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Board Notices • RAADSKENNISGEWINGS

BOARD NOTICE 806 OF 2025

SOUTH AFRICAN PHARMACY COUNCIL

CRITERIA TO ACCREDIT A COURSE TO BE COMPLETED BY FOREIGN- QUALIFIED PHARMACY TECHNICIANS

The South African Pharmacy Council intends to publish in terms of Sections 3(e)(i), 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 course to be* completed by foreign-qualified Pharmacy Technicians.

Interested parties are invited to submit, within **30 days** of publication of this notice, substantiated comments on or representations regarding the proposed Criteria. Comments must be addressed to the Registrar, for the attention of the Company Secretary, via email, at: <u>BN@sapc.za.org.</u>

<u>SCHEDULE</u>

CRITERIA TO ACCREDIT A COURSE TO BE COMPLETED BY FOREIGN QUALIFIED PHARMACY TECHNICIANS

MR VM TLALA REGISTRAR

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083, Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

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



CRITERIA TO ACCREDIT A COURSE TO BE COMPLETED BY FOREIGN-QUALIFIED PHARMACY TECHNICIANS

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1. RATIONALE FOR TRAINING FOREIGN-QUALIFIED PERSONS

The Office of the Registrar receives applications from foreign-qualified candidates seeking registration as Pharmacy Technicians in South Africa. The South African Pharmacy Council (hereafter referred to as "Council") processes these applications in terms of Regulations 56N, 56O and 56P of the *Regulations relating to the registration of persons and maintenance of registers* (GNR. 1160 of 2000) as amended, as well as the *Criteria for the evaluation of foreign applications* approved by Council.

The Minister of Health promulgated the *Regulations relating to the registration of persons and the maintenance of registers: Amendment Regulations 2024* on 19 April 2024, thereby establishing the register for Pharmacy Technicians and the registration requirements therein.

On 24/25 July 2024, Council resolved that the Education Committee develop a programme that will be completed by all foreign-qualified Pharmacy Technicians.

2. PURPOSE OF TRAINING FOREIGN-QUALIFIED PERSONS

The course aims to prepare foreign-qualified Pharmacy Technicians with the necessary contextual knowledge and skills required for practice in South Africa, as well as to prepare them to write the external integrated summative assessments (EISA) as resolved by Council on 24/25 July 2024. Candidates will be permitted to write the EISA only after completing this course.

3. TARGET GROUP FOR TRAINING

Foreign-qualified candidates who meet the minimum criteria as stipulated in Section 4 below.

4. MINIMUM ENTRANCE CRITERIA FOR FOREIGN-QUALIFIED PERSONS

According to the Regulations relating to the registration of persons and maintenance of registers (hereafter "Registration Regulations"), any person with a Pharmacy Technician gualification obtained outside the Republic of South Africa who wishes to apply for registration must do so on a form approved and provided by the Council. Foreigngualified persons wishing to be registered as Pharmacy Technicians should follow the process application as described the SAPC website on at: http://www.sapc.za.org/fgpersons. Once on the Foreign-Qualified Persons Portal on the SAPC website, they may click on "Application Form" to apply and submit supporting documents to the Registrar. If the application is successful, a Council decision letter will be issued to the candidate, which they may then submit as part of their application to an accredited provider of the Foreign-Qualified Pharmacy Technician Course.

5. DURATION OF THE TRAINING FOR FOREIGN-QUALIFIED PERSONS

		Notional Hours
IS	Interactive Sessions	74
Р	Practical/Tutorial sessions/Simulated learning (Work- based learning)	37,5
Α	Assessments	19
SS	Self-study	199,5
Total		330

The recommended duration of the course is 330 notional hours.

6. TRAINING RULES

To successfully complete the course, a candidate must:

- (a) complete all the training modules; and
- (b) achieve the minimum pass mark of 50% for each module as stipulated in the module documents.

7. RECOGNITION OF PRIOR LEARNING

Not applicable to the course.

8. OUTCOMES AND ASSOCIATED ASSESSMENT CRITERIA

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
ELO 1: Apply scientific knowledge to provide technical support in delivering pharmaceutical services.	1.1 The candidate should be able to demonstrate and understand the structure and function of the South African (SA) health systems.	 1.1.1 Demonstrate an understanding of the key components of healthcare systems, governance, financing, health human resources, pharmaceutical management and service delivery in both private and public sectors. 1.1.2 Demonstrate an understanding of healthcare systems, including an understanding of past, present and emerging structures. 1.1.3 Demonstrate an understanding of different health financing models in both the private and public sector and their applicability to SA. 1.1.4 Demonstrate an understanding of the national core standards in SA. 	IS - 8 H P - 0 H A - 2 H SS - 20 H
	1.2 The candidate should be able to demonstrate detailed knowledge and understanding of regulatory bodies and professional associations.	1.2.1 Demonstrate knowledge and an understanding of the role of the South African Health Products Regulatory Authority, the South African Pharmacy Council and professional associations.	IS - 6 H P - 0 H A - 2 SS - 16 H

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
	1.3 The candidate must be able to practise ethically, legally and professionally, within the scope of practice.	1.3.1 Explain legislation related to the relevant scope of practice of Pharmacy Technicians in pharmaceutical services in the South African context with a keen focus on the Pharmacy Act, 53 of 1974, Medicines and Related Substances Act, 101 of 1965, and other relevant legislation, Rules relating to Good Pharmacy Practice (GPP), Rules relating to Code of Conduct, Good Warehousing Practice (GWP), current Good Manufacturing Practice (cGMP), Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines, National Drug Policy and standard operating procedures (SOPs).	IS - 2,5 H P - 6 H A - 0,5 H SS - 7 H
		 1.3.2 Demonstrate ethical and professional conduct in relation to the relevant scope of practice in the provision of pharmaceutical technical support services with an understanding of the ethical rules and code of conduct. 1.3.3 Supervise Pharmacist's Assistants as specified by 	
		 1.3.3 Supervise Pharmacist's Assistants, as specified by the Responsible Pharmacist. 1.3.4 Demonstrate competence in maintaining accurate and up-to-date patient records and documentation as per the GPP and current SA legislative requirements. 	

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
	1.4 The candidate must be able to explain basic pharmaceutical terms and scientific principles in relation to sterile and non- sterile pharmaceutical preparations.	 1.4.1 Demonstrate an understanding of the history of pharmacy, the origin of medicines and pharmaceutical terminology. 1.4.2 Explain and apply fundamental pharmaceutical principles, including medicine properties, stability factors, active ingredients, dosage forms, routes of administration, and pharmaceutical product classification. 1.4.3 Accurately perform pharmaceutical calculations and unit conversions relevant to the scope of practice. 	IS - 15 H P - 0 H A - 3 H SS - 42 H
	1.5 The candidate must be able to explain basic concepts of physiology, patho- physiology and pharmacology of common acute and chronic conditions endemic to South Africa as per the Standard Treatment Guidelines (STG) and Essential Medicines List (EML).	 1.5.1 Define concepts and explain the pathophysiology of common infectious conditions such as human immunodeficiency syndrome (HIV), acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), malaria, sexually transmitted diseases (STIs) and other opportunistic infections in SA. 1.5.2 Demonstrate an understanding of the basic principles and concepts of pharmacology of common infectious conditions such as HIV/AIDS, TB, malaria, STIs and other opportunistic infections in SA. 	IS - 12 H P - 12 H A - 3 H SS - 33 H

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
ELO 2: Provide	2.1 The candidate must be able	 1.5.3 Define concepts and explain the pathophysiology of common non-communicable diseases (NCD) in SA. 1.5.4 Demonstrate an understanding of the basic principles and concepts of pharmacology of common non-communicable diseases in SA. 1.5.5 Apply the STG and EML in accordance with the scope of practice. 1.5.6 Identify different types of screening tests and their application relevant to common conditions in SA. 2.1.1 Identify and explain the different stock management 	IS - 10 H
technical support for the ordering, managing, despatch and disposal of medicines, scheduled substances, medical supplies and devices in compliance with Good Wholesaling and Distribution	to demonstrate an understanding of the principles of GWDP in relation to the management of stock in SA.	 systems used in different categories of pharmacies. 2.1.2 Perform calculations relevant to stock inventory management. 2.1.3 Demonstrate understanding of the procurement, storage and distribution of medicines and related products according to Rule 2.3 of the <i>Rules relating to Good Pharmacy Practice</i>. 	P - 5 H A - 2 H SS - 23 H

TOPICS	SPECIFIC OUTCOMES		ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
Practices (GWDP) and legal requirements.		2.1.4	Demonstrate comprehensive knowledge of the South African health system and its impact on the medicine supply chain.	
		2.1.5	Demonstrate application of the logistics management information system (LMIS) in the medicine supply chain process.	
		2.1.6	Demonstrate an understanding of the safe disposal of medicines.	
		2.1.7	Describe an understanding of the relevant documents in accordance with applicable legislation, process documentation and SOPs.	
ELO 3: Provide technical support for the manufacture, packaging and re- packaging of sterile and non-sterile medicines and scheduled substances in compliance with GMP guidelines	3.1 The candidate must be able to demonstrate an understanding of GMP and quality assurance principles in the manufacture of sterile and non-sterile medicines in SA.	3.1.1	Explain the principles of quality assurance, quality control and GMP.	IS - 5 H P - 3 H A - 2 H SS - 20 H

TOPICS under the supervision of a pharmacist.	SPECIFIC OUTCOMES		ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
ELO 4: Provide technical support for the compounding, manipulation and preparation of sterile and non-sterile medicines and scheduled substances (extemporaneous compounding) in compliance with	4.1 The candidate must be able to demonstrate an understanding of compounding, manipulation and preparation of sterile and non-sterile medicines and scheduled substances (extemporaneous compounding) in compliance with standards as described in the GPP rules and GMP guidelines under the supervision of a pharmacist.	4.1.1	Demonstrate an understanding of sterile and non- sterile compounding in accordance with Rule 2.18 of the <i>Rules relating to GPP</i> and relevant sections of GMP. Identify and describe requirements for premises, services, facilities and equipment for sterile and non- sterile compounding according to the <i>Rules relating to</i> <i>GPP</i> and relevant sections of GMP	IS – 1,5 H P - 2 H A – 0,5 H SS - 3 H
standards as described in the GPP rules and GMP guidelines under the supervision of a	4.2 The candidate must be able to demonstrate an understanding of Sterile preparations that are compounded, manipulated	4.2.1	Demonstrate understanding of sterile admixtures compounding, manipulation and preparation according to Rule 2.17 of the <i>Rules relating to GPP</i> and relevant sections of GMP.	IS – 3 H P - 3 H A - 1 H SS - 6 H
pharmacist.	and prepared following relevant SOPs and process documentation, using	4.2.2	Demonstrate understanding of aseptic techniques in manufacturing according to cGMP.	

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
	aseptic techniques and the principles of cGMP and/or GPP for specific patients.		
ELO 5: Provide technical support to dispense prescriptions and to	5.1 The candidate must be able to provide technical support to dispense prescriptions and to sell Schedule 0, 1 and 2 medicines in	5.1.1 Assess a primary healthcare prescription for legality/authenticity in accordance with the Medic and Related Substances Act and alignment with STG and EML.	ines P - 4 H
sell Schedule 0, 1 and 2 medicines in compliance with legal requirements,	compliance with legal requirements, including GPP Rules 2.7, 2.8, 2.9, 2.10, 2.12, Sections 18, 22A, 22G	5.1.2 Demonstrate an understanding of med scheduling in the SA context in accordance with GPP and current SA legislative requirements.	
including GPP.	of the Medicines and Related Substances Act, and Regulation 33 of the	5.1.3 Demonstrate an understanding of the phase dispensing as per the scope of practice.	s of
	<i>General Regulations</i> made in terms of the Medicines and Related Substances	5.1.4 Demonstrate an understanding of pharmaceuterminology and abbreviations used in dispensing	
	Act.	5.1.5 Demonstrate how medicines are prepared labelled in accordance with the GPP and curren legislative requirements.	
		5.1.6 Demonstrate the ability to provide information patient, caregiver or the agent of the patient regar the correct use of the medicine.	

TOPICS	SPECIFIC OUTCOMES	ASSESSMENT CRITERIA	Notional Hours (Interactive Sessions = IS Practical/Tutorial sessions/Simulated learning (work- based learning) = P Assessments = A Self-study = SS)
	5.2 The candidate must be able	 5.1.7 Demonstrate the ability to recognise cultural differences, including beliefs, values and customs that influence health behaviours. 5.1.8 Demonstrate the ability to adapt communication based on the health literacy and linguistic needs of the patient/carer by using the appropriate sources of information and communication tools. 5.2.1 Describe health promotion and lifestyle modifications are diagonal with a life appropriate source of the patient of the promotion and lifestyle modifications are diagonal with a life appropriate source of the patient of the promotion and lifestyle modifications are diagonal with a life appropriate source of the patient of the promotion and lifestyle modifications are diagonal with a life appropriate source of the patient of the pa	IS - 3 H
	to demonstrate the ability to communicate preventative measures and lifestyle modification in relation to identified conditions endemic to SA.	on diseases such as HIV/AIDS, TB, malaria, STIs, other opportunistic infections and common NCDs in SA.	P - 2,5 H A - 0.5 H SS - 9 H
ELO 6: Provide technical support in the management of pharmacy resources.	6.1 The candidate must be able to assist the pharmacist in the management of pharmacy resources.	6.1.1 Manage the infrastructure, finance, equipment and human resources for a primary healthcare dispensary within the scope of practice under the delegation of a supervising pharmacist or Responsible Pharmacist.	IS - 4 H P - 0 H A - 0,5 H SS - 10,5 H

9. CRITICAL CROSS-FIELD OUTCOMES

- (a) Identify and solve problems related to the provision of pharmaceutical care using creative approaches.
- (b) Work effectively with others as a member of a team of health care professionals by applying pharmaceutical care management principles.
- (c) Organise and manage pharmaceutical activities responsibly and effectively by contributing to the institution and broader community.
- (d) Collect, analyse, organise, and critically evaluate information.
- (e) Communicate effectively using visual, mathematical, and/or language skills in oral, written, and/or practical presentation modes in a sustained discourse.
- (f) Use science and technology, including informatics in pharmacy, effectively and critically, demonstrating responsibility towards the environment and health of others by promoting ethical conduct in all contexts.
- (g) Demonstrate an understanding of the pharmaceutical environment as a set of related systems by recognising that problem-solving contexts do not exist in isolation.
- (h) Learner and societal development in the healthcare environment.

10. QUALIFICATIONS AND EXPERIENCE OF PRESENTERS/FACILITATORS

The presenters of the course must have an undergraduate pharmacy qualification, i.e. Bachelor of Pharmacy (BPharm) degree and be registered as a practising pharmacist with the SAPC.

11. STANDARDS FOR PRESENTATION OF THE COURSE FOR FOREIGN-QUALIFIED PERSONS

The course must be offered by a Skills Development Provider (SDP) or a Higher Education Institution (HEI) accredited by Council to offer the course.

12. MODE OF DELIVERY

The course must be completed by foreign-qualified pharmacy support personnel (PSP) wishing to be registered in the relevant category in South Africa. The interactive sessions of the short course should be presented using an online platform or face-to-face and must be presented in a manner that allows flexible study hours. There should be face-to-face contact sessions for skills-based practicals (e.g., blood pressure measurements). Tutorials can be conducted either face-to-face or online.

The SDP or HEI must use an electronic platform that makes provision for the sharing of study material and resources. This platform must have access control and, at a minimum, support the following:

- (a) General announcements;
- (b) Communication with students;
- (c) Resources and training material (for example, study guides, PowerPoint presentations, videos);
- (d) Submission of work assignments; and
- (e) Online assessments.

A comprehensive study guide must be available. This guide should lead students through the learning process and integrate all the topics covered in each module, and time should be allocated for self-study

as per the recommended notional hours. In addition, additional textbooks and references should be used, with citations provided in the study guide.

13. ASSESSMENT OF ENROLLED STUDENTS

The course must include assessments such as formative, summative, and/or continuous assessments. Both formative and summative assessments should be developed in accordance with the assessment policies of the SDP or HEI provider. Evidence of the practical skill of candidates, which is assessed based on a competency framework, should be available. The minimum pass mark for the course should be 50%.

14. PROCESS OF APPEAL

An appeal process must be in place in cases where students disagree with the outcome of an assessment (written or practical). The process for appeals against assessment decisions on the demonstration of competence by candidates must be described in the study guide of the course.

15. PROCESS IN CASE OF DISHONESTY AND PLAGIARISM

The course should include a disciplinary process for academic dishonesty, including plagiarism, that is developed in accordance with the SDP or HEI disciplinary policies. This process should be outlined in the study guide. Students found guilty of academic dishonesty under the SDP or HEI disciplinary procedures should be reported to Council.

16. STANDARDS FOR ADMINISTRATION AND RECORD KEEPING

A student administration system must be in place to maintain and update each enrolled student. This information must include, but may not limited be to, the following:

- (a) Student's full name and surname;
- (b) Maiden name (if applicable);
- (c) Identification or passport number;
- (d) Contact numbers (cell phone and landline);
- (e) Email address;
- (f) Postal address;
- (g) Qualifications; and
- (h) Past and current employment (indicating work experience).

The system must include a functionality to generate a document that can be used as a "Proof of Registration" for each enrolled student.

The student administration system must also allow for record-keeping of the marks that each student has obtained in each of the assessments.

Confidentiality of personal information must be maintained at all times.

17. CERTIFICATION METHODS AND PROCEDURES

Procedures must be in place to ensure that student certification is managed securely and safely. The security and accuracy of certificates during printing, filing, and distribution must be assured. The following minimum information is required for certification of the course:

(a) Provider name and/or logo;

(b) Name of the course;

- (c) Student's full name (first name(s) followed by surname);
- (d) Student identification;
- (e) Date of issue of the certificate; and
- (f) Signatories.

18. FACILITIES, EQUIPMENT AND CONSUMABLES

The physical facilities must be adequate to deliver both the theoretical and practical components of the training. For theoretical training, presenters and students must have access to the necessary devices, software, and data for online teaching, as well as access to the provider's online platform. Where face-to-face theory lectures are conducted, suitable lecture venues must be available. The facilities and equipment for practical training should meet the minimum standards prescribed in the Good Pharmacy Education (GPE) and Council requirements.