South African
Pharmacy Council

GOOD INSPECTION GUIDELINES

A guide for inspectors of the South African Pharmacy Council

Issued January 2016

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GOOD INSPECTION GUIDELINES – A GUIDE FOR INSPECTORS OF THE SOUTH AFRICAN PHARMACY COUNCIL

1. INTRODUCTION

Section 4(i) and (v) of the Pharmacy Act empowers Council, inter-alia:

(a) Subject to the provisions of this Act, to register a person as a pharmacist, to inspect the records and accounts of or investigate the activities at a pharmacy carried on by a person so registered, or to require any person so registered to submit to the Council such information as the Council may deem necessary;

(b) To appoint any officer or inspector to perform any duty or act on behalf of the Council in terms of this Act and to prescribe and determine their powers and duties.

Section 22(6) of the pharmacy Act states that, Council shall have the right to inspect premises in which the business of a pharmacy is carried on in terms of this Act, and the registrar shall provide the Director-General and the person who made the application in terms of subsection (1) with a written report of the findings of its inspection if it has been found that the inspected premises are not suitable for the business of a pharmacy.

Section 35A (d) states that council shall be entitled to investigate and inspect the practice and the conduct of the business of a pharmacy.

Section 38A (1) states that any officer appointed in terms of this Act who is required or authorised to perform any duty on behalf of the Council and any person appointed by virtue of the provisions of section 49 (1) (/) (v) to make any inspection, may enter any pharmacy at any time reasonable for the proper performance of such duty or the making of such inspection.

Regulations (36-40) of the regulations relating to pharmacy education and training highlights the requirement of an inspections as part of the process of premises approval.

2. PURPOSE

(a) To guide Council inspectors on how to conduct the different types of pharmacy inspections in line with Council approach of educating the profession;

(b) To provide guidance to inspectors on how to deal with certain observations or responses to questions on the inspection questionnaires;

(c) To inform the profession on what to expect during an inspection;

3. GENERAL CONSIDERATIONS

(a) These guidelines must be read in conjunction with:

(i) Rules relating to Good Pharmacy Practice in terms of section 35(A) (b) (ii);
(ii) Rules relating to Acts or Omissions in respect of which the Council may take disciplinary steps in terms of Section 41(1);
(iii) Rules relating to Code of Conduct in terms of section 35A(b) (i)

(b) Inspections must be conducted in line with the inspector's code of conduct.

4. GENERAL GUIDELINES

(a) Upon entering the pharmacy, an SAPC inspector must observe the activities of the pharmacy for compliance with the Pharmacy Act and other applicable legislation;

(b) The inspector must request to speak to the responsible pharmacist or the pharmacist in charge;

(c) The inspector must identify himself/herself to the responsible pharmacist or pharmacist in charge by producing his/her SAPC inspector's card;

(d) The inspector must explain the inspection process to the responsible pharmacist or the pharmacist in charge;

(e) The inspector must allow for 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) The inspector must inspect the pharmacy using an appropriate inspection questionnaire in order to ensure that all inspections are fair and consistent across all pharmacies;

(g) The inspector must contact the Office of the Registrar if they experience any technical or inspection related challenges;

(h) The inspector must submit the inspection results and/or report to the SAPC on the same day or within a reasonable period once any technical or inspection related challenges have been dealt with;

(i) The inspector must 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 questionnaires.

5. GUIDELINES RELATING TO MONITORING INSPECTIONS

(a) Inspectors must identify any duplication of pharmacy names on their list of allocated pharmacies for the year, prior to conducting inspections;

(b) Inspectors must check the current grading of the pharmacy appearing on the inspection list, prior to conducting an inspection, to ensure that the pharmacy is not inspected earlier than the year its grading expires;

(c) The average number of inspections conducted per month must be adequate to ensure that all inspections on the inspection list are concluded by 30 November each year.

6. GUIDELINES RELATING TO TRAINING INSPECTIONS

(a) Inspectors must conduct a pharmacy inspection on request by the Office of the Registrar within 5 working days (7 days);

(b) Inspections must be conducted in line with Regulations relating to pharmacy Education and training (regulations (36-40).

7. GUIDELINES RELATING TO DISCIPLINARY INSPECTIONS

(a) An inspector must conduct a full inspection, with the focus on areas of investigation as instructed by the Office of the Registrar;

(b) Inspectors must conduct a pharmacy inspection on request by the Office of the Registrar within 5 working days (7 days).

8. GUIDELINES RELATING TO PHARMACY INSPECTION QUESTIONNAIRE/DAY TO DAY PHARMACY INSPECTION PROCEDURES – FREQUENTLY ASKED QUESTIONS

Issue	Guidelines
8.1 It takes time to complete the staffing requirements sheet	(a) Give the pharmacy the staff requirement sheet beforehand to complete while you carry on with the inspection; (b) Encourage pharmacies to do a self-inspection where they would complete the staffing sheet in line with GPP requirements; (c) Online completion of inspections questionnaires will automatically populate the staff and the inspector will only add those that are not registered with Council; (d) Remind the Responsible pharmacist that there is an online functionality to update staff employed at his pharmacy and that this can be done at any at his/her convenience.
8.2 GPS coordinates	(a) The pharmacy should know their GPS location and will provide those to the inspector; (b) The inspector can go onto internet and search on Google maps.
8.3 The Responsible Pharmacist (RP)/pharmacist is not at the pharmacy on a full time basis. Is it legitimate?	(a) Verify if the RP is still registered as such with SAPC (b) An RP may only be absent from his/her pharmacy under specified conditions. GPP Annexure A sec 2.1.1 (c) A pharmacy may not be operated without a pharmacist. (d) Conduct the inspection, advise the staff to lock the pharmacy and put a note indicating that there is currently no pharmacist and handover the keys to the authority, refer GPP Annexure A sec 2.1.1
8.4 What is the minimum time, in hours per day, an RP can work and still be officially a RP?	(a) An RP may only be absent from his/her pharmacy under specified conditions. GPP Annexure A sec 2.1.1
8.5 The SAPC did not conduct a new premises inspection yet the pharmacy Y-number appears on my monitoring list.	Call and request the floor plans from the office, and continue with the inspection
8.6 An unregistered wholesaler bought medicine from a manufacturer without the relevant licence.	Capture as such on the questionnaire, and also advise the manufacturer to get an updated list of registered pharmacies from the office/check on website from time to time before releasing an order. If the pharmacy name does not appear on the register of pharmacies, then the pharmacy should be regarded as unregistered.
8.7 I did an inspection at a CHC dispensary, where a Learner Basic Pharmacist Assistant/ Professional Nurse was deployed to manage the pharmacy, whereas the tutor was in another pharmacy. Is this legitimate?	(a) The learner and the tutor should be in the same pharmacy premises and the premises should be approved for purposes of training. (b) The pharmacy should only be managed by a pharmacist and not a pharmacist assistant (c) Identify and note the name of the tutor and the facility the learner is assigned to

Issue	Guidelines
	(d) Conduct the inspection, advise the staff to lock the pharmacy and put a note indicating that there is currently no pharmacist and handover the keys to the authority, refer GPP sec 2.1.1
8.8 There seems to be 2 sets of rules for state and private sectors? Do you charge the state when they transgress?	(a) The same law applies to all pharmacies (public or private) (b) Yes, the state is fined also as per Chapter 5 of the Pharmacy Act.
8.9 A pharmacy moved from one premise to another without notifying SAPC.	(a) Note it as such and submit to SAPC; matter will be handed over to the professional conduct and law enforcement unit since SAPC does not have jurisdiction over unregistered premises (b) Mark this pharmacy as closed and note on comments section that the pharmacy has moved to another location.
8.10 There are no air conditioners, the temperature goes up to 45 degrees C.	Note the shortcomings and submit the report to SAPC and they will be dealt with according to Chapter 5 of the Pharmacy Act.
8.11 If I arrive at a premises where there is supposed to be a pharmacy and they have no certificates to prove that I am at the right pharmacy, how do I fill in the questionnaire, where they ask for the pharmacy registration number, RP, etc?	(a) Mark as 'Does not comply' and fill in necessary comments. Complete each section according to your findings. (b) Inspector should advise the RP or pharmacist in charge during inspection to obtain and display original certificates of the pharmacy.
8.12 My cell phone and/or tablet are giving me problems. What do I do?	Either call the office or send the gadget back to the SAPC to get it fixed.
8.13 The questionnaires must have a section, where you as an inspector, can refer the inspection for special attention.	Additional inspection comments page available/comment on the online inspection questionnaire.
8.14 The new cards are valid for 5 years, how do I check that the person has paid annual fees for the current year.	The inspector should immediately go online (www.sapc.za.org) and type the credentials of the person on the search functionality to verify registration.
8.15 S1 and S2 counter is too close to the waiting area and/or too far from the dispensary. How do I capture this?	(a) See GPP criteria sections 1.2.2; 1.2.11.5; 2.29 and 2.31 (b) Note the shortcomings and advise the RP about GPP shortcomings. (c) See GPP criteria 2.31.2.13 which specifically states that the S1/S2 counter should not be a separate counter from the dispensary. (d) The pharmacies are required to correct these GPP shortcomings including plans as to how they are going to make those counters compliant.
8.16 I did an inspection at a pharmacy, but i was told that they could not find a pharmacist. Why was the pharmacy licence not withdrawn?	Capture as non-compliant and complete an additional inspection comments page and email to inspection@sapc.za.org
8.17 The pharmacy has moved without notifying Council, what should I do?	(a) Scenario 1– if the pharmacy has moved to a location known to the inspector, conduct the inspection and mark the address as 'does not comply' and write comprehensive comments

Issue	Guidelines
	(b) Scenario 2 – if the pharmacy is at an unknown location, write comprehensive comments and mark as 'closed'
8.18 I went to a pharmacy to perform a monitoring inspection, but the pharmacist refused that I perform the inspection. What do I do?	Write comprehensive comments, mark sections as 'does not comply' and escalate the report for urgent attention by the office.
8.19 The office has sent a request to conduct a training inspection, but the RP says they are not ready, they will call.	Report to the office, and advise the RP to notify the office in writing. If no notification is received, the application will be regretted and the RP will have to re-apply,
8.20 What do I do, I cannot submit the inspection online?	If you cannot submit your online questionnaire or the system does not acknowledge your submission, phone and/or email the SAPC IT department or you're allocated SAPC Officer from with the requisite Y number and they will assist you with the submission.
8.21 I have duplicates on my inspection list, what do I do?	(a) Inform the office about the duplication (b) Perform the inspection on the list for that Y number, if all of them are marked 'to be processed', (c) For a pharmacy which has been marked, "processed", contact the office to verify if an inspection has been conducted
8.22 An inspection was conducted for the pharmacy in the previous year	Call the office to verify and authorise if the inspection should continue.
8.23 Performing a disciplinary inspection	(a) Maximum number of hours is 5 hours (for a normal inspection maximum is three hours except for a no-stock wholesale pharmacy where the maximum is 1.5 hours) (b) The office of the Registrar will assess **(Senior Manager: professional affairs (Practice) and Senior Manager: Legal services and professional conduct)** if there is need to exceed the maximum of five hours on a case by case basis and will give a prior approval for such deviations from the policy; (c) Such prior approval shall be given in writing by the **Senior Manager: Professional Affairs (Practice)**
8.24 Why must I make elaborate notes and comments on the items I marked "does not comply", for example "a pharmacist assistant dispensed medicines" and supplying prescriptions numbers only on the comments to an inspection – " pharmacist assistant "A" dispensed prescription 143567"	(a) Inspector to provide evidence in the form of copies of prescriptions to support the allegation; (b) Provide P number, names, surnames, and ID number, in case of an unregistered person provide names, surnames, and ID number;