BOARD NOTICES • RAADSKENNISGEWINGS

BOARD NOTICE 794 OF 2025

SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes, for implementation, amendments to the minimum standards as contained in Annexure A of the *Rules relating to good pharmacy practice,* which was published on 17 December 2004, Government Gazette No: 27112, in Board Notice 129 of 2004 (as amended), in terms of Section 35A(b)(ii) of the Pharmacy Act, 53 of 1974.

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 in Annexure A of the *Rules relating to good pharmacy practice* is hereby amended –

   (a) Rule 1.2.11.5: MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT: Dispensary - Reference sources

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MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

Rule 1.2.11.5: Dispensary - Reference Sources **is hereby deleted and replaced with Rule 1.2.11.5 as follows:**

1.2.11.5.1 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:** a list of reference materials 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 supplementary services:** these are pharmacies where there is a pharmacist who has completed and registered a supplementary training and who has been issued with the relevant Section 22A(15) permit; and a pharmacist offering services according to the list of conditions or medicines published by the National Department of Health from time to time.

(f) **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.

1.2.11.5.2 GENERAL CONSIDERATIONS

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

(a) reference material can be made available as hard copies or be accessible on electronic devices;

(b) all reference material must be current as specified in the lists;

(c) 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;

(d) pharmacies where permit holders practice must have access to reference sources according to the permit as issued by the Director-General: Health;

(e) the reference material must be accessible to all registered pharmacy personnel;

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

(g) a Responsible Pharmacist may, in exceptional circumstances, apply to Council for a relaxation of the minimum requirements relating to reference books; and

(h) all pharmacies must have a readily accessible telephone number for the following-

(i) poison control centre;

(ii) medicines information centre; and

(iii) vaccines hotline.

1.2.11.5.3 LIST OF REFERENCE MATERIAL

(a) Core Reference Material List

The list has been categorised as Core Reference Material List.

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

Core Reference Material List
1. Pharmacy Practice (https://www.sapc.za.org/Legislation) (a) Pharmacy Act, 53 of 1974 (b) Regulations relating to the practice of pharmacy, 2000 (as amended) (c) Regulations relating to continuing professional development, 2019 (d) Rules relating to good pharmacy practice (GPP), 2004 (as amended) (e) Rules relating to the code of conduct for pharmacists and other persons registered in terms of the Pharmacy Act, 2008 (f) Rules relating to acts or omissions in respect of which the Council may take disciplinary steps, 1989 (g) Rules relating to services for which a pharmacist may levy a fee (h) Access to all other Regulations, Rules and Notices published in terms of the Pharmacy Act
2. Medicines and Related Substances (https://www.sahpra.org.za/government-gazette/) (a) Medicines and Related Substances Act, 101 of 1965 (b) General Regulations, 2017 (as amended) and any other Regulations published under the Medicines and Related Substances Act (c) Access to South African Health Products Regulatory Authority (SAHPRA) guidelines relevant to the category of pharmacy
3. National Legislation (a) National Health Act, 61 of 2003

	(b)	Basic Conditions of Employment Act, 75 of 1997
	(c)	Disaster Management Act, 57 of 2003
	(d)	Hazardous Substances Act, 15 of 1973
	(e)	Occupational Health and Safety Act, 85 of 1993
4.	International resources	
	(a)	Martindale (one of the last 5 editions)
5.	Other resources	
	(a)	South African Medicines Formulary (SAMF), or other appropriate reference (one of the last 2 editions)
	(b)	Standard Treatment Guidelines and Essential Medicines List (STGs and EML) for all levels of care
	(c)	Access to the Essential Medical Guidance (https://info.emguidance.com/);
	(d)	Access to the Website of the National Center for Complementary and Integrative Health (www.nccih.nih.gov) OR a comprehensive textbook on complementary medicine

(b) 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				
Community	**Consultant**	**Institutional**	**Manufacturing**	**Wholesale**
Any drug interaction resource	Any drug interaction resource	Any drug interaction resource	SA Guide to Good Manufacturing Practice (GMP)	SA Guide to Good Warehousing Practice (GWP)
Pharmacology textbook (one of the last 2 editions or not older than 10 years)	Pharmacology textbook (one of the last 2 editions or not older than 10 years)	Pharmacology textbook (one of the last 2 editions or not older than 10 years)	SA Good Clinical Practice: Practice Clinical Guidelines (GCP) (where applicable)	SA Good Clinical Practice: Clinical Trial Guidelines (GCP) (where applicable)
Medical dictionary (one of the last 4 editions)	Medical dictionary (one of the last 4 editions)	Medical dictionary (one of the last 4 editions)	Good Laboratory Practise Handbook (GLP/WHO Guidelines)	
Paediatric Dosing Reference Guide	Paediatric Dosing Reference Guide	Paediatric Dosing Reference Guide	Pharmacopoeia (BP, USP, EP) (one of the last 2 editions)	
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)	**Additional for pharmacies offering supplementary services:** Access to the Knowledge Hub website (https://knowledgehub.health.gov.za)		

(c) Pharmacies Offering Approved Specialised Services Reference Material List

This list is applicable to the pharmacies offering specialised services and/or additional 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					
Clinical Trials	**Compounding**	**Oncology**	**Radiopharmaceutical**	**Veterinary**	**Veterinary Continued**
SA Good Clinical Practice: Clinical Trial Guidelines (GCP)	SA Guide to Good Manufacturing Practice (GMP)	SA Guide to Good Manufacturing Practice (GMP)	EANM (European Agency of Nuclear Medicines, guideline for radio medicine)	Animals' Diseases Act, 35 of 1984 (incl. compounding)	Index of Veterinary Specialties (IVS)
	SA Guide to Good Warehousing Practice (GWP)	SA Guide to Good Warehousing Practice (GWP)	Good Radiopharmacy Practice (European edition)	Fertilisers, Farm Feeds, Seeds and Remedies Act, 36 of 1947 (incl. compounding)	Merck Veterinary Manual (one of the last 2 editions)
	Guideline For Section 21 Access to Unregistered Medicines (SAHPRA)		Pharmaceutical Inspection Convention or Co-operation Scheme (PIC/S) guidelines (section C)	Veterinary And Para-Veterinary Professions Act, 19 of 1982	Vaccines for animals
	Pharmacopoeia (BP, USP, EP) (one of the last 2 editions)		SA Guide to Good Manufacturing Practice (GMP)	Plumb's Veterinary Drug Handbook (one of the last 2 editions)	Parasites in animals
				Veterinary anatomy and physiology textbook	Veterinary health & diseases textbook