

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

**INSTITUTIONAL (HOSPITAL)
PHARMACIES**

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*The confidentiality of this document may be withdrawn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



THE SOUTH AFRICAN PHARMACY COUNCIL,

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(A) INSPECTION DETAILS

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

1. Language preference for inspection report	English ¹	Afrikaans ²	2. Date of inspection	D	D	M	M	Y	Y	Y	Y
3. Name of inspector (in block capitals)				Inspector Code			Inspection start time				
4. Type of inspection	Monitoring ¹	Training Assistants ²	Training Interns ³	New Premises ⁴	Disciplinary ⁵	Follow-up ⁶					

(B) PHARMACY DETAILS

5. Name of hospital (in block capitals)																						
6. Name of pharmacy (if different) (in block capitals)																						
7. Pharmacy registration number	Y						OFFICE USE ONLY	Pharmacy details confirmed	Inspection cycle													
8. Licence number (if applicable)																						
9. Telephone number(s)	()			-					()			-				
10. Fax number							-															
11. E-mail address																						
12. Postal address											13. Physical address											
	Postal Code											Street Code										
14. What is the nature of the pharmacy?	Public/state hospital ¹	State subsidised ²	Private hospital ³	Mine hospital ⁴																		
15. How is the hospital classified?	N/A	Tertiary/academic ¹	Regional hospital ²	District hospital ³	Community Health Centre or PHC Clinic ⁴	Psychiatric/Long-term facility ⁵	Private: ⁶	Please specify other: ⁶														
16. To whom are services rendered?	In-patients ¹	Out-patients/Passing trade ²	Clinics/Other hospitals ³																			
17. In which province is the pharmacy situated?	Eastern Cape ¹	Free State ²	Gauteng ³	Kwazulu-Natal ⁴	Mpumalanga ⁵	Northern Cape ⁶	Limpopo ⁷	North West ⁸	Western Cape ⁹													
18. Where is the pharmacy situated?	City centre ¹	City suburb ²	Small town ³	Rural # ⁴																		

#< 40,000

(C) PHARMACY STAFFING

19.	Name of pharmacy owner as registered			
	Name	Registration Number		
20.	Name of responsible pharmacist as registered			Office use
21.	Name of pharmacist in charge during inspection			Office use
22.	Name of (prospective) tutor(s) if applicable			Office use
				Office use
				Office use
23.	How many community service pharmacists are in the employ of the pharmacy? (<i>public health facilities only</i>) (fill in name and number under comments).			
24.	How many full-time pharmacists are in the permanent employ of the pharmacy? (<i>at least 5 hours per day</i>) (fill in name and number under comments).			
25.	How many part-time pharmacists are in the permanent employ of the pharmacy? (<i>less than 5 hours per day</i>) (fill in name and number under comments).			
26.	How many pharmacist interns are undergoing practical training in the pharmacy?			
27.	How many registered pharmacist's assistants (basic) work in the pharmacy?			
28.	How many registered pharmacist's assistants (post-basic) work in the pharmacy?			
29.	How many registered pharmacist's assistants (learner basic) are undergoing practical training in the pharmacy?			
30.	How many registered pharmacist's assistants (learner post-basic) are undergoing practical training in the pharmacy?			
31.	How many unregistered persons performing acts falling within the scope of practice of pharmacists and/or pharmacist's assistants would require training in order to register as pharmacist's assistants with the Council?			
32.	Who does the actual picking of medicines prior to dispensing?	Other personnel ¹	Registered pharmacist's assistant ²	Pharmacist and/or pharmacist intern ³
33.	Who hands the medicine to the patient or care-giver?	Porter/driver/courier ¹	Other personnel ²	Registered pharmacist's assistant ³
			Pharmacist and/or pharmacist intern ⁴	
34.	How many items prescribed by an authorised prescriber are dispensed per day on average?	In-patients:		}
		Out-patients/ passing trade:		
35.	How many P.I.T. items are dispensed per day on average?	N/A		
36.	How many surgical items are dispensed/issued per day on average?	N/A		
37.	How many ethical stock items are dispensed/issued per day on average?			

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

(D) REGISTRATION DETAILS

	N/A	Does not comply	Partially complies	Complies
38. The name of the responsible pharmacist is displayed conspicuously over the main entrance of the pharmacy.		1	2	3
39. The name of the pharmacist(s) on duty is/are displayed conspicuously in/or outside the pharmacy for the purpose of identification of such person(s) by the public.		1	2	3
40. The pharmacist(s) on duty is/are wearing a nametag or badge indicating his/her name and designation for the purpose of identification of such person(s) by the public.		1	2	3
41. The pharmacy is under the constant personal supervision of a pharmacist.		1	2	3
42. A currently valid annual registration card(s) is available for the pharmacist(s) (<i>refer questions 20, 21, 23,24 and 25</i>).		1	2	3
43. A currently valid annual registration card(s) is available for the pharmacist's assistant(s) (basic/post-basic) (<i>refer questions 27 and 28</i>).	N/A	1	2	3
44. A currently valid annual registration card(s) is available for the pharmacist's assistant(s) (learner basic/learner post-basic) (<i>refer questions 29 and 30</i>).	N/A	1	2	3
45. A currently valid certificate for the recording of the pharmacy is available.	N/A	1	2	3

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

(E) PREMISES AND LAYOUT

		N/A	Does not comply	Partially complies	Complies
46.	The premises are clean.		1	2	3
47.	The premises are orderly and tidy.		1	2	3
48.	The pharmacy is suitably located in the institution.		1	2	3
49.	The pharmacy is accessible to persons with disabilities.		1	2	3
50.	The floor surface in the dispensing area is of impermeable material.		1	2	3
51.	All working surfaces are finished with a smooth, impermeable and washable material.		1	2	3
52.	Countertops are finished with a smooth, impermeable and washable material which is easy to maintain and in a hygienic condition.		1	2	3
53.	Shelves are finished with a smooth, impermeable and washable material which is easy to maintain and in a hygienic condition.		1	2	3
54.	Walls are finished with a smooth, impermeable and washable material which is easy to maintain and in a hygienic condition		1	2	3
55.	Approval has been obtained from Council in the event that a person who is not registered with Council conducts a separate practice/business within the pharmacy (<i>Ethical Rule 13(a)</i>).	N/A	1 No		3 Yes
56.	The lighting is suitable and effective.		1	2	3
57.	The temperature in the pharmacy is below 25°C (<i>as checked with a thermometer</i>).		1	2	3
58.	The temperature in the pharmacy is controlled 24 hours a day as demonstrated by a maximum/minimum thermometer.		1	2	3
59.	There is an air conditioner in the pharmacy and is in good working condition.		1	2	3
60.	The temperature is recorded on a daily basis.		1	2	3

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

PREMISES AND LAYOUT(Continued)

	N/A	Does not comply	Partially complies	Complies
61. There is at least one fire extinguisher or fire hose in the pharmacy.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
62. If there is a fire extinguisher, it has been serviced within the last year (as indicated on the cylinder)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
63. The electrical equipment is regularly maintained and safe.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
64. 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(s) registered with Council who work in the dispensary).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
65. The total floor area is sufficient for the efficient operation of dispensary staff.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
66. The workflow in the pharmacy is efficient.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
67. There is a suitable waiting area, which is under cover.	<input type="checkbox"/> No out-patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
68. The waiting area is situated near the dispensary area, areas for counselling and the furnishing of information and/or consultation areas.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
69. The waiting area has comfortable seating available/provided.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
70. There is a suitable semi-private area for the provision of information and advice, in accordance with GPP standards.	<input type="checkbox"/> N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
71. There is a suitable private area for the provision of information and advice, in accordance with GPP standards.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
72. There is a suitable consultation area for the provision of screening and monitoring test.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
73. The professional image of the dispensing area is not affected by the display of commercial material not directly linked with health.	<input type="checkbox"/> N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
74. Medicinal and non-medicinal products are displayed separately in the pharmacy.	<input type="checkbox"/> N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

PREMISES AND LAYOUT(Continued)

	N/A	Does not comply	Partially complies	Complies
75. Key, key card or other device or the combination of any device, which allows access to a pharmacy when it is locked, is kept in person of the responsible pharmacist or the person of another pharmacist at all times.		1	2	3
76. Only the pharmacist(s) has keys to the pharmacy area where schedules 1–6 items are kept.		1	2	3
77. Control of access to pharmacy premises, which include the design and layout of the pharmacy is of such a nature that only registered pharmacy personnel have direct access to medicine.		1	3	3
78. There is sufficient security to prevent unauthorised access to medicines.		1	2	3
79. The pharmacy is designated as a non-smoking area.		1	2	3
80. There is a separate facility for washing hands.	N/A	1	2	3
81. There is a separate facility for cleaning of equipment.	N/A	1	2	3
82. There is a separate service area for outpatients.		1	2	3
83. There is a separate service area for staff.		1	2	3
84. There is a suitable separate facility that comply with GMP standards where compounding is carried out.		1	2	3
85. There is a suitable separate facility that comply with GMP standards where pre-packaging is carried out		1	2	3

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

(F) EQUIPMENT

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

N/A	Does not comply	Partially comply	Complies
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The pharmacy has:

86.	- adequate pestles and mortars.	N/A	1	2	3
87.	- adequate spatulas.	N/A	1	2	3
88.	- a suitable mass meter for dispensing.	N/A	1	2	3
89.	- adequate graduated measures.		1	2	3
90.	- adequate medicine containers for the dispensing of medicines.		1	2	3
91.	- adequate warning labels or clearly noticeable warning indications on the label.		1	2	3
92.	- suitable laminar flow cabinet(s) for preparation of parenteral fluids/TPN (e.g. <i>antibiotics</i>) which is validated.	N/A	1	2	3
93.	-suitable laminar flow cabinet(s) (vertical) for preparation of biohazardous preparations (e.g. <i>cytotoxics</i>) which is validated.	N/A	1	2	3
94.	- sufficient counting apparatus for tablets and capsules.		1	2	3
95.	Counting trays are cleaned in order to prevent cross-contamination.		1	2	3
96.	All the equipment in the pharmacy is clean.		1	2	3
97.	All the equipment in the pharmacy is in good working order.		1	2	3
98.	The pharmacy has suitable refuse receptacles (<i>with closing lids where applicable</i>).		1	2	3

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

(G) STORAGE

		N/A	Does not comply	Partially complies	Complies
99.	Medicines are stored according to a system.		1	2	3
100.	Storage areas are situated so that products are protected from potentially harmful influences.		1	2	3
101.	All goods are stored off the floor.		1	2	3
102.	Raw materials known to be at risk for cross-contamination are stored separately.	No stock	1	2	3
103.	Proper care and control is exercised over hazardous substances (e.g. caustic soda, insecticides etc.) which are stored separately.	No stock	1	2	3
104.	Proper care and control is exercised over flammable substances (e.g. ether, methylated spirits etc.) which are stored separately.	No stock	1	2	3
105.	A system is in place to ensure effective stock rotation (refer also SOP section).		1	2	3
106.	There are no expired medicines on the shelves (as observed).		1	2	3
107.	Expired, damaged and/or contaminated stock is clearly separated.		1	2	3
108.	Expired, damaged and/or contaminated stock is destroyed in a safe manner (e.g. returned to supplier or waste disposal company) (refer also SOP section and Regulation 27 of Act 101 of 1965).		1	2	3

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

STORAGE (Continued)

	N/A	Does not comply	Partially complies	Complies
109. Storage area is large enough to allow for orderly arrangement of stock and proper stock rotation.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
110. The store is kept locked at all times when not in use (if dedicated bulk pharmacy store).	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
111. There are no cracks, holes or signs of water damage in the facility.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
112. The ceiling is in good condition.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
113. The floor is swept daily.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
114. Shelves are dusted daily.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
115. Walls are clean	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
116. The storage area is tidy.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
117. There are no signs of pest infestations (e.g. cockroaches, rats).	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
118. Medicines are stored according to a system.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
119. Storage areas are situated so that products are protected from potentially harmful influences.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
120. All goods are stored off the floor.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

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

STORAGE (Continued)

		N/A	Does not comply	Partially complies	Complies
121.	There is a separate and secure receiving area, which is under cover	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
122.	There is a separate and secure dispatch area, which is under cover.	<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
123.	The receiving area is under impermeable cover.		<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
124.	The receiving area is effectively separated.		<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
125.	Stock is checked on receipt for quantity, quality, damaged containers, type, storage conditions and expiry dates.		<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
126.	A list of product types requiring special storage or handling instructions is available and consulted on receipt of stock (<i>refer also SOP section</i>).		<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
127.	There is a system for the correct handling of the various types of goods returned from patients, wards, clinics etc. (<i>refer also SOP section</i>).		<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
128.	Is any pre-packing performed on the premises? (<i>refer also SOP section</i>).		<input type="checkbox"/> No		<input type="checkbox"/> Yes
129.	Is pre-packing done in accordance with Regulation 33 of Act 101 of 1965 with regard to temperature, humidity, area and GMP requirements (<i>refer also SOP section</i>).	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

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

(H) CONTROL OF MEDICINES/RECORD KEEPING

		N/A	Does not comply	Partially complies	Complies
130.	All medicines sold for human use, comply with Regulation 8 of Act 101 of 1965 i.e. labelling requirements.		1	2	3
131.	Medicines are purchased only through legally authorised entities/suppliers (as confirmed by pharmacist in charge during inspection).		1	2	3
132.	There are no unregistered medicines on the premises (as observed).		1	2	3
133.	A computerised programme is used for dispensing.		1 No		3 Yes
134.	An effective stock control system is in place.		1	2	3
135.	A computerised programme is used for stock control.		1 No		3 Yes
136.	Controls are in place for issuing ward stock (refer also SOP section).	N/A	1	2	3
137.	Controls are in place for issuing of medicines per patient to the wards (refer also SOP section).	N/A	1	2	3
138.	The pharmacist exercises control over medicines kept in places other than the pharmacy (e.g. wards, theatres etc). (refer also SOP section).	N/A	1	2	3

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

CONTROL OF MEDICINES/RECORD KEEPING (Continued)

	N/A	Does not comply	Partially complies	Complies
139. A prescription book/permanent record for S2-S6 medicines is kept as required in Regulation 11(1) of Act 101 of 1965.		1	2	3
140. A prescription record is kept for 5 years as required in Regulation 11(3) of Act 101 of 1965.		1	2	3
141. Original prescriptions are kept in a safe place and are easily retrievable.		1	2	3
142. A patient profile detailing all prescriptions dispensed to the patient is kept for 2 years.		1	2	3
143. A patient profile detailing all P.I.T. dispensed to the patient is kept for 2 years.	N/A	1	2	3
144. S1-S5 medicine are stored/displayed in areas inaccessible to the public.		1	2	3
145. All S1 medicines sales are recorded in a prescription book or other permanent record as required in Regulation 11(2) of Act 101 of 1965.	Not sold	1	2	3
146. All S2 medicine sales are recorded in a prescription book or other permanent record as required in Regulation 11(1) of Act 101 of 1965.	Not sold	1	2	3

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

CONTROL OF MEDICINES/RECORD KEEPING (Continued)

N/A	Does not comply	Partially complies	Complies
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147.	Are S6 medicines ordered, stored or supplied at any time?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			No	Yes	
148.	There is a system in place for the correct handling by the pharmacist of specified S5 and S6 medicines (refer also SOP section).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not stocked	1	2	3
149.	S6 medicines are locked away and the key is under the control of the pharmacist.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not stocked	1	2	3
150.	There is an up-to-date register of all specified S5 & S6 purchases and sales as required in Regulation 30 of Act 101 of 1965.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not stocked	1	2	3
151.	The specified S5 and S6 substances register was balanced on the last day of March, June, September and December of each year or within 14 days as required in Regulation 30(2) of Act 101 of 1965.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not stocked	1	2	3

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

CONTROL OF MEDICINES/RECORD KEEPING (Continued)

152.	Does the pharmacy deliver medicines by mail?	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 2 No
153.	Does the pharmacy deliver medicines by courier?	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 2 No
154.	Does the pharmacy deliver medicines by delivery person/porter?	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 2 No
155.	Does the pharmacy deliver medicines by any other means (e.g. train etc.)?	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 2 No

156. If question 145 was answered 'yes', PLEASE SPECIFY by which means:

	N/A	Does not comply	Partially complies	Complies	
<i>Such indirect supplies (see questions 119 to 123) comply with all GPP requirements i.r.o. the following:</i>					
157.	A control system is implemented that enables detection and correction of a delay in the delivery process.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
158.	Medicines are packaged and stored in accordance with registration requirements throughout the delivery process.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
159.	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.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
160.	Medicines prescribed for acute ailments or conditions are not delivered by mail/ courier/train.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

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

(I) THERMOLABILE MEDICINES

	N/A	Does not comply	Partially complies	Complies
161. Are thermolabile medicines purchased, stored or supplied at any time?	No	2 Yes		
162. All thermolabile medicines are stored in a refrigerator.	Not stocked	1	2	3
163. Only medicines are stored in the refrigerator.	Not stocked	1	2	3
164. Medicines are stored in the refrigerator according to a system.	Not stocked	1	2	3
165. The refrigerator is suitable and in good working order.	N/A	1	2	3
166. The refrigerator is connected to a standby generator or other emergency power system to ensure uninterrupted power supply in case of power (current) failure.		1	2	3
167. The refrigerator is fitted with a warning system to indicate that refrigeration has failed or temperatures are above or below 2°C and 8°C.		1	2	3
168. The temperature of the refrigerator is between 2°C and 8°C (as checked with a thermometer).	N/A	1	2	3
169. The temperature of the refrigerator(s) is controlled 24 hours a day as demonstrated by a WHO approved dial thermometer or alcohol or mercury thermometer.	N/A	1	2	3
170. The temperature of the refrigerator is recorded twice daily in accordance with GPP guidelines.	N/A	1	2	3
171. Thermolabile medicines are stored/supplied maintaining the cold chain.	Not stocked	1	2	3
172. If thermolabile medicines are supplied by courier, temperature is being monitored by a WHO approved dial thermometer or alcohol or mercury thermometer from dispatch point to delivery point.		1	2	3

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

(J) DISPENSING OF PRESCRIPTIONS

N/A	Does not comply	Partially complies	Complies
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173.	Generic substitution is applied in accordance with Section 22(F) of Act 101 of 1965.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
174.	Dispensed medicine is labelled as required in Regulation 8(4) of Act 101 of 1965.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175.	The pharmacist checks the dispensed medicine after it has been labelled and before it is handed or delivered to the patient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
176.	The original prescription states who the dispenser was.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
177.	The final price that the patient pays is indicated on the copy for the payer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

(K) PROVISION OF PHARMACEUTICAL CARE

		N/A	Does not comply	Partially complies	Complies													
178.	The pharmacist obtains all the relevant patient information before dispensing the prescription.	1	2	3														
179.	The pharmacist evaluates the prescription to identify any possible problems before dispensing the prescription.	1	2	3														
180.	The pharmacist takes the necessary action if there are any problems with the prescription and/or medicine prescribed.	1	2	3														
181.	The pharmacist gives advice to the patient or care-giver after the prescription has been dispensed.	1	2	3														
182.	The pharmacist gives advice to patients who receive OTC medicines.	N/A	1	2	3													
183.	Advice is given to the patient in a suitable semi-private area.	1	2	3														
184.	Is a hatch used when providing patient counselling?	No			Yes													
185.	If a hatch is used, eye contact is possible between the pharmacist and the patient.	N/A	1	2	3													
186.	If a hatch is used, easy communication is facilitated.	N/A	1	2	3													
187.	Support aids are used when supplying advice (<i>as observed</i>).	1	2	3														
188.	Form(s) of support aids used:	<table border="1"> <thead> <tr> <th>0 N/A Not used</th> <th>1 Pamphlets/information leaflets</th> <th>2 Manufacturers package inserts</th> <th>3 Computer printouts</th> <th>4 Visual aids e.g. diagrams/posters</th> <th>5 Please specify other:</th> </tr> </thead> <tbody> <tr> <td colspan="6" style="height: 20px;"></td> </tr> </tbody> </table>					0 N/A Not used	1 Pamphlets/information leaflets	2 Manufacturers package inserts	3 Computer printouts	4 Visual aids e.g. diagrams/posters	5 Please specify other:						
0 N/A Not used	1 Pamphlets/information leaflets	2 Manufacturers package inserts	3 Computer printouts	4 Visual aids e.g. diagrams/posters	5 Please specify other:													
189.	Patient information leaflets are available at the dispensary.	1	2	3														
190.	A procedure is in place for monitoring the patients progress.	1	2	3														
191.	A pharmacist can be contacted 24 hours a day.	1 No			3 Yes													
The pharmacy is open		From	To	And again: From	To	Total hours open/day												
192.	Mondays to Thursdays:																	
193.	Fridays:																	
194.	Saturdays:																	
195.	Sundays:																	
196.	Public holidays:																	

(L) COMPOUNDING

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

		N/A	Does not comply	Partially complies	Complies
197.	The pharmacy performs bulk compounding (e.g. dilution of antiseptic solutions, creams, mixtures etc.) (refer also SOP section).	No		2 Yes	
198.	TPN/large volume parenterals are prepared in the pharmacy (refer also SOP section).	No		2 Yes	
199.	Cytotoxic admixtures are prepared in the pharmacy (refer also SOP section).	No		2 Yes	
200.	IV additives are prepared in the pharmacy (refer also SOP section).	No		2 Yes	

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

(M) WRITTEN STANDARD OPERATING PROCEDURES

There are written standard operating procedures for:		N/A	Does not comply	Partially complies	Complies
201.	good housekeeping (<i>cleaning procedures etc.</i>)		1	2	3
202.	pest (<i>insects, rodents etc.</i>) elimination.		1	2	3
203.	receipt of stock.		1	2	3
204.	effective stock rotation (FEEFO – <i>First entry, expiry, first out</i>).		1	2	3
205.	disposal or removal of S1 – S6 expired, damaged and/or contaminated stock as required in Regulation 27 of Act 101 of 1965.		1	2	3
206.	product types requiring special storage or handling instructions.		1	2	3
207.	separation and handling of goods returned from patients, wards, clinics etc.		1	2	3
208.	recall of medicine.		1	2	3
209.	delivery of medicines.	N/A	1	2	3
210.	a <i>locum</i> /relief pharmacist to be followed regarding the handling of keys, money, etc.	N/A	1	2	3
211.	cold chain management (<i>including procedures to be followed in the event of a power failure</i>).	N/A	1	2	3
212.	pre-packing (<i>including quality assurance procedures</i>).	N/A	1	2	3
213.	compounding operations (<i>including quality assurance procedures</i>).	N/A	1	2	3

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

WRITTEN STANDARD OPERATING PROCEDURES (Continued)

	N/A	Does not comply	Partially complies	Complies
214. a procedures to be followed regarding the handling of keys, money, etc for a locum or relief pharmacist(s) (where applicable).		1	2	3
215. daily routine and working hours		1	2	3
216. enquiry or complaint procedures.		1	2	3
217. stock-taking		1	2	3
218. obsolete or unusable stock		1	2	3
219. storage of medicine		1	2	3
220. procurement of medicine		1	2	3
221. handling of product complaints		1	2	3
222. handling of S5 and S6 medicines		1	2	3
223. preparation of TPN/large volume parenterals (<i>including quality assurance procedures</i>).	N/A	1	2	3
224. oncology mixing (<i>including quality assurance procedures</i>).	N/A	1	2	3
225. preparation of IV additives (<i>including quality assurance procedures</i>).	N/A	1	2	3
226. control over medicines kept in places other than the pharmacy (<i>e.g. wards, theatres etc.</i>) (<i>including controls for issuing ward stock and medicine per patient to the wards</i>)	N/A	1	2	3
227. SOPs are reviewed/updated on a regular basis.		1	2	3

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

(N) REFERENCES

The pharmacy has copies of, or electronic access to:		Does not comply	Partially complies	Complies
228.	- one of the last 3 editions of the Martindale.	1	2	3
.	- the latest edition of the Good Pharmacy Practice (GPP) Manual.	1	2	3
.	- the latest edition of MIMS.	1	2	3
.	- a comprehensive textbook on complementary medicine (<i>private sector</i>).	Not Sold	2	3
.	- the latest edition of Daily Drug Use (Tincture Press Publications) or other Drug Interactions reference source.	1	2	3
.	- the latest edition of either MDR or SAMF.	1	2	3
234.	- a recent and comprehensive textbook on Pharmacology (<i>not older than 10 years.</i>)	1	2	3
235.	a paediatric Dosing Reference Guide.	1	2	3
236.	NDOH – Adult Standard Treatment Guidelines for Hospital.	1	2	3
237.	NDOH – Paediatric Standard Treatment Guidelines for Hospital.	1	2	3
238.	NDOH – Primary Health Care Standard Treatment Guidelines.	1	2	3
239.	- a medical dictionary.	1	2	3
240.	- a latest copy of the Pharmacy Act, 1974 (Act 53 of 1974) as amended and the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) as amended.	1	2	3

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

(O) GENERAL

	Does not comply	Partially complies	Complies
241. The pharmacy is designated as a non-smoking area.	1	2	3
242. No medicines are advertised in any way that is contrary to GPP guidelines and Regulation 45 of Act 101 of 1965.	1	2	3
243. A pharmacist has undergone a form of continued education/professional development the last 2 years.	No	In-formal	Formal
244. No arms/ammunition are sold in the pharmacy.	1	2	3
245. No fireworks are sold in the pharmacy.	1	2	3
246. No alcohol, other than for medicinal purposes, is sold in the pharmacy.	1	2	3
247. No tobacco, snuff, cigarettes and tobacco related substances are sold in the pharmacy (<i>this excludes medicinal snuff and anti-smoking aides</i>).	1	2	3
248. Lotto tickets are not sold in the pharmacy.	1	2	3

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

(P) PROMOTION OF PUBLIC HEALTH

249.	Are Family Planning services rendered at the pharmacy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
250.	Has the pharmacist(s) registered his/her Family Planning qualification with Council?	<input type="checkbox"/> N/A	<input type="checkbox"/> 1 No	<input type="checkbox"/> 2 Yes	
251.	Is the necessary Section 22A(15) permit from the Department of Health available for purposes of providing family planning? (<i>previously Section 22A(12)</i>)	<input type="checkbox"/> N/A	<input type="checkbox"/> 1 No	<input type="checkbox"/> 2 Yes	
252.	Are Primary Care Drug Therapy (PCDT) services rendered at the pharmacy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
253.	Has the pharmacist(s) registered his/her Primary Care Drug Therapy (PCDT) qualification with Council?	<input type="checkbox"/> N/A	<input type="checkbox"/> 1 No	<input type="checkbox"/> 2 Yes	
254.	If medicines in higher schedules are provided during the provision of PCDT, is the necessary Section 22A(15) permit from the Department of Health available? (<i>previously Section 22A(12)</i>)	<input type="checkbox"/> N/A	<input type="checkbox"/> 1 No	<input type="checkbox"/> 2 Yes	
The following services are rendered in accordance with GPP guidelines:		<input type="checkbox"/> N/A	<input type="checkbox"/> Does not comply	<input type="checkbox"/> Partially complies	<input type="checkbox"/> Complies
255.	Blood pressure monitoring.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
256.	Pregnancy testing.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
257.	Determining of blood sugar levels.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
258.	Visiometric determinations.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
259.	Audiometric determinations.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
260.	Cholesterol screening tests.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
261.	Urine analysis screening tests.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
262.	Immunisation services (<i>in accordance with National guidelines</i>).	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
263.	AIDS testing on request from patient (<i>in accordance with National guidelines</i>).	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
264.	Mother and childcare services	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
265.	Please specify other:				
266.	The above-mentioned services are rendered in a suitable private area.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
267.	Who renders the above services?	<input type="checkbox"/> N/A No services rendered 0	<input type="checkbox"/> Other health care professional 1	<input type="checkbox"/> Registered Pharmacist's assistant 2	<input type="checkbox"/> Pharmacist and/or pharmacist intern 3
Please specify other:		4			

(Q) 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 a pharmacist intern and/or pharmacist's assistant effectively.

268.	A pharmacist intern was trained within the last 3 years.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
269.	A pharmacist's assistant was trained within the last 3 years.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
270.	Pharmacy: recommended for training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
271.	Would the pharmacist accept responsibility as a tutor for the training of a pharmacist intern or pharmacist's assistant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
272.	Is there evidence that the prospective tutor participates in continuing education/professional development?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
273.	Is there disciplinary action pending against the prospective tutor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
274.	Is there evidence that the prospective tutor/pharmacist upholds the principles of pharmaceutical care/GPP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
275.	Tutor: recommended for training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Recommendations made by the inspector with respect to training do not necessarily 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'

(R) 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.

276.	Recommended re-inspection	1 Follow-up 3 months	2 Follow-up 6 months	3 Routine
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277. Signature of **pharmacist in charge during inspection**:

278. Name of above pharmacist in charge during inspection
(in block capitals) (refer question 21):

279. Signature of **inspector**:

280.	Duration of inspection: <i>(refer inspection start time on page 2)</i>	Inspection end time:		Duration (no. of hours)
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FURTHER COMMENTS
