

Inspection and Grading of Pharmacies

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Pharmacy Council**

Accessible quality pharmaceutical services for all

Overview

- ▶ **Inspections**
- ▶ **Risk based approach to inspections**
- ▶ **Grading system**
- ▶ **Classification of Inspection**
- ▶ **Inspection Reports**
- ▶ **Review of inspection questionnaire**
- ▶ **Self Inspection**
- ▶ **Improvement plans**
- ▶ **Review of grading methodology**



Why inspections

SAPC the statutory body established in terms of the Pharmacy Act (53 of 1974)

- ▶ **Section 3(d), “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”; and**
- ▶ **Section 3(e)(iii), “to establish, develop, maintain and control universally acceptable standards of the practice of the various categories of persons required to be registered in terms of this Act”.**



Why inspections

The SAPC carries its mandate in terms of section 3 (d) and 3(e) by doing the following:

- ▶ **Publication of the Rules relating to GPP in terms of Section 35A(b) of the Act and monitoring compliance thereof;**
- ▶ **Conducting regular inspections of pharmacy premises to assess compliance with GPP and other relevant legislation**
- ▶ **Approval of pharmacy premises for purposes of education and training of pharmacist interns and pharmacist support personnel following inspections of the pharmacy by the SAPC inspectorate; and**
- ▶ **Registration of pharmacists, pharmacist interns, pharmacy support personnel and pharmacies.**



Pharmacy Inspection

- ▶ Inspections were conducted on a two-year cycle regardless of their level of compliance
- ▶ The SAPC revised the inspection cycle by introducing classification of the inspection based on the outcome of the findings of the inspection, i.e. the grading system of pharmacies.
- ▶ Inspection grading was implemented in 2013 as an audit tool to monitor and compare the level of compliance with GPP standards across all categories of pharmacies



Sa risk-based approach to pharmacy inspection

Risk rating	Deficiency		Explanations
Low compliance risk	Minor	Grade A	The pharmacy is committed to doing the right thing or striving to reach high compliance levels.
Medium compliance risk	Major	Grade B	The pharmacy is trying to meet compliance levels or to do the right thing but do not always succeed.
High compliance risk	Critical	Grade C	The pharmacy is not committed to complying with the standard and will only comply if compelled to do so through punitive measures.



Why grading system

- ▶ **To determine the cyclical period of inspection and the scheduling thereof, i.e.**
 - **graded low (Grade C) are inspected annually,**
 - **graded average (Grade B) are inspected every two years,**
 - **graded excellent (Grade A) are inspected on a three-year cycle;**
- ▶ **To let the cycle of inspection coincide with the approval period of pharmacy premises for the training of pharmacy support personnel and pharmacist interns;**
- ▶ **To enforce non-compliant pharmacies to undergo disciplinary processes to ensure that the responsible pharmacist (RP) and pharmacy owner can move speedily in resolving the non-compliance issues identified during the inspection and as recorded in the inspection report.**



Classification of inspection findings by SAPC for SA pharmacies

Grading System	Inspection findings	Classification	Percentage score	Inspection cycle	Training approval periods
Grade A	The pharmacy premises complies with most of the GPP standards.	Minor deficiencies	90 - 100%	3 years	3 years
Grade B	The pharmacy premises complies with some of the GPP standards.	Major deficiencies	80-890%	2 years	2 year
Grade C	The pharmacy premises does not comply with most of the GPP standards.	Critical deficiencies	79-1%	1 year	No approval



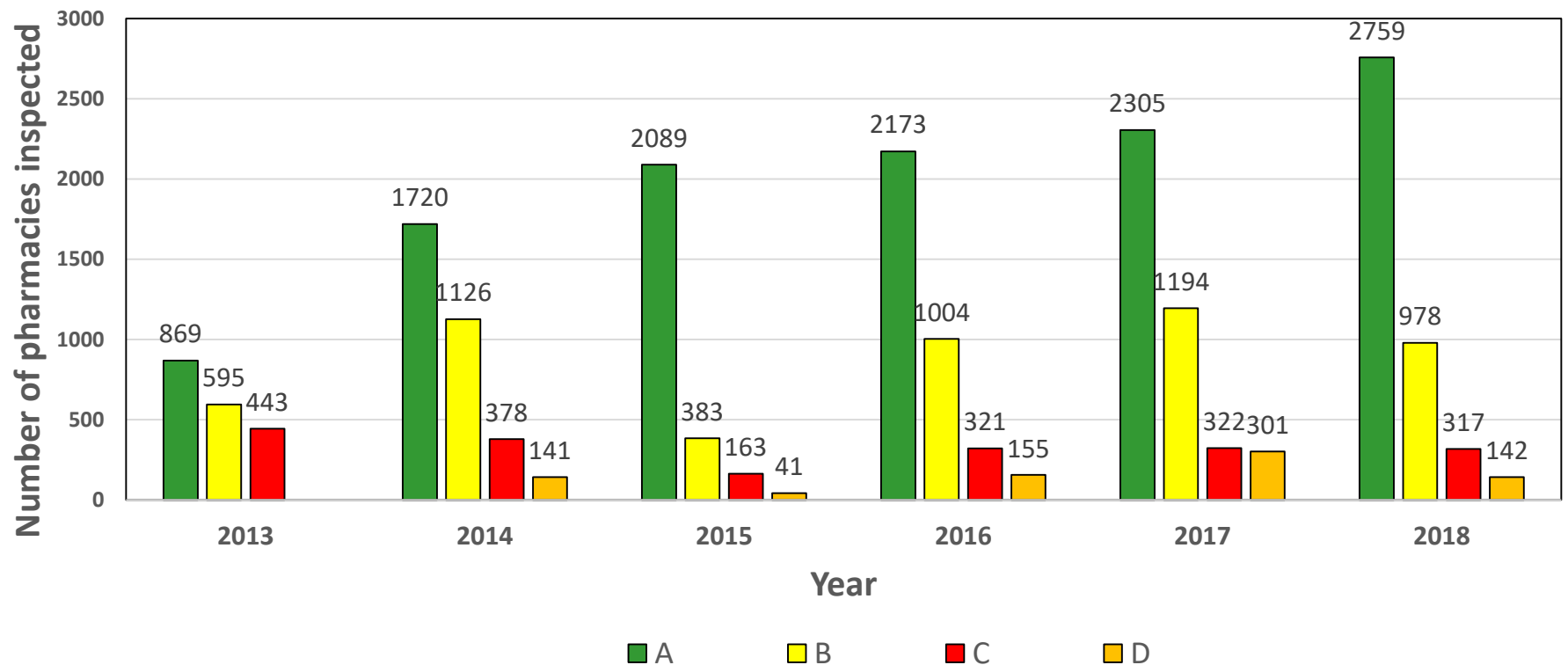
Number of pharmacies per province

Category of pharmacy	Eastern Cape	Free State	Gauteng	KwaZulu- Natal	Limpopo	Mpumalanga	North West	Northern Cape	Western Cape	Total
Community pharmacy	275	154	1164	554	202	260	182	65	473	3329
Consultant pharmacy	0	0	8	1	0	0	0	0	2	11
Institutional private	26	18	112	57	10	15	18	7	46	309
Institutional public	104	50	79	102	40	48	39	39	134	635
Manufacturing pharmacy	9	1	203	9	0	1	5	0	31	259
Wholesale Private	20	6	114	24	4	2	2	2	33	207
Total	434	229	1680	747	256	326	246	113	719	4750



Inspection Report

Inspection results (all pharmacy types) January 2013 to December 2018



Inspections and grading

- ▶ **Introducing new pharmacy inspection questionnaire**
 - **remove ambiguity**
 - **remove double questions**
 - **all question have reference to the law**
 - **include new weights per section and compliance value**



Inspections Questionnaire

No.	Questions	Complies	Does not comply	Source/Reference
		3	0	
•	The name of the responsible pharmacist is displayed conspicuously at the main entrance of the pharmacy for the purpose of identification of such person(s) by the public.			Rule 1.2.1(c) of Rules relating to GPP
•	The pharmacy is under the direct personal supervision of a responsible pharmacist, If not, is there a delegated pharmacist			Regulation 22 of practice regulations
•	The name of the pharmacist(s) on duty is/are displayed visibly in/or outside the pharmacy for the purpose of identification of such person(s) by the public.			Rule 1.2.1(d) of Rules relating to GPP
•	All registered persons on duty is/are wearing a nametag or badge indicating his/her name and designation for the purpose of identification of such person(s) to the public.			Rule 1.2.1(e) of Rules relating to GPP



Self Inspections and Grading

▶ Self Inspection pharmacy inspection questionnaire and guidance document

- RP can conduct self inspection
- All questions are referenced to the law
- Inform you what the inspector would require and what evidence responsible pharmacist(RP) must produce during inspections
- RP will have indication of what grade to expect
- RP can implement corrective measures in advance

Community Pharmacy self-assessment questionnaire



Self Inspections and Grading

Section Description	Weight	Compliance Value	Outcome	Compliance	Status
<u>ACCESS CONTROL, SAFETY AND SECURITY IN THE PHARMACY</u>	2	80.00 %	0 %	Not Yet Compliant	To be Processed
<p>Rules 1.2.3, 1.2.4, 1.2.5 of the Rules relating to GPP Inspector will verify if the keys and key cards are in control of the pharmacist Compliance to occupational health. There's a barrier for unauthorised persons</p>					
<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 in person of the responsible pharmacist or the person of another pharmacist at all times; • pharmacist has unfettered 24-hour access to the pharmacy • all pharmacy equipment's are connected to individual fixed socket outlets; • there are no trailing wires across floors, surfaces or basins/sinks; and • barrier for unauthorised persons 					



Improvement Plans

- ▶ **An improvement plan must be submitted with every self-inspection and an actual inspection**
- ▶ **RP must provide Council with a plan to rectify shortcomings indicating the following:**
 - ❖ **Responsible person to fix the identified shortcoming**
 - ❖ **Time frame to fix the identified noncompliance or**
 - ❖ **Whether the identified shortcomings are already fixed (applicable to improvement plan following an inspection)**



Review of the grading methodology

Purpose of evaluating the current grading methodology is to assist the Committee to:

- ▶ understand the current inspection grading methodology and its processes;
- ▶ identify areas in (i) that require improvement (to develop or strengthen existing standards for proper interventions so that pharmacies improve on compliance);
- ▶ improve the impartiality of inspection grading and process using scientific evidence; and
- ▶ implement the revised inspection grading methodology and process as soon as possible



Sections in inspection questionnaire

- ▶ **Patient-related factors**
- ▶ **Profession-related factors**
- ▶ **Pharmacy-related factors**
- ▶ **Medicine-related factors**



Review of the grading methodology

- Increase the population of persons assigning the importance of weight per question from 4 practice committee members to include; Implementers, Evaluators, Decision makers, Representative of the profession, Heads of pharmacy school and FET providers and Responsible Pharmacist
- Develop an instrument to assign the weight be section. i.e. scoring matrix ([Click Here](#))
- Test the instrument
- Submit the methodology NWU scientific committee to Health Research Ethics Committee for approval
- Conduct an electronic survey
- Analysis of the result and present to committee
- Pilot the result of the new grading methodology on 2017-2018 inspections
- Provide report to the committee



Classification of section

Patient-related factors according to critical factors

Rate the importance of compliance of this section in the practice setting	Extremely important = 3	Very important = 2	Important = 1
Areas for counselling, furnishing advice and waiting			
Dispensing of prescriptions			
Promotion of public health			

NB: when rating the sections, take into account the following associated elements:

Avoid harm to the patient, prevent permanent incapacity, prevent unnecessary loss of life, ensure best therapeutic outcomes, ensure reduction in dispensing errors, ensure patient privacy, ensure patient confidentiality and result in promotion of health.



Classification of section

Profession-related factors according to critical factors

Rate the importance of compliance of this section in the practice setting	Extremely important = 3	Very important = 2	Important = 1
Pharmacy details			
Operating hours of pharmacy			
Premises and layout			
Access control, safety and security			
Equipment			
Dispensary including compounding area			
Written standard operating procedures			

NB: when rating the sections, take into account the following associated elements:

Ensure public trust in the profession, create a positive professional image, and useful for training pharmacist interns and pharmacy support personnel



Classification of section

Profession-related factors according to critical factors(contd)

Rate the importance of compliance of this section in the practice setting	Extremely important = 3	Very important = 2	Important = 1
Pharmacy staffing			
Registration details			
References			
Continuing professional development and training			
Products which may not be sold in a pharmacy			

NB: When rating the sections, take into account the following associated elements:

Lead to a pharmacy functioning optimally, result in good operations, improve access to pharmaceutical services, improve access control of a pharmacy premises, improve security of a pharmacy, and lead to reduction in unauthorised access to medicine by unregistered persons.



Classification of section

Medicine-related factors according to critical factors

Rate the importance of compliance of this section in the practice setting	Extremely important = 3	Very important = 2	Important = 1
Storage or storage area for medicines			
Control of medicines, scheduled substances and active pharmaceutical ingredients/medicines			
Sale and record keeping of scheduled medicines			
Control of schedule 6 substances			
Delivery of medicines			
Thermolabile medicines			

NB: When rating the sections, take into account the following associated elements: Have a positive impact on the efficacy, safety and quality of medicines; strengthen the prevention and treatment of substance abuse, including narcotic drug abuse; improve control of medicines; improve record keeping regarding the sale of medicines; and improve storage of medicines



Review of the grading methodology

Three-point Likert weighting scale

Importance	Weighting	Compliance value
Important	1	70-79%
Very important	2	80-89%
Extremely important	3	90-100%



QUESTIONS



THANK YOU!



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