BOARD NOTICE 514 OF 2023

SOUTH AFRICAN PHARMACY COUNCIL

CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR A PHARMACIST WHO WISHES TO APPLY FOR REGISTRATION AS A RESPONSIBLE PHARMACIST.

The South African Pharmacy Council intends to publish in terms of Section 3(e)(i), Sections 33 and 34 of the Pharmacy Act, 53 of 1974, read together with the *Regulations relating to pharmacy education and training* the **CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR A PHARMACIST WHO WISHES TO APPLY FOR REGISTRATION AS A RESPONSIBLE PHARMACIST.**

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the proposed Guidelines. Comments must be addressed to the Registrar, the South African Pharmacy Council by way of email BN@sapc.za.org (for the attention of the Company Secretary and Legal Services).

SCHEDULE

1. CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR A PHARMACIST WHO WISHES TO APPLY FOR REGISTRATION AS A RESPONSIBLE PHARMACIST

VM TLALA
REGISTRAR

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To obtain the full content of this Board Notice please visit the 'Proposed Legislation' section on the South African Pharmacy Council's website: https://www.sapc.za.org/Legislation_Proposed

South African
Pharmacy Council

CRITERIA TO ACCREDIT A GENERIC SHORT COURSE FOR A PHARMACIST WHO WISHES TO APPLY FOR REGISTRATION AS A RESPONSIBLE PHARMACIST

Table of Contents

Abbreviations

ADU	Automated Dispensing Unit
CCFO	Critical Cross-Field Outcomes
GMP	Good Manufacturing Practice
GPES	Good Pharmacy Education Standards
GPP	Good Pharmacy Practice
GDWP	Good Distribution and Wholesale Practice
HEI	Higher Education Institution
RADU	Remote Automated Dispensing Unit
RP	Responsible Pharmacist
POPIA	Protection of Personal Information Act, 4 of 2013
QMS	Quality Management System
SAPC	South African Pharmacy Council
SAQA	South African Qualifications Authority
SDP	Skills Development Provider
SOP	Standard Operating Procedure

Definitions

Accreditation[1]	The certification, usually for a particular period of time, of a person, a body or an institution as having the capacity to fulfil a particular function in the quality assurance system set up by the Council.
Assessment[2]	The process of identifying, gathering and interpreting information and evidence against competencies in order to make a judgement about a student's achievement.
Assessor[3]	Any pharmacist registered by Council in accordance with criteria determined and published for this purpose by Council to measure outcomes of pharmacy education and training.

[1] Definition sourced from: South African Pharmacy Council. (2020) Good Education Pharmacy Standards. Accessed at: https://www.sapc.za.org/Media/Default/Documents/BN78_2020_GPES%20(OCSF)_Implementation.pdf

[2] Definition sourced from SAQA. 2005. Guidelines for integrated assessment https://www.saqa.org.za/documents/guidelines/guidelines-integrated-assessment

[3] Definition sourced from SAQA. 2014. National Policy Criteria for designing and Implementing Assessment for QF Qualifications and Part- Qualifications and Professional Designations in South Africa. Accessed at: means a person

Applied Competence[2]	A student's ability to integrate concepts, ideas and actions in authentic, real-life contexts which is expressed as practical, foundational and reflexive competence.
Council[4]	The South African Pharmacy Council, the regulator established in terms of the Pharmacy Act, 53 of 1974, to regulate pharmacists, pharmacy support personnel and pharmacy premises in South Africa.
Credits[3]	The amount of learning contained whereby one credit is equal to ten (10) notional learning hours.
E-learning[3]	A mode of teaching and learning that makes use of technology-mediated features.
Formative assessment[2]	Assessment that takes place during the process of teaching and learning and which has as its purpose the progressive development of students' abilities.
Moderation[3]	The internal and external verification that an assessment system is credible, that assessors and students behave in an ethical way and that assessments are fair, valid, reliable and practicable.
Moderator[1]	A person qualified to moderate the academic performance of students against specified pharmacy-related standards and qualifications and includes persons registered as such with the Council.
Provider[1]	Any person or institution approved by and registered with Council to provide education and training for purposes of conferring a qualification in pharmacy or a certificate of qualification or for purposes of continuing professional development.
Summative Assessment[2]	An assessment undertaken to make a judgement about achievement. This is carried out at the end of a learning programme.

[4] Definition sourced from: South African Pharmacy Council. (2000). Regulations relating to pharmacy education and training. GNR1156 of 20 November 2000. Accessed at: https://www.pharmcouncil.co.za/media/default/Documents/Pharmacy_Education__Training%20(2000).pdf

1. RATIONALE FOR TRAINING RESPONSIBLE PHARMACISTS

Responsible pharmacists are accountable to the South African Pharmacy Council (SAPC) in terms of the Pharmacy Act, 53 of 1974. They are responsible for complying with all the provisions of this Act and other legislation applicable to services rendered in the pharmacy and the legislation applicable to the pharmacy which is under his or her personal supervision. According to Regulation 28(2) of the *Regulation Relating to Practice of Pharmacy* published in terms of the Pharmacy Act, the Responsible Pharmacist must have appropriate qualifications and experience in the services being rendered by such pharmacy.

2. PURPOSE OF THE RESPONSIBLE PHARMACIST TRAINING

The purpose of this short course is to equip Responsible Pharmacists with the theoretical and practical knowledge to realise and act on their responsibility in terms of the Pharmacy Act, 53 of 1974, and other legislation, as well as Good Pharmacy Practice rules (GPP), Good Manufacturing Practice (GMP) and Good Distribution and Wholesale Practice (GDWP) guidelines.

3. TARGET GROUP FOR THE RESPONSIBLE PHARMACIST TRAINING

Pharmacists who wish to be registered as a Responsible Pharmacist as defined in the Pharmacy Act, 53 of 1974.

4. MINIMUM ENTRY CRITERIA TO THE RESPONSIBLE PHARMACIST TRAINING

Pharmacists who wish to enrol for the short course must:

- be designated with the SAPC as a practising pharmacist; and
- have been practising as a pharmacist for at least three years.

5. REQUIREMENTS FOR PHARMACISTS TO REGISTER AS A RESPONSIBLE PHARMACIST

To register as a Responsible Pharmacist, the pharmacist is required to:

- successfully complete the short course with an accredited provider;
- record the certificate of successful completion of the course with the SAPC; and
- comply with the criteria for registration of a Responsible Pharmacist.

6. DURATION OF THE SHORT COURSE

The duration of the short course must be a minimum of 70 hours (7 credits).

	Credits	Hours
Interactive sessions	1,6	16 hours
Practical sessions	0,4	4 hours
Assessments and self-study	5	50 hours
Total	7	70 hours

7. RESPONSIBLE PHARMACIST TRAINING RULES

To successfully complete the short course, a student must be competent in all the learning outcomes and assessment criteria.

8. RECOGNITION OF PRIOR LEARNING

Recognition of prior learning is not applicable to the short course.

9. OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA

The training provider must provide evidence that the topics and associated outcomes, as listed in the table below, are covered in the course material. Course material must cover all categories of pharmacy (community, institutional, manufacturing, wholesale and consultant).

Topic	Exit level outcomes	Assessment criteria	No. of credits
Basic principles of management	Understand the concepts and principles of management	Demonstrate an understanding of the basic principles of management.	2
		Apply the basic principles of communication and communication styles.	
		Apply the principles of planning, prioritising and the use of task lists.	
		Explain the difference between issuing instructions and delegating responsibility.	
		Implement the principles of contingency planning.	
		Determine and implement appropriate conflict management principles in the pharmacy.	
Regulatory environment	Understand, interpret and apply the legislative and practice environment as it applies to the Responsible Pharmacist	Describe the role of the RP in terms of the Pharmacy Act, 53 of 1974.	1
		Describe the role of the RP in terms of the Medicines and Related Substances Act, 101 of 1965.	
		Explain the role and responsibility of the RP in terms of other legislation such as: • Consumer Protection Act, 68 of 2008 • Protection and Personal Information Act, 4 of 2013 • Occupational Health and Safety Act, 85 of 1993 • Labour Relations Act, 66 of 1995 • Basic Conditions of Employment Act, 75 of 1997	

		• Compensation for Occupational Injuries and Disease Act, 130 of 1993 • Income Tax Act, 58 of 1962	
		Identify the various fees that must be paid in terms of the pharmacy, owner, and registered persons to the various regulatory and statutory bodies.	
		Describe the licensing and registration processes of pharmacy premises.	0.5
Human Resources	Understand, interpret and apply legislation and provide guidance to human resources in the pharmacy.	Describe and compare the various scopes of practice of pharmacy personnel.	
		Manage the registration of pharmacy personnel with the SAPC.	
		Explain the responsibility of an RP in terms of training and development of staff members.	
		Manage the responsibilities of the RP in terms of human resources management (labour relations, human relations, performance management, training, and wellness).	
Responsibilities of the RP	Describe, understand and correctly implement the role and functions of the RP in terms of GPP	Explain the competency standards at an advanced level related to the function of an RP.	1
		Explain the authority, duties, and responsibilities of an RP.	
		Manage the delegation of the responsibilities of the RP during times of absence from the pharmacy (e.g., during inactive shifts or emergency hours).	
		Manage the responsibilities of the RP in terms of pharmacy premises.	
		Explain the responsibilities of an RP in terms of pharmacy ownership.	
		Describe the duties and responsibilities of the RP in terms of GxP (GPP, GMP and GWP).	
		Describe the conditions under which an RP may be absent from the pharmacy.	
	Describe the role and functions of the RP in terms of quality assurance	Develop and implement standards for quality management and assurance.	2 (of which PS*=0,2)
		Manage financials in terms of professional fees, analysis of financial data and adherence to all relevant legislative prescripts.	

The RP and quality assurance		Manage pharmaceutical infrastructure (need analysis of infrastructure requirements).	
		Manage operational systems (IT, access control, workflow, human resources system, financial, etc.) for the successful running of the pharmacy.	
		Manage change management in a pharmacy environment.	
		Develop, implement, and manage policies relating to the practice in a pharmacy.	
		Develop, implement, and manage standard operating procedures (SOPs).	
The RP and pharmacy operations	Understand the responsibilities of the Responsible Pharmacist in operations	Explain and implement the responsibilities of the RP in the supply of medicines and dispensing.	0.1
		Explain and implement the responsibilities of the RP in stock management, ADUs and RADUs.	
Performing a self-inspection	Prepare for and perform SAPC and SAHPRA (if applicable) inspection	Implement the requirements of an SAPC inspection.	0.4
		Implement the requirements of a SAHPRA inspection (if applicable).	(of which PS*=0,2)3

*PS: practical session

10. CRITICAL CROSS-FIELD OUTCOMES

- Identify, analyse, and solve problems related to the role and responsibilities of a Responsible Pharmacist.
- Work effectively with others as a member of a team.
- Collect, analyse, organise, and critically evaluate information as a Responsible Pharmacist.
- Communicate effectively using visual, and/or language skills in the modes of oral, written and/or practical presentation in a sustained discourse.
- Use the science and technology, including informatics, in pharmacies effectively and critically, showing responsibility towards the environment and health of others by promoting ethical conduct in all contexts.
- Promote public health and education on public health matters as a Responsible Pharmacist.

11. QUALIFICATIONS AND EXPERIENCE OF PRESENTERS/FACILITATORS

The presenters/facilitators of this short course must:

- be registered with the SAPC and designated as a Practising Pharmacist(s); and
- 10ave a minimum of five (5) years' experience as a practising pharmacist and a minimum of three (3) years' experience in an education and training institution.

12. STANDARDS FOR PRESENTATION OF THE RESPONSIBLE PHARMACIST TRAINING

The Responsible Pharmacist training must be presented by a Higher Education Institution (HEI) or Skills Development Provider (SDP) accredited by the SAPC.

13. CRITERIA FOR COMPLIANCE WITH QUALITY MANAGEMENT SYSTEMS (QMS)

The prospective provider must provide evidence that a satisfactory quality management system is in place according to Good Pharmacy Education Standards.

14. MODE OF DELIVERY

The learning may be presented through an online platform or through traditional face-to-face classroom sessions. The facilitation methodology must allow for flexible study hours and self-study. The provider must have a reliable electronic platform that makes provision for the sharing of study material and resources. This platform must have access control and as a minimum requirement, it must allow for the following:

- Resources and training material (for example study guides, PowerPoint® presentations, videos) to guide the student through the learning material and provide student support through the learning process.

- General announcements.
- Communication with students.
- Submission of work assignments.
- Formative and summative assessments.
- In the case of online assessment, necessary proctoring tools for authenticity reasons.

Comprehensive study material must be available. The study guide(s) must guide the students through the learning material and should include all the topics which form part of each specific outcome and assessment criteria. Additional textbooks and reference material must also be used. References to additional textbooks and reference material must also be supplied.

15. ASSESSMENT CRITERIA

The provider must provided evidence that:

- both formative and summative forms of assessment are applied appropriately throughout the learning and assessment process;
- the student has obtained 70% for the formative assessments as a qualifying criterion for summative assessment;
- admission to the summative assessment of the course is obtained through the successful completion of the course content and formative assessments, confirming that the student has met the requirements for admission to the summative assessment;
- the integrated summative assessment must be in the form of a written in-person/online examination; and
- the student must achieve 70% in the integrated summative assessment to be deemed competent in the course.

Competence must be achieved in all modules in the learning programme. This learning programme is a requirement for approval by Council as a Responsible Pharmacist. Successful completion of this learning programme does not automatically qualify the student for approval as a Responsible Pharmacist. All other GPP and Council requirements for approval as a Responsible Pharmacist must also be fulfilled.

16. MODERATION OPTIONS

Formative and summative assessments must be internally and externally moderated according to the provider's approved QMS. Moderators must be registered pharmacists with at least three years' experience in the pharmacy education environment.

17. CRITERIA FOR THE REGISTRATION OF ASSESSORS AND MODERATORS

Assessors and moderators must be registered as assessors with the SAPC. Assessors and moderators must have proven experience in pharmacy practice, including three years as a Responsible Pharmacist.

18. PROCESS OF APPEAL

An appeals process must be in place in cases where students disagree with the outcome of an assessment (formative or summative). The process for appealing against assessment decisions on the demonstration of competence by candidates must be described in the learning material of the course and must be included in the provider's QMS.

19. PROCESS IN CASE OF DISHONESTY AND PLAGIARISM

Students must be warned against dishonesty and plagiarism. A procedure must be in place to address this kind of misconduct, which must include the reporting of such offences to the SAPC. This policy must be included in the provider's QMS.

20. STANDARDS FOR ADMINISTRATION AND RECORD KEEPING

A student administration system must be available for maintaining and updating detailed student information. Information must be included but not be limited to the following:

- Student's full names and surname.
- Maiden name (if applicable).
- Identity or passport number.
- Contact numbers (cell phone and landline).
- E-mail address.
- Postal address.
- Physical residential address.
- Qualifications.
- SAPC P-number.

The student administration system must include functionality to generate a document that can be used as a "Proof of Registration" for each enrolled student. It must also allow for record keeping of the marks and judgements of student assessments. Confidentiality of personal information must be maintained at all times, according to POPIA requirements.

21. CERTIFICATION METHODS AND PROCEDURES

Procedures must be in place to ensure that the certification of students is managed in a secure and safe manner. The security and accuracy of certificates during printing, filing

and distribution must be assured. The following minimum information is required for the certification of the Responsible Pharmacist course:

- Provider name and/or logo.
- Name of the course.
- Student's full name (first names followed by surname).
- Student's identity or passport number.
- Date of issue of the certificate.
- Signatories.

22. FACILITIES, EQUIPMENT AND CONSUMABLES

The prospective provider must provide evidence of the following:

- If the course is presented in a mode that requires contact sessions with the students, then the provider must supply proof of the following:
    - Physical facilities such as:
        - Adequate lecture rooms (this may include title deeds of buildings and/or lease agreements).
        - Lecture rooms that are sufficient in number and adequate in size to accommodate the number of students, keeping all current social distancing regulations in mind (if applicable).
        - Lecture rooms that are adequately equipped and well maintained, providing a reasonably attractive environment for teaching and learning. Minimum equipment are:
            - Table and chair for each student.
            - Sufficient lightingand ventilation.
            - Technological equipment, e.g., a projector to facilitate teaching.
    - Lecture rooms must be Occupational Health and Safety compliant.
- If the course is presented as an online learning course, then the provider must provide proof of the following:
    - A reliable electronic platform that makes provision for:
        - the sharing of study material and resources;
        - the submission of assessments by the students;
        - functionality that allows students to write online assessments;

    - the protection of student information and course content;
    - a secure login process;
    - robust anti-hijacking (computer systems), virus and malware protection; and
    - a proctoring tool to verify the authenticity of assessments.
- Availability of sufficient office space for administrative staff.
- Availability of sufficient, suitable and safe storage space for physical documents.
- Availability of sufficient office equipment for the delivery and administration of the course.
- Availability of suitably qualified course coordinators/presenters (qualifications must be provided as supporting documents).
- Availability of suitably qualified assessors and moderators (qualifications must be provided as supporting documents).