card.
- (d) They explain the inspection process to the RP or pharmacist in charge.
- (e) They allow pharmacy services to continue to be offered to members of the public, unless the pharmacy is in serious contravention of the Pharmacy Act and/or other applicable legislation.
- (f) They inspect the pharmacy using an appropriate inspection questionnaire to ensure that all inspections are fair and consistent across all pharmacies.
- (g) They contact the Office of the Registrar if they experience any technical or inspection-related challenges.

- (h) They offer the RP or pharmacist in charge an opportunity to comment or sign the inspection report.
- (i) They explain and discuss the findings of the inspection with the RP or pharmacist in charge.
- (j) They identify any areas not covered or insufficiently covered in the inspection questionnaire and provide input to the Office of the Registrar to consider amending the inspection questionnaire.
- (k) They submit the inspection report to the SAPC on the same day or within a reasonable period once any technical or inspection-related challenges have been resolved.
- (l) They submit an inspection report to the SAPC with five working days of the inspection.

8.2 How to prepare for inspection

SAPC's main objective in conducting inspections is to monitor pharmacies' compliance with the *Rules relating to GPP* and other relevant legislation. It is therefore important for pharmacy owners and RPs to understand the applicable legislation. RPs must engage inspection officers during an inspection to improve their understanding of legislation and aim to improve future outcomes of their inspections.

When conducting inspections, inspection officers concentrate on the following areas:

- (a) Pharmacy premises layout, access control, safety and security in the pharmacy, areas for counselling and furnishing advice, waiting area, compounding area, and storage area, including the availability of equipment in the pharmacy;
- (b) Dispensing of prescriptions, sale and supply of schedule-1 and schedule-2 medicines by registered persons, including record keeping;
- (c) Control of medicines, thermolabile medicines, specified schedule-5 medicines in wholesale and manufacturing pharmacies, schedule 6 medicines, and storage and delivery of medicines;
- (d) Overall management of the pharmacy and supervision of pharmacy personnel, including participation in continuing professional development;
- (e) Availability of reference sources, policies, processes and written SOPs;
- (f) Screening and monitoring areas that are appropriate for the services provided; and
- (g) Promotion of public health, products which may not be sold in pharmacies, and services provided from mobile units and websites linked to a pharmacy.

Inspection officers gather and record evidence in several ways, including:

- (a) Looking at written or documented evidence, such as prescriptions, invoices, SOPs, policies, processes, etc;
- (b) Observing interactions between pharmacy personnel and patients;
- (c) Testing systems, processes and procedures; and
- (d) Questioning and posing scenarios to staff.

8.3 Referral to Professional Conduct

A pharmacy will be referred to the Professional Conduct Unit of SAPC if the pharmacy is Grade C or Grade D, where an inspection officer is refused access to inspect the pharmacy. The Professional Conduct Unit will conduct an investigation in the case of a pharmacy obtaining Grade D to establish why the inspection officer could not conduct a scheduled inspection.

Once an inspection is finalised and the outcome requires that the pharmacy must be referred to the Professional Conduct Unit, the system will not allow the RP to respond online. All communication will directly be between the Professional Conduct Unit and the RP and the pharmacy owner.

9. GUIDE TO INSPECTION

Table 2: Summary of sections in the inspection questionnaire and relevant legislation

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
Inspection details	The inspection officer populates this section with their personal details as well as the date and time of inspection	None	Section 38(A) of the Pharmacy Act, 53 of 1974
Pharmacy details	<p>The inspection officer verifies the physical address and checks the authenticity and validity of the following documents:</p> <ul style="list-style-type: none"> • Trading title as approved by SAPC • Certificates for RP, owner and pharmacy • Pharmacy licence • Pharmacy name displayed outside, and the pharmacy name consistent with the approved trading title • Pharmacy name displayed on all documentation, such as invoices, and receipts consistent with the approved trading title 	<p>The RP and/or pharmacy owner must conspicuously display the following documents in the dispensary:</p> <ul style="list-style-type: none"> • Pharmacy licence • Certificate for RP • Recording certificate for owner • Recording certificate for pharmacy premises • Approved trading title certificate • Pharmacy name displayed on all documentation, such as invoices, and receipts consistent with approved trading title 	<p>Section 22A and 35A of the Pharmacy Act, 53 of 1974</p> <p>Regulations 7 and 8 of the <i>Regulations relating to the ownership and licencing of pharmacies</i></p>
Operating hours of pharmacy	The inspection officer verifies the weekly operating hours of the pharmacy, checks whether a pharmacist can be contacted 24 hours a day and whether their contact details are displayed conspicuously at the entrance of the pharmacy	<p>The RP and/or pharmacy owner must conspicuously display the following at the entrance of the pharmacy:</p> <ul style="list-style-type: none"> • Contact details of the pharmacy • Operating hours of the pharmacy • Alternate facilities where pharmaceutical services can be 	<p>Rules 4.2.3.2 and 4.3.6 of the <i>Rules relating to good pharmacy practice</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
		obtained in an emergency when the pharmacy is closed	
Pharmacy staffing	<p>The inspection officer verifies that all pharmacy staff are registered with SAPC by checking against SAPC Register:</p> <ul style="list-style-type: none"> • Where necessary, they advise the RP to update details, including any other healthcare professionals employed in the pharmacy • They identify the staff involved in the dispensing process: picking, counselling, etc. 	<p>The RP and/or pharmacy owner must provide inspection officers with the following:</p> <ul style="list-style-type: none"> • Current valid registration cards of all personnel • Current valid certificates/licenses for other healthcare practitioners • Permit, where necessary <p>The RP and/or pharmacy owner must ensure that:</p> <ul style="list-style-type: none"> • The pharmacy is always under the continuous personal supervision of a pharmacist • All staff handling medicines are registered with SAPC • Employment details of all registered persons working in the pharmacy are up to date 	<p>Section 14 of the Pharmacy Act, 53 of 1974</p> <p>Section 22(15) of the Medicines Act</p> <p>Section 56(6) of the Nursing Act</p>
Registration details	<p>The inspection officer validates pharmacy staff details and checks the authenticity and validity of the following documents:</p> <ul style="list-style-type: none"> • The certificates and/or registration cards of the RP, pharmacists and pharmacy support personnel against SAPC's Register 	<p>The RP and/or pharmacy owner must ensure that the following equipment are available during the inspection:</p> <ul style="list-style-type: none"> • All employees must have name tags indicating name, surname and designation 	<p>Section 14 of the Pharmacy Act, 53 of 1974</p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	<ul style="list-style-type: none"> • Other forms of identification: ID and/or SAPC card/s 	<ul style="list-style-type: none"> • Registration cards for all registered persons must be available • The RP's name must be displayed conspicuously at the entrance of the pharmacy • The names of all pharmacists on duty must be displayed in the dispensary • Proof of personal indemnity cover for all registered persons must be available • Poster for patient rights and responsibilities must be displayed 	
Pharmacy premises and layout	<p>The inspection officer verifies that the floor plan is consistent with the plans submitted to and approved by SAPC. He/she also checks:</p> <ul style="list-style-type: none"> • The overall cleanliness, organisation and security of the pharmacy • That working surfaces present no risk of contamination • Whether the pharmacy is accessible to people with disabilities • That there is access to pharmaceutical services 24 hours a day • That the pharmacy is clearly demarcated in a situation where there is another business operated in the same building • That the temperature is controlled (below 25°C) 	<p>The RP and/or pharmacy owner must ensure that the following are available during the inspection:</p> <ul style="list-style-type: none"> • Approved plans by SAPC • Approval letter from SAPC where another business is approved to operate in the pharmacy • Daily/hourly cleaning logbook or sheets indicating when the pharmacy was last cleaned • Temperature charts for the pharmacy • Working air conditioner or other cooling systems • All surfaces to be of impermeable material • Visible signs indicating that the pharmacy is a non-smoking zone 	<p>Occupational and Health Safety Act, 181 of 1993</p> <p>Rules 1.2 of the <i>Rules relating to GPP</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	<ul style="list-style-type: none"> • That there is a facility for compounding in accordance with good manufacturing practice 	<ul style="list-style-type: none"> • Entrances, dispensing counters and doorways of the pharmacy to be accessible to people with disabilities • Certificate of pest control in the last 12 months • All lighting in good working condition and effective to ensure sufficient vision of detail 	
Access control, safety and security in the pharmacy	<p>The inspection officer verifies:</p> <ul style="list-style-type: none"> • Whether the keys and key cards are in control of a pharmacist • Compliance with occupational health and safety • Whether there is an effective barrier to unauthorised persons • Whether fire extinguishers were serviced in the last 12 months 	<p>The RP and/or pharmacy owner must ensure that the following are available during the inspection:</p> <ul style="list-style-type: none"> • Label or documentation indicating last service date for the fire extinguisher/hose • Key, key card or other device or the combination of any device is kept on the person of the RP or the person of another pharmacist at all times, as per GPP • The RP has unfettered 24-hour access to the pharmacy • All pharmacy equipment is connected to individual, fixed socket outlets • There are no trailing wires across floors, surfaces or basins/sinks • A barrier against unauthorised persons 	Rules 1.2.3, 1.2.4 and 1.2.5 of the <i>Rules relating to GPP</i>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
Dispensary, including compounding area	The inspection officer verifies that the dispensary is suitably located in relation to the waiting, consultation and compounding areas	<p>The RP and/or pharmacy owner must ensure that the following are available during the inspection:</p> <ul style="list-style-type: none"> • The dispensing surface area is sufficient for the volume of prescriptions dispensed. A clear working surface area of at least 90cm to 1m must be provided for each pharmacist or other person registered with SAPC who works in the dispensary at one time • The dispensary is visibly designated as a non-eating area • The dispensary has sufficient security to prevent unauthorised access to scheduled medicines, including a lockable door with a no-entry sign • Extemporaneous compounding is carried out in a separate area • There is a separate facility for washing hands with hot and cold water • There is a separate facility for cleaning equipment 	Rules 1.2.11, 1.4.4, 2.8, 2.9 of the <i>Rules relating to GPP</i>
Areas for counselling, furnishing advice and waiting	<p>The inspection officer verifies whether the pharmacy has the following areas</p> <ul style="list-style-type: none"> • Semi-private • Private 	The RP and/or pharmacy owner must ensure that the pharmacy has sufficient areas for the volume of patients being serviced by the pharmacy:	Rules 1.2.13 of the <i>Rules relating to GPP</i>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	<ul style="list-style-type: none"> • Consultation • Waiting 	<ul style="list-style-type: none"> • A semi-private area at every dispensing point for the provision of information and advice • A private area for the provision of information and advice where a patient requires full privacy • A consultation area for the provision of screening and monitoring tests • A covered waiting area near the dispensary 	
Equipment	The inspection officer checks whether the pharmacy has adequate, clean equipment that is in good working order	<p>The RP must ensure that the following equipment is available during the inspection:</p> <ul style="list-style-type: none"> • Graduated measuring cylinders of different sizes • Mortar and pestles • Weighing scale • Counting trays and spatulas • Other utensils and equipment used for compounding and dispensing in the pharmacy 	Rules 1.2.11.4 of the <i>Rules relating to GPP</i>
Dispensing of prescriptions	<p>The inspection officer observes a random sample of prescriptions and medicines labels/copies to check for the following:</p> <ul style="list-style-type: none"> • The pharmacist evaluates and interprets the prescription 	<p>The RP and/or pharmacy owner must ensure that the following are adhered to for a successful inspection:</p> <ul style="list-style-type: none"> • Phase 1 of the dispensing process is performed by a pharmacist 	<p>Section 22(F) of the Medicines Act, 101 of 1965</p> <p>Regulations 10(5) and (6) of the <i>General</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	<ul style="list-style-type: none"> • The pharmacist resolves any issues relating to the prescription • Generic substitution is applied where possible • Dispensed medicine is labelled appropriately • Every prescription dispensed is checked and signed off by a pharmacist by both trailer label and signature • The final price that the patient pays is indicated on the copy for the payer (as applicable) • An adverse drug reaction reporting system is in place • The correct ratio of pharmacist to pharmacy support personnel is maintained 	<ul style="list-style-type: none"> • Generic substitution is applied where possible • Dispensed medicine is labelled appropriately • Every prescription dispensed is checked and signed off by a pharmacist by both trailer label and signature • The final price that the patient pays is indicated on the copy for the payer (as applicable) • An adverse drug reaction reporting system is in place • The correct ratio of pharmacist to pharmacy support personnel is maintained 	<p><i>regulations</i> of Act 101 of 1965</p> <p>Rules 2.7, 2.8 and 2.9 of the <i>Rules relating to GPP</i></p>
Storage area	<p>The inspection officer checks:</p> <ul style="list-style-type: none"> • Whether the storage area is in a good condition (no cracks on walls, painted walls and ceiling not peeling) • Whether pest control is in place • The area for receiving and dispatching stock 	<p>The RP and/or pharmacy owner must ensure that the following is maintained for a successful inspection:</p> <ul style="list-style-type: none"> • Clean storage area as demonstrated by a logbook showing the dates and times when the storage area was cleaned • No dust on the walls and ceiling • Adequate lighting in the storage area • Working air-conditioner • Logbook/charts for temperature recording of storage areas 	<p>Rules 1.2.10 and 1.8 of the <i>Rules relating to GPP</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
		<ul style="list-style-type: none"> • Separate storage area for flammable and hazardous substances • Latest pest control certificate 	
Storage of medicines	<p>The inspection officer checks:</p> <ul style="list-style-type: none"> • Whether medicines in the storage area are stored according to a system and are packed on a shelf with no medicines stored on the floor • That there is proper care for hazardous and flammable stock • That there is no expired stock on operational shelves 	<p>The RP and/or pharmacy owner must ensure the following is maintained for a successful inspection:</p> <ul style="list-style-type: none"> • No medicines are stored on the floor • Medicines are stored according to a system e.g. First in first out (FIFO), first expiry first out (FEFO) • Expired medicines are stored separately or quarantined • Flammable substances are stored separately • Hazardous substances are stored separately • Products are protected from potentially harmful influences 	Rules 1.8 of the <i>Rules relating to GPP</i>
Control of medicines, scheduled substances and active pharmaceutical ingredients	<p>The inspection officer checks that:</p> <ul style="list-style-type: none"> • Medicines are stored appropriately (i.e. in original boxes, fully labelled, no loose blisters or mixed batches, and in an organised fashion) • There are no counterfeit medicines and that there is relevant documentation for any unlicensed medicines in stock 	<p>The RP and/or pharmacy owner must ensure that the following are in place for inspection:</p> <ul style="list-style-type: none"> • There is a procedure to dispose of unusable (expired, damaged, returned and/or contaminated) stock in a safe manner • Unusable stock is quarantined 	<p>Act 101 of 1965</p> <p>Rule 1.2.11.4 of the <i>Rules relating to GPP</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	<ul style="list-style-type: none"> • Medicines are packaged and stored in appropriate conditions (e.g. temperature), including during delivery to patients or other healthcare facilities • There is a stock management system in place • Appropriate dispensing containers are used when pre-packaging medicine 	<ul style="list-style-type: none"> • No counterfeit medicines are kept in stock • Appropriate labels and containers are used to dispense medicines • Medicines are packaged and stored in appropriate conditions • Correct documentation (consent forms, recordkeeping, ADR forms) are used for section 21 medicines 	
Sale and record keeping of scheduled medicines	<p>The inspection officer verifies that:</p> <ul style="list-style-type: none"> • Sale and labelling occur according to Regulation 10 of the Medicines Act, 101 of 1965. • Records are kept according to Regulation 35 of the Medicines Act, 101 of 1965. 	<p>The RP must show and/or provide the inspection officer with the following</p> <ul style="list-style-type: none"> • Records and register of dispensed scheduled substances, including invoices, receipts, prescription books, prescriptions from authorised prescribers, orders, etc. 	<p>Regulation 10 of the Medicines Act, 101 of 1965</p> <p>Regulation 35 of the Medicines Act, 101 of 1965</p>
Control of schedule 6 substances	<p>The inspection officer verifies whether schedule 6 medicines are stored separately, recorded and balanced</p>	<p>The RP must show and or provide the inspection officer with the following:</p> <ul style="list-style-type: none"> • Balanced register of schedule 6 substances • Keys/key card to the schedule cupboards • Lockable cupboard of schedule 6 substances 	<p>Regulation 36 of the Medicines Act, 101 of 1965</p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
Delivery of medicines	<p>The inspection officer verifies whether:</p> <ul style="list-style-type: none"> • The pharmacy delivers medicines via mail, courier or any other method • Control is exercised during delivery • Storage conditions are observed during the delivery of medicines 	<p>The RP and/or pharmacy owner must ensure that the following are available for inspection:</p> <ul style="list-style-type: none"> • A control system for delivering medicines, including cold chain • Records of delivery and receipt (proof of delivery signed by the patient or the patient's caregiver) to ensure that medicines have been delivered and received by the patient or patient caregiver 	<p>Rule 2.7.5 of the <i>Rules relating to GPP</i></p>
Thermolabile medicines	<p>The inspection officer checks that cold chain is maintained throughout by confirming the following:</p> <ul style="list-style-type: none"> • There is a fridge that is in good working order and able to control temperature continuously • Thermolabile medicines are stored in the fridge and at the temperature stipulated by the manufacturer • The cold chain is maintained during dispensing and delivery to patients or other healthcare facilities • The refrigerator is fitted with a warning system if refrigeration has failed or temperatures are outside acceptable levels 	<p>The RP and/or pharmacy owner must ensure that the following is available during inspection:</p> <ul style="list-style-type: none"> • A fridge in good working order able to control temperature continuously • Logbooks/charts with temperature recording for the refrigerator or cold room • Data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards to prove the temperature history of transport and of the thermolabile pharmaceutical product • Contingency plans to ensure cold chain is maintained 	<p>Rules 2.3.5, 2.3.6 and 2.3.7 of the <i>Rules relating to GPP</i></p>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
References	The inspection officer checks that there are information services and/or reference sources available that are up to date	The RP and/or pharmacy owner must ensure that references sources are available either as hard copies or in electronic format. Where relevant, an annual subscription must be in place	Rule 1.2.11.5 of the <i>Rules relating to GPP</i>
Written SOPs	<p>The inspection officer verifies that there are adequate, site-specific, up-to-date SOPs in place as stipulated in the <i>Rules relating to GPP</i> and that staff is appropriately trained for the tasks undertaken or are undergoing appropriate training. Among other things, SOPs assist the RP to:</p> <ul style="list-style-type: none"> • Ensure quality and consistency of service to patients • Ensure good practice is achieved at all times • Utilise the expertise of the pharmacy personnel effectively • Facilitate delegation of appropriate tasks to trained members of the pharmacy personnel • Provide role clarification for all members of the pharmacy personnel • Provide staff training • Provide assurance that staff understands the processes to be followed in the pharmacy • Provide an opportunity for pharmacists to define and assess their practice • Facilitate communication 	<p>The RP and/or pharmacy owner must ensure that the following records are available during the inspection:</p> <ul style="list-style-type: none"> • Signed copies of SOPs • Training records to show that pharmacy personnel were trained on how to use SOPs • An audit trail to show that SOPs are reviewed every two years, or when required <p>A good SOP should contain the following:</p> <ul style="list-style-type: none"> • Purpose – why it exists and its importance • Objective – what it is trying to achieve • Scope – what it covers • Processes – descriptions of how tasks should be carried out • Roles and responsibility – who is responsible for carrying out each stage of the processes 	Rule 4.2.3.3 of the <i>Rules relating to GPP</i>

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
		<ul style="list-style-type: none"> • Training – whether staff has been trained on the SOP • Review – when it is due for revision (currency) and whether it still relevant and valid 	
Products which may not be sold in a pharmacy	The inspection officer verifies that the pharmacy is not selling any products that should not be sold in a pharmacy	<p>The RP and/or pharmacy owner must ensure that the pharmacy is not selling any outlawed products in the pharmacy, such as:</p> <ul style="list-style-type: none"> • Arms/ammunition • Fireworks • Tobacco, snuff, cigarettes, and tobacco-related substances (excluding medicinal snuff and anti-smoking aides) • Liquor, other than that registered for medicinal purposes • Lotto tickets, including the sale or promotion of any gambling services 	Rule 2.29 of the Rules relating to GPP
Promotion of public health	<p>The inspection officer verifies whether the pharmacy renders additional services and whether the relevant qualification has been registered with SAPC. Additional services include:</p> <ul style="list-style-type: none"> • Family planning • Primary care drug therapy (PCDT) 	<p>The RP and/or pharmacy owner must ensure that the following are available during the inspection:</p> <ul style="list-style-type: none"> • Certificate of registration for PCDT and/or family planning pharmacist • Permit for PCDT or family planning 	Section 22A (15) of the Medicines Act, 101 of 1965

Sections in the questionnaire	Inspection officer's role	RP and pharmacy owner's role	Relevant legislation
	The inspection officer authenticates and validates the relevant permit from the Department of Health. The inspection officer also verifies that any screening services rendered are done according to GPP standards and that there is a suitable consultation area		Rules 2.13.1 and 2.15 of the <i>Rules relating to GPP</i>
Services provided from mobile unit and website linked to a pharmacy	The inspection officer verifies whether the pharmacy is: <ul style="list-style-type: none"> • Providing pharmacy services from a mobile unit • Selling medicines from a website • Approval certificate from SAPC • Mobile unit complies with rule 1.4 	The RP and/or pharmacy owner must ensure that the following are available during the inspection: <ul style="list-style-type: none"> • Approval certificate for a mobile unit • Mobile unit for inspection 	Rules 1.4 and 1.5 of the <i>Rules relating to GPP</i>
Continuing professional development and training	The inspection officer verifies that there are records of formal and informal training taking place in the pharmacy	The RP and/or pharmacy owner must ensure that the following are available during the inspection: <ul style="list-style-type: none"> • Certificate(s) of attendance • Certificate(s) of competence • Recording of CPD activities 	Rule 1.4 of the <i>Rules relating to the Code of Conduct</i>
Completion of inspection and signatures	The inspection officer asks the pharmacist to confirm the content recorded in the inspection report	The RP or pharmacist in charge must sign the inspection report on completion of the inspection	Section 38(A) of the Pharmacy Act, 53 of 1974 Regulation 38 of the Education and training regulations

ⁱ Pre May 2003 pharmacies-refers to all pharmacies that were registered with SAPC on or before this date and they are deemed to be licensed.