

**WHOLESALE INSPECTION
QUESTIONNAIRE
TO ESTABLISH THE NATURE, EXTENT AND
STANDARD OF PHARMACEUTICAL SERVICES**



**South
African
Pharmacy
Council**

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PHARMACY NAME					
Y NUMBER	Y				
CASE NUMBER					
INSPECTION TYPE	Monitoring	Training	New Premises	Disciplinary	Follow-up

PLEASE NOTE:

The confidentiality of this document may be withdrawn should the information furnished lead to further investigation(s)

Please refer this questionnaire for special attention:

 YES

 NO


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NOTE: Throughout this questionnaire all questions carry a specific weighting.

WEIGHTING KEY	
1.	Not at all important but necessary to document
2.	Low importance
3.	Slight importance
4.	Neutral importance
5.	Moderate important
6.	Very important
7.	Extremely important

(A) INSPECTION DETAILS

NOTE: Throughout this questionnaire legislative requirements are indicated with an *

1.0 Date of inspection	D	D	/	M	M	/	Y	Y	Y	Y				
2.0 Name of inspector <i>(in block capitals)</i>						2.2 Inspector P Number								
3.1 Type of inspection	Monitoring	Training	New Premises	Disciplinary	Follow-up	3.2 Inspection start time	H	H	M	M				

(B) PHARMACY DETAILS

4. Name of pharmacy <i>(in block capitals)</i> ^{1**}											0	3	
5. Pharmacy registration number	Y										OFFICE USE ONLY	Pharmacy details confirmed	Inspection cycle
6. License number: DoH and type of authorised site activity (e.g. manufacturer; packer, testing laboratory, import, export) <i>(if applicable)</i> **	DOH										0	3	
7. License number: MCC and type of authorised site activity (e.g. manufacturer; packer, testing laboratory, import, export) <i>(if applicable)</i> **	MCC											3	
8. Telephone number(s)			-								8.1 Ext.		
9. Cellphone number													
10. Fax number			-										
11. Pharmacy and/or Responsible Pharmacist e-mail address if not the same	11.1 Pharmacy e-mail address					11.2 Responsible Pharmacist e-mail address							
12.1 Pharmacy: Registered postal address											12.2 Postal code		
13.1 Pharmacy: Registered physical address**											0	3	
											13.2 Street code		
14.0 Does the pharmacy keep stock?	Yes			No									
15.0 In which province is the pharmacy situated?	Eastern Cape			Free State			Gauteng		Kwazulu-Natal				
	Mpumalanga			Northern Cape			Limpopo		North West				
	Western Cape												

¹ As per the displayed recording certificate and license issued by the Department of Health

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

16.0 Where is the pharmacy situated? (for statistical purposes)	City centre ²	City suburb ³	Town ⁴	Township ⁵	Rural ⁶			
17.0 Where is the pharmacy situated (Others please specify)								
18.0 GPS Co-ordinates	18.1 X (Latitude)			18.2 Y (Longitude)				
	18.1 X (Latitude) - Deg			18.2 Y (Longitude) - Deg				
	18.1 X (Latitude) - Min			18.2 Y (Longitude) - Min				
	18.1 X (Latitude) - Sec			18.2 Y (Longitude) - Sec				

² Refers to the central business district area.

³ A residential area within the boundaries of a town or city.

⁴ Usually a town or part of a town.

⁵ 'township' in South Africa referred to an urban residential area created for migrant labour, usually beyond the town or city limits. Generally, every town/city has one or several townships associated with it.

⁶ Any area that is not classified *urban*. Rural areas are subdivided into tribal areas and commercial farms.

Responsible Pharmacist or Pharmacist Initials/signature

(C) PHARMACY STAFFING

19.1 Name of pharmacy owner as registered <i>(in block capitals)</i> ⁷				0	3
19.2 Registration number as per CIPI documents (if applicable)					
20.1 Name of responsible pharmacist as registered		20. 2 P		0	3
21.1 Name of pharmacist in charge during inspection		21. 2 P		0	3
22.0 Name of (prospective) tutor(s) if applicable	22.1 Tutor 1 name:	22. 1 P			Office Use
	22.2 Tutor 2 name:	22. 2 P			Office Use
	22.3 Tutor 3 name:	22. 3 P			Office Use
23.	How many community service pharmacists are in the permanent employ of the pharmacy? <i>(public health facilities only)</i>				
24.	How many full-time pharmacists are in the permanent employ of the pharmacy? <i>(at least 5 hours per day)</i>				
25.	How many part-time pharmacists are in the permanent employ of the pharmacy? <i>(less than 5 hours per day)</i>				
26.	How many registered pharmacist's assistants (basic) work in the pharmacy?				
27.	How many registered pharmacist's assistants (post-basic) work in the pharmacy?				
28.	How many registered pharmacist's assistants (learner basic) work in the pharmacy?				
29.	How many registered pharmacist's assistants (learner post-basic) work in the pharmacy?				
30.	How many registered pharmacy technical assistants trainees are undergoing practical training in the pharmacy? <i>(Fill in details as required in the table attached as schedule A).</i>				
31.	How many registered pharmacy technicians trainees are undergoing practical training in the pharmacy? <i>(Fill in details as required in the table attached as schedule A).</i>				
32.	How many registered pharmacy technicians work in the pharmacy?				
33.	How many unregistered persons performing acts falling within the scope of practice of pharmacists and/or pharmacy support personnel who would require training in order to register as pharmacist's assistants with the Council? ⁸				
Comments and/or corrective action					

⁷ As per SAPC recording certificate and DOH License

⁸ Inspector must explain legal requirement

Responsible Pharmacist or Pharmacist Initials/signature

(E) PREMISES AND LAYOUT

	N/A	Does not comply	Complies	Weight
44. The premises are clean.		0	3	5
45. The premises are organised.		0	3	5
46. There is a facility for washing hands.		0	3	5
47. The floor surface is of impermeable material.	No Stock	0	3	5
48. All working surfaces are finished with a smooth impermeable and washable material which is easy to maintain in a hygienic condition.	No Stock	0	3	5
49. Countertops are finished with a smooth impermeable and washable material, which is easy to maintain in a hygienic condition.	No Stock	0	3	5
50. Shelves are finished with a smooth impermeable and washable material, which is easy to maintain in a hygienic condition.	No Stock	0	3	5
51. Walls are finished with a smooth impermeable and washable material, which is easy to maintain in a hygienic condition.	No Stock	0	3	5

Comments and/or corrective action required for all items marked 'does not comply'

PREMISES AND LAYOUT (Continued)

	N/A	Does not comply	Partially complies	Complies	Weight
52. There are no open drain channels.		0	1	3	5
53. There is sufficient lighting.		0	1	3	5
54. Forklift machines (if used) do not have combustion engines.	Not used	0	1	3	5
55. The temperature in the pharmacy is maintained below 25 degrees Celsius (<i>as checked with a thermometer</i>).	No Stock	0	1	3	5
56. The temperature in the pharmacy is controlled 24 hours a day as demonstrated by a maximum/minimum thermometer.	No Stock	0	1	3	5
57. The temperature in the pharmacy is recorded daily.	No Stock	0	1	3	5
58. There is an air conditioning system in the pharmacy.		0	1	3	5
59. The air conditioning system in the pharmacy is in good working condition to keep the temperature below 25 degrees Celsius.		0	1	3	5
60. There is at least one fire extinguisher or fire hose in the pharmacy.		0	1	3	5
61. The electrical equipment is regularly maintained and safe.		0	1	3	5
62. The total floor area is sufficient for the efficient operation of staff.		0	1	3	5
63. The workflow in the pharmacy is efficient.		0	1	3	5

Responsible Pharmacist or Pharmacist Initials/signature

(G) CONTROL OF MEDICINES, SCHEDULED SUBSTANCES AND ACTIVE PHARMACEUTICAL INGREDIENTS/MEDICINES

	N/A	Does not comply	Partially complies	Complies	Weight
99. A computerised programme is used for stock control. ¹⁷		No		Yes	
100. An effective stock control system is in place.	No Stock	0	1	3	7
101. All medicines sold for human use, comply with Regulation 8 of Act 101 of 1965 i.e. labelling requirements for human medicine.	Do not supply	0	1	3	7
102. All veterinary medicines sold, comply with Regulation 48 of Act 101 of 1965 i.e. labelling requirements for veterinary medicines.	Do not supply	0	1	3	7
103. Medicines are purchased only from licensed manufacturers in accordance with Section 22H(1)(a) of Act 101 of 1965.	No stock	0	1	3	7
104. An up-to-date list of pharmacies registered with the SAPC is available.	No stock	0	1	3	7
105. Copies of permits (detailing applicable medicines lists) of all Section 22A(15) permit holders are available (<i>previously Section 22A(12)</i>).	Do not supply	0	1	3	7
106. Medicine lists for permit holders are available and consulted.	Do not supply	0	1	3	7
107. There is an up-to-date list of Veterinarians registered with the South African Veterinary Council.	Do not supply	0	1	3	7
108. There is an up-to-date list of dispensing doctors registered with the Health Professions Council of South Africa (<i>dispensing license as from 2.05.2004</i>).	Do not supply	0	1	3	7
109. There is a recording system that enables the chain of supply (<i>specific batch numbers</i>) to be traced.		0	1	3	7
110. Records of all invoices of S2-S5 medicine purchases and sales are kept as required in Regulation 11(4) of Act 101 of 1965.	Not stocked	0	1	3	7
111. Records are kept for a minimum of 5 years after the date of sale of medicines, as required by Act 101 of 1965.		0	1	3	7
112. Records of all sales of medicines are kept in a safe place and are easily retrievable.		0	1	3	7
113. A control system is implemented that enables detection and correction of a delay in the delivery process.		0	1	3	7
114. Medicines are supplied only on valid sales orders (<i>as confirmed by pharmacist in charge during inspection</i>).		0	1	3	7
115. Medicines are packaged and stored in accordance with registration requirements throughout the delivery process.	Not stock	0	1	3	7
116. Control is exercised so that products are not subjected to unacceptable degrees of heat, cold, sunlight or any other adverse influences during the transportation process.	Not stock	0	1	3	7
117. Does the pharmacy deliver medicines by mail?		Yes		No	
118. Does the pharmacy deliver medicines by courier?		Yes		No	
119. Does the pharmacy deliver medicines by delivery person?		Yes		No	
120. Does the pharmacy deliver medicines by any other means (<i>e.g. train etc.</i>)?		Yes		No	
121. If question 121 was answered 'yes', PLEASE SPECIFY by which means: ¹⁸					

¹⁷ For Information only¹⁸ For Information only (questions 116 to 119)

Responsible Pharmacist or Pharmacist Initials/signature

Comments and/or corrective action required for all items marked 'does not comply' or only 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(J) WRITTEN STANDARD OPERATING PROCEDURES

There are written standard operating procedures for:	N/A	Does not comply	Partially complies	Complies	Weight
145. good housekeeping (<i>cleaning procedures etc.</i>).		0	1	3	3
146. pest (<i>insects, rodents etc.</i>) elimination.		0	1	3	3
147. receipt of stock.		0	1	3	3
148. effective stock rotation (<i>FEEFO – First entry, expiry, first out</i>).		0	1	3	3
149. disposal or removal of S1 – S6 expired, damaged and/or contaminated stock as required in Regulation 27 of Act 101 of 1965.		0	1	3	3
150. product types requiring special storage or handling instructions.		0	1	3	3
151. separation and handling of goods returned from patients.		0	1	3	3
152. recall of medicine.		0	1	3	3
153. delivery of medicines.	N/A	0	1	3	3
154. procedures to be followed regarding the handling of keys, money, etc for a locum or relief pharmacist(s) (where applicable).	N/A	0	1	3	3
155. cold chain management (<i>including procedures to be followed in the event of a power failure</i>).	N/A	0	1	3	3
156. pre-packing (<i>including quality assurance procedures</i>).	N/A	0	1	3	3
157. handling of product complaints.		0	1	3	3
158. daily routine and working hours.		0	1	3	3
159. enquiry or complaint procedure		0	1	3	3
160. stock-taking.		0	1	3	3
161. obsolete or unusable stock.		0	1	3	3
162. storage of medicine.		0	1	3	3
163. procurement of medicine.		0	1	3	3
164. handling of S5 and S6 medicines.		0	1	3	3
165. advertising of medicines.		0	1	3	3
166. reporting of adverse drug reactions.		0	1	3	3
167. SOPs are reviewed/updated on a regular basis and are adapted to the operations of the specific pharmacy, and staff trained on the SOP's		0	1	3	3

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(M) RECOMMENDATIONS IN RESPECT OF TRAINING

NB: RECOMMENDATIONS MUST ALSO BE MADE IN THE CASE OF MONITORING INSPECTIONS.

The inspector must, through his/her observations, take notice of all aspects of pharmacy practice, to give an objective evaluation of the training facilities in the pharmacy and the ability of a prospective tutor to train pharmacy support personnel effectively. **Note: Training of interns may not be undertaken in wholesale pharmacies.**

184. A pharmacy support personnel was trained within the last 3 years.	No	Yes
185. Would the pharmacist accept responsibility as a tutor for the training of pharmacy support personnel?	No	Yes
186. Is there evidence that the prospective tutor participates in continuing education/professional development?	No	Yes
187. Is there disciplinary action pending against the prospective tutor?	No	Yes
188. Is there evidence that the prospective tutor/pharmacist upholds the principles of GPP/GWP/GDP?	No	Yes

**! Recommendations made by the inspector with respect to training do not constitute approval for training by the Council.
Final approval of the pharmacy premises and tutor is made by the Council.**

Comments and/or corrective action required for all items marked 'no' or 'see comments'

Responsible Pharmacist or Pharmacist Initials/signature

(N) SIGNATURES

I, THE UNDERSIGNED, AM FAMILIAR WITH THE CONTENTS OF THIS INSPECTION REPORT. THE RECOMMENDED CORRECTIVE ACTION TO BE TAKEN IN INSTANCES WHERE A QUESTION WAS ANSWERED AS EITHER 'DOES NOT COMPLY' OR 'PARTIALLY COMPLIES' HAS BEEN EXPLAINED AND WRITTEN IN THIS REPORT, IN EVERY SUCH INSTANCE.							
189. Signature of pharmacist in charge during inspection : the pharmacy is under direct continuous supervision of a pharmacist							
190.1 Name and 190.2 P number of above pharmacist in charge during inspection (in block capitals) (refer question 20):							
		P					
191. Signature of inspector :							
192.1 Duration of inspection: (refer inspection start time on page 2)				192.2 Duration (no. of hours)		192.3 Inspection end time	H H M M

FURTHER COMMENTS	

Responsible Pharmacist or Pharmacist Initials/signature
