South African Pharmacy Council

REVIEW OF THE PHARMACY INSPECTION GRADING METHODOLOGY - 2020

Contents

1. INTRODUCTION

The mandate of the South African Pharmacy Council (Council) 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 private sector. Council fulfils this mandate by conducting pharmacy premises inspections in terms of section 38A of the Act. These inspections are carried out to assess compliance to 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, Council assures patients and the public that the pharmaceutical services offered by each category of pharmacy is of such a nature that it encourages patient safety and the provision pharmaceutical care.

Council performs unannounced inspection visits to a pharmacy on a regular basis to assess how a pharmacy and its personnel conduct business on daily basis and for Council to satisfy itself that the public and patients are offered services that are compliant with GPP standards. Pharmacies are expected to provide a high standard of pharmaceutical care and excellent pharmaceutical services daily and not only when they are expecting inspections by Council.

Council conducts inspections in the various categories of pharmacies, namely:

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

2. GRADING OF PHARMACIES

Council resolved in 2009 to introduce a pharmacy grading system instead of scheduling inspections for all pharmacies on a two-year cycle regardless of their level of compliance. 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 (SAPC, 2009). The SAPC revised the inspection cycle by introducing the grading system of pharmaciesi.e. classifying pharmacies based on the outcome of inspection findings. This classification assisted in matching the inspection cycle with the approval periods for training pharmacist interns and pharmacy support personnel at pharmacy premises.

Table 1 describes classification in terms of inspection findings, scoring, inspection cycle, training approval period and grading system based on the outcome of inspection results.

Table 1: Classification of inspection findings

Grading system	Inspection findings	Classification	Percentage score	Inspection cycle	Training approval period
Grade A	The pharmacy premises comply with most of the GPP standards	Minor deficiencies	90–100%	3 years	3 years or less
Grade B	The pharmacy premises comply with some of the GPP standards	Major deficiencies	80–89%	2 years	2 years or less
Grade C	The pharmacy premises do not comply with most of the GPP standards	Critical deficiencies	1–79%	1 year	No approval
Grade D	The pharmacy was found to be closed during an inspection	Pharmacy closed	0	Not Applicable	None

3. FORMER GRADING METHODOLOGY 2013 - 2019

The inspection grading was developed on the following principles:

(a) Questions in the inspection questionnaires are weighted per section

(b) All questions in a specific section have the same weighting

(c) The final compliance percentage of a pharmacy is determined by the sum of the compliance percentage of all the individual sections divided by the number of sections

(d) Every section contributes the same percentage to the final compliance percentage of a specific pharmacy

(e) The overall effect of the application of the weighting per question is cancelled out.

Table 2: Sections of an institutional pharmacy inspection questionnaire with weightings

Section in questionnaire	Relevant legislation	Recommended weighting
Pharmacy details	Sections 22A and 35A of the Pharmacy Act,53 of 1974 Regulation 7 and 8 of the *Regulations relating to the ownership and licencing of pharmacies*	6
Pharmacy staffing	Section 14 of the Pharmacy Act,53 of 1974	7
Registration details	Section 14 of the Pharmacy Act,53 of 1974	3
Premises and layout	Occupational and Health Safety Act,181 of 1993	5

Section in questionnaire	Relevant legislation	Recommended weighting
	Rule 1.2 of the *Rules relating to GPP*	
Equipment	Rule 1.2.11.4 of the *Rules relating to GPP*	2
Control of medicines, scheduled substances and active pharmaceutical ingredients/medicines	Rule 1.2.11.4 of the *Rules relating to GPP*	7
Thermolabile medicines	Rules 2.3.5, 2.3.6 and 2.3.7 of the *Rules relating to GPP*	6
Dispensing of prescriptions	Section 22(F) of the Medicines Act,101 of 1965 Regulations 10 (5) and (6) of the *General Regulations* of Act, 101 of 1965 Rules 2.7, 2.8 and 2.9 of the *Rules relating to GPP*	5
Provision of pharmaceutical care	Rules 2.7, 2.8, 2.9, 2.11 and 2.12 of the *Rules relating to GPP*	2
Written standard operating procedures	Rule 4.2.3.3 of the *Rules relating to GPP*	3
References	Rule 1.2.11.5 of the *Rules relating to GPP*	3
General	Section 22A (15) of the Medicines Act,101 of 1965 Rule 2.13.5.10 of the *Rules relating to GPP*	1
Promotion of public health	Section 22A (15) of the Medicines Act,101 of 1965 Rules 2.13.1 and 2.15 of the *Rules relating to GPP*	4

The weightings in Table 2 are explained in Table 3.

Table 3: Weighting explanation

Weightage key	
1	Not at all important but necessary to document
2	Less important
3	Slightly important
4	Neutrally important

5	Moderately important
6	Very important
7	Extremely important

In addition to the weighting allocated per section, non-negotiable criteria per section were also developed. The non-negotiable criteria for the different sections consisted of different values that vary from 30% for the general section to 90% for the section on control of medicines. (See Table 4).

Pharmacies that perform badly on a section that carries a high percentage on the non-negotiable criteria automatically obtain a lower grade. It means that a pharmacy that obtains one or two shortcomings on the non-negotiable section but performs well in other sections ends up with a Grade C.

Table 4: Non-negotiable criteria per section

Section in questionnaire	**Required % for non-negotiable criteria**
Inspection officer details	None
Pharmacy details	None
Pharmacy staffing	90%
Registration details	50%
Premises layout	70%
Equipment	40%
Storage	50%
Control of medicines, scheduled substances and active pharmaceutical ingredients	90%
Thermolabile medicines	80%
Dispensing of prescriptions	70%
Provision of pharmaceutical care	40%
Compounding	70%
Written standard operating procedures	50%
References	50%
General	30%
Promotion of health	60%
Recommendations in respect of training	None

Signatures	None

There are no non-negotiable criteria for four sections: inspection details, pharmacy details, recommendations in respect of training, and signatures. These sections are not evaluated for the purpose of grading.

When the grading system was introduced, it was envisaged that, over time, all sections would be weighted equally, as GPP recognises all sections as equally important.

4. NEW GRADING METHODOLOGY 2020

The following principles apply in the revised grading methodology approved by Council in February 2020:

(a) The inspection questionnaire is categorised into sections and each section has a group of questions which are inter-related and/or interdependent

(b) The inspection questionnaire tests critical factors that relate to either the patient, medicines, pharmacy premises and the pharmacy profession

(c) Each section and question in the inspection questionnaire is important, but the level of importance differs according to the weight assigned to a specific section

(d) A revised three-point Likert weighting scale (Table 5) together with new compliance values will be used to determine the importance of each section instead of the previously adopted seven-point Likert weighting scale

Table 5: Three-point Likert weighting scale

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

(e) The weighting of a section will depend on the weighting assigned in relation to the critical factors that relate to either the patient, medicines, pharmacy premises and the pharmacy profession

(f) To determine the weight per section, an inspection electronic scoring matrix comprising of the critical factors was used

(g) Various role players that are involved in the usage and approval of inspections voluntarily participated in the inspection electronic scoring matrix survey to decide on the weighting per section. The following role players were involved in the survey:

(i) **Implementers** of inspection questionnaires – SAPC inspection officers
(ii) **Evaluators** of inspection questionnaires – SAPC staff members
(iii) **Decision makers** regarding inspections questionnaires – Practice Committee members
(iv) **Representatives of the profession** – heads of pharmaceutical services (groups, metro and provincial) and heads of professional associations
(v) **Responsible pharmacists** – responsible and accountable to Council for the overall continuous supervision of a pharmacy**.**

(h) All sections in the questionnaire are grouped according to the critical factors.

(i) Grouping of sections in terms of critical factors is done according to the inherent impact and inherent likelihood of occurrence.

(j) All questions in a specific section are assigned the same weighting score.

(k) All questions in the inspection questionnaire that are evaluative are assigned an inspection score as follows:

- 0 = noncompliant
- 1 = partially compliant
- 3 = compliant
- N/A = which will result in the reduction of the total number of questions in that section

(l) The total score per question is e calculated by the inspection score multiplied by the assigned weighting per section, as represented by the formula below:
total score per question = inspection score x weighting

(m) The total percentage score per section is calculated as follows: section score multiplied by weighting for that section divided by the maximum section score that can be obtained multiplied by 100%, as represented by the formula below:

$$\textbf{Percentage score per section} = \frac{(\text{section score} \times \text{section weighting})}{\text{Maximum section score}} \times 100\%$$

(n) A section is deemed compliant if the minimum percentage score is equivalent or above the percentage compliance value assigned to that section (refer to Table 5). The following rules apply:

(i) If a section is assigned the **weight of 3**, the minimum compliance value to be attained in that section must be **90%**. Any score below 90% will make the section non-compliant.

(ii) If a section is assigned the **weight of 2**, the minimum compliance value to be attained in that section must be **80%**. Any score below 80% will make the section non-compliant.

(iii) If a section is assigned the **weight of 1**, the minimum compliance value to be attained in that section must be **70%**. Any score below 70% will make the section non-compliant.

(o) All sections that are assigned the same weighting are grouped together. See Table 6.

Table 6: Section of inspection questionnaire according to compliance value and weighting

Sections in 2018 questionnaire	**Minimum compliance value**	**Final average weighted score**
Operating hours of pharmacy	**70%**	**1**
Sections in 2018 questionnaire	**Minimum compliance value**	**Final average weighted score**
Storage area	**80%**	**2**
Storage of medicines	**80%**	**2**
Sale and record keeping of scheduled medicines	**80%**	**2**
Delivery of medicines	**80%**	**2**
Areas for counselling and the furnishing of advice and waiting area	**80%**	**2**
Promotion of public health	**80%**	**2**
Pharmacy details	**80%**	**2**
Pharmacy premises and layout	**80%**	**2**
Access control, safety and security in the pharmacy	**80%**	**2**
Dispensary including compounding area	**80%**	**2**
Equipment	**80%**	**2**
Written standard operating procedures	**80%**	**2**
Services provided from mobile unit and website linked to a pharmacy	**80%**	**2**
Pharmacy staffing (a)	**80%**	**2**
Registration details	**80%**	**2**
References: the pharmacy has copies of, or electronic access/mobile applications	**80%**	**2**
Products which may not be sold in a pharmacy	**80%**	**2**
Continuing professional development and training	**80%**	**2**
Pharmacy staffing (b)	**80%**	**2**

Sections in 2018 questionnaire	Minimum compliance value	Final average weighted score
Control of medicines, scheduled substances and active pharmaceutical ingredients	**90%**	**3**
Control of schedule 6 substances	**90%**	**3**
Thermolabile medicines	**90%**	**3**
Schedule 5 and 6 medicines, scheduled substances and active ingredients	**90%**	**3**
Dispensing of prescriptions	**90%**	**3**

(p) For a pharmacy to be declared compliant, the minimum score must be equivalent to or above the percentage compliance value per grouped sections.

(q) The total percentage score per grouped sections is the percentage sum of all sections with similar weighting divided by the total number of sections, represented by the formula below:

$$\textbf{Total percentage score per grouped sections} = \frac{\text{percentage sum of all sections with same weighting}}{\text{Total number of sections}}$$

(r) Any pharmacy with total percentage scores per grouped sections below the minimum compliance value per grouped section will automatically be graded C.

(s) Grading score is determined by the percentage sum of all grouped sections divided by the total number of grouped sections represented by the formula below:

$$\textbf{Grading score} = \frac{\text{percentage sum of all groups}}{\text{Total number of groups (N=3)}}$$

(t) Grading for a pharmacy will be determined by the percentage grading score obtained. See Table 7.

Table 7: Grading system

Grading system	Inspection findings	Classification	Grading score
Grade A	The pharmacy premises comply with most of the GPP standards.	Minor deficiencies	90–100%
Grade B	The pharmacy premises comply with some of the GPP standards.	Major deficiencies	80–89%
Grade C	The pharmacy premises do not comply with most of the GPP standards.	Critical deficiencies	1–79%
Grade D	The pharmacy was found to be closed during an inspection.	Pharmacy closed	0%

(u) A pharmacy will automatically be graded C irrespective of the grading score obtained if it is found to be non-compliant with the non-negotiable critical questions in Table 8.

Table 8: Non-negotiable critical questions

Section in questionnaire	Relevant legislation
***Name of pharmacy (trading title as on the licence and Council register)	Section 35 (A)(c) of the Pharmacy Act, 53 of 1974 Code of Conduct 1.12 Rule 2.31.3 of *Rules relating to GPP*
***Pharmacy registration number	Section 22 of the Pharmacy Act, 53 of 1974
***A valid original licence issued by the Director-General is displayed visibly in the pharmacy for identification by the public	Section 22 of the Pharmacy Act, 53 of 1974
***A valid original recording certificate signed by the Registrar of the SAPC for the recording of the pharmacy is available for identification by the public (not for pharmacies registered before May 2003)	Section 22 of the Pharmacy Act, 53 of 1974
***Name of responsible pharmacist as registered (as per the SAPC registration certificate)	Rule 1.2.1 of *Rules relating to GPP* Regulation 28 of Practice Regulations
***Is there a pharmacist present during the inspection?	Regulation 22 of Practice Regulations
***P number of the pharmacist in charge during the inspection	
***There are no illegal or counterfeit medicines on the premises (as observed).	Rule 1.9.2 of Code of Conduct
***Schedule 6 medicines or substances are stored in designated places under lock and key at all times.	Rule 2.27(a) of *Rules relating to GPP*
*** The schedule 6 substances register was balanced on the last day of March, June, September and December of each year, or within 14 days.	Regulation 36 (1) of Act 101 of 1965
There is a refrigerator in the pharmacy for the storage of thermolabile medicines.	Rules 1.2.8 (a)(b), 1.2.11.4(d) and 2.35 of *Rules relating to GPP*

5. SCORING MATRIX

To determine the weight per section, an electronic inspection scoring matrix of the critical factors will be used. Various groups of people that are involved in the usage and approval of the inspection will be voluntarily involved to decide on the weighting per section.

The group will consist of the following:

(a) **Implementers** of inspection questionnaires – SAPC inspection officers

(b) **Evaluators** of inspection questionnaires – SAPC staff members

(c) **Decision makers** regarding inspection questionnaires – Practice Committee members

(d) **Representatives of the profession** – heads of pharmaceutical services (groups, metro and provincial) and heads of professional associations

(e) **Responsible pharmacists** – responsible and accountable to Council for the overall continuous supervision of a pharmacy**.**

6. SECTIONS IN QUESTIONNAIRE

The inspection questionnaire is divided into various sections. To assign a weight to a section, a section must first be classified according to the critical factor that is pertinent to that section. The following factors are to be considered when assigning weighting per section in the inspection questionnaire:

(a) Patient-related factors

(b) Profession-related factors

(c) Pharmacy-related factors

(d) Medicine-related factors

6.1 Classification of sections according to critical factors

Table 9: Patient-related factors

No	**Rate the importance of compliance of this section in the practice setting**	Extremely important = 3	Very important = 2	Important = 1
1	Areas for counselling, furnishing advice and waiting			
	Dispensing of prescriptions			
	Promotion of public health			
NB: When rating the sections, consider 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.				

Table 10: Pharmacy-related factors

No	**Rate the importance of compliance of this section in the practice setting**	Extremely Important = 3	Very important = 2	Important = 1
2	Pharmacy details			
	Operating hours of pharmacy			
	Premises and layout			
	Access control, safety and security			

No	**Rate the importance of compliance of this section in the practice setting**	Extremely Important = 3	Very important = 2	Important = 1
	Equipment			
	Dispensary including compounding area			
	Written standard operating procedures			
NB: When rating the sections, consider 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.				

Table 11: Profession-related factors

No	**Rate the importance of compliance of this section in the practice setting**	Extremely Important = 3	Very important = 2	Important = 1
3	Pharmacy staffing			
	Registration details			
	References			
	Continuing professional development and training			
	Products which may not be sold in a pharmacy			
NB: When rating the sections, consider 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.				

Table 12: Medicine-related factors

No	**Rate the importance of compliance of this section in the practice setting**	Extremely Important = 3	Very important = 2	Important = 1
4	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, consider 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.				