BOARD NOTICE 652 OF 2024

SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments to Annexure A of the *Rules relating to Good Pharmacy Practice,* which was published on 17 December 2004, Government Gazette No: 27112, Board Notice 129 of 2004, in terms of section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

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

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following rule to Annexure A of the *Rules relating to good pharmacy practice* are hereby **amended** –

   (a) Rule 1.2.11.5 Minimum Standards for pharmacy premises, facilities and equipment: Reference Sources

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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.pharmcouncil.co.za/Legislation_Proposed

MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT: REFERENCE SOURCES

***Rule 1.2.11.5 is hereby repealed and replaced as follows*:**

REFERENCE SOURCES

1. PURPOSE

The purpose of this minimum standard is to regulate the reference materials that are required to be available in a pharmacy.

2. DEFINITIONS

(a) **Core Reference Material List:** this is a list of reference material that is compulsory for all categories of pharmacies.

(b) **Categories of pharmacies:** institutional; community; wholesale; manufacturing and consultant pharmacies in terms of the *Regulations relating to the practice of pharmacy*.

(c) **Pharmacy Category Specific Reference Material List:** list of reference material that a prescribed category of pharmacy will be required to have over and above the core reference material list.

(d) **Pharmacies offering specialised services:** these are pharmacies offering services in terms of the limited conditions specified on their licences as issued by the National Department of Health, which may include radiopharmaceutical, oncology, compounding, and veterinary pharmacy, and any other that may be approved by Council.

(e) **Pharmacies Offering Specialised Services Reference Material List:** List of reference material that pharmacies offering specialised services will be required to have over and above the core reference material list and where applicable the pharmacy category-specific reference material list.

3. GENERAL CONSIDERATIONS

3.1.1 The following principles relating to reference material in a pharmacy must be adhered to:

3.1.1.1 reference material can be made available as hard copies or be accessible on electronic devices;

3.1.1.2 all reference material must be current as specified in the lists;

3.1.1.3 pharmacy premises approved for pre-registration training are also required to have additional reference sources as specified in the intern manual as published by Council;

3.1.1.4 the reference material must be accessible to all registered pharmacy personnel;

3.1.1.5 reference material must be accessible for verification when the pharmacy is routinely inspected for compliance with the legislation by the Council Inspection Officer;

3.1.1.6 a responsible pharmacist may in exceptional circumstances apply to Council for a relaxation of the minimum requirements relating to reference books; and

3.1.1.7 all pharmacies must have a readily accessible telephone number for the following-

(a) poison control centre that serves the area;

(b) medicines information centre; and

(c) vaccines hotline.

4. LIST OF REFERENCE MATERIAL

4.1.1 Core Reference Material List

The list has been categorised as a Core Reference Material List.

This list is applicable to **ALL Pharmacy Categories** and pharmacies offering specialised services.

Core Reference Material List
1. Pharmacy Practice (a) Pharmacy Act No 53 of 1974 (b) Regulations relating to the Practice of Pharmacy, GNR.1158, 2000 (c) Rules relating to Good Pharmacy Practice (GPP), 2004 (as amended) (d) Rules relating to the Code of Conduct for pharmacists and other persons registered in terms of the Pharmacy Act (e) Standard Treatment Guidelines and Essential Medicines List (STGs and EML) for all levels of care
2. Medicines and Related Substances (f) Medicines and Related Substances Act No 101 of 1965 (g) Access to the South African Health Products Regulatory Authority (SAHPRA) guidelines relevant to the category of pharmacy
3. National Legislation (h) The National Health Act No 61 of 2003 (i) Basic Conditions of Employment Act No 75 of 1997 (j) Disaster Management Act No 57 of 2003 (k) Hazardous Substances Act No 15 of 1973 (l) Occupational Health and Safety Act 85 of 1993

Core Reference Material List
4. International resources (m) Martindale (one (1) of the last five (5) editions) 5. Other resources (n) South African Medicines Formulary (SAMF), or other appropriate reference (one (1) of the last two (2) editions) (o) Access to the Essential Medical Guidance (https://info.emguidance.com/) Website of the National Center for Complementary and Integrative Health - www.nccih.nih.gov.

4.1.2 Pharmacy Category Specific Reference Material List

This list is applicable to a prescribed category of pharmacy and the pharmacy in each category will be required to have the listed resources over and above the core reference materials list.

Pharmacy Category Specific Reference Material List				
Institutional	**Community**	**Wholesale**	**Manufacturing**	**Consultant**
Access to Medical Schemes rules and guidelines.	Access to Medical Schemes rules and guidelines.	SA Guide to Good Warehousing Practice (GWP) (latest edition).	SA Guide to GMP.	Access to Medical Schemes rules and guidelines.
Any drug interaction resource.	Any drug interaction resource.	SA Good Clinical Practice: Clinical Trial Guidelines (GCP) (Where applicable).		Any drug interaction resource.
Pharmacology textbook (one (1) of the last two (2) editions or not older than ten (10) years).	Pharmacology textbook (one (1) of the last two (2) editions or not older than ten (10) years).		South African Good Clinical Practice: Clinical Trial Guidelines (GCP) (where applicable).	Pharmacology textbook (one (1) of the last two (2) editions or not older than ten (10) years).
Medical dictionary (one (1) of the last four (4) editions).	Medical dictionary (one (1) of the last four (4) editions).		Good Laboratory Practise Handbook (GLP/WHO Guidelines).	Medical dictionary (one (1) of the last four (4) editions).
Paediatric Dosing reference guide or EML paediatric guide.	Paediatric Dosing reference guide or EML paediatric guide.		Pharmacopoeia (BP, USP, EP) (One of the last 2 editions).	Paediatric Dosing reference guide or EML paediatric guide.
Comprehensive textbook on complementary medicine.	Comprehensive textbook on complementary medicine.			Comprehensive textbook on complementary medicine.
Additional For Pharmacies offering supplementary services: Access to the Knowledge Hub website (https://knowledgehub.health.gov.za)	**Additional For Pharmacies offering supplementary services:** Access to the Knowledge Hub website (https://knowledgehub.health.gov.za)			Access to the Knowledge Hub website. (https://knowledgehub.health.gov.za)

4.1.3 Pharmacies Offering Approved Specialised Services Reference Material List

This list is applicable to the pharmacies offering any of the approved specialised services and these pharmacies will be required to have the listed resources over and above the core reference materials list.

Pharmacies Offering Specialised Services Reference Material List				
Radiopharmaceutical	**Oncology**	**Compounding**	**Veterinary**	**Clinical Trials**
EANM (European Agency of Nuclear medicines, guideline for Radio medicine).	SA Guide to Good Manufacturing Practice (GMP).		Animals' Diseases Act No 35 of 1984(incl. compounding).	South African Good Clinical Practice: Clinical Trial Guidelines (GCP)
Good Radio Pharmacy Practice (European edition).	SA Guide to Good Warehousing Practice (GWP).		Fertilizers, Farm Feeds, Seeds and Remedies Act No 36 of 1947 (incl. compounding).	
Pharmaceutical Inspection Convention or Co-operation Scheme (Pics) guidelines (section C).		SA Guide to Good Manufacturing Practice (GMP).	Medical Schemes Act No 131 of 1998.	
SA Guide to GMP.		SA Guide to Good Warehousing Practice (GWP).	Veterinary And Para-Veterinary Professions Act 19,1982.	
			Plumb's Veterinary Drug Handbook (One (1) of the last two (2) editions).	
		Guideline For Section 21 Access To Unregistered Medicines (SAHPRA)	Index of Veterinary Specialties (IVS)	
		Pharmacopoeia (BP, USP, EP) (One (1) of the last two (2) editions).	Merck veterinary manual (One (1) of the last two (2) editions).	
			Vaccines for animals.	

			Parasites in animals.	
			Veterinary health & diseases textbook	
			Veterinary anatomy and physiology Textbook.	
			Veterinary Complementary Medicines textbook	
			Complementary and alternative medicines textbook (human).	