
BOARD NOTICES

BOARD NOTICE 271 OF 2013

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes amendments to minimum standards to 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 minimum standard as published herewith shall constitute an additional standard to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act:
 - (a) Minimum standard relating to the supervision of Pharmacy Support Personnel



TA MASANGO
REGISTRAR

MINIMUM STANDARD RELATING TO THE SUPERVISION OF PHARMACY SUPPORT PERSONNEL

1. Definitions

“Pharmacy Support Personnel” means the various categories of support personnel as prescribed and registered as such in terms of the Pharmacy Act. These include Pharmacist’s Assistants (learner basic, basic, learner post basic and post basic), Pharmacy Technicians, Pharmacy Technical Assistants and Pharmacy General Assistants.

2. Introduction

Pharmacy support personnel form an integral part of the system in the delivery of pharmaceutical services. The functions performed by a pharmacist can be categorised as either product orientated or patient orientated. In efforts to improve service delivery and develop the concept of comprehensive pharmaceutical care, it is essential that the pharmacist as far as possible devolves responsibility and functions related to product supply to appropriate pharmacy support personnel, within their scope of practice, thus allowing pharmacists more time for patient orientated activities. It is the responsibility of the pharmacist to supervise the pharmacy support personnel with regard to the control, purchase, sale, manufacturing, pre-packaging, dispensing and supply of medicines.

3. Purpose

The purpose of this standard is to give guidance to pharmacists and pharmacy support personnel on how to manage the supervision. The standard will further expand on the independent role of a pharmacy technician based at a primary health care clinic.

4. General considerations applicable to all sectors

- 4.1 Pharmacy support personnel may practise in any category of pharmacy i.e. manufacturing, wholesale, community, institutional pharmacy, in either the public or private sector or public sector primary health care clinic in either the public or the private sector provided that they are competent to practise and are appropriately registered with Council to practise in that sector.
- 4.2 All pharmacy support personnel are responsible for their own safe and efficient practice and are bound by the applicable legislation, the Rules relating to good pharmacy practice, the Rules relating to acts or omissions for which the council may take disciplinary action, the Code of Conduct for persons registered with the Council, as well as guidelines published in terms of the legislation.
- 4.3 Clear and detailed job descriptions must be in place describing the role and responsibilities of all pharmacy support personnel.
- 4.4 A pharmacy technician or a pharmacist’s assistant (post basic) may have direct interaction with patients and health care professionals.

- 4.5 A pharmacy technician or a pharmacist's assistant (post basic) may not dispense prescriptions containing Schedule 5 and 6 medicines except in the case of a pharmacy technician or a pharmacist's assistant (post basic) working under the indirect supervision of a pharmacist in a primary health care clinic. The pharmacy technician or a pharmacist's assistant (post basic) may, however, issue Schedule 5 medicines on prescriptions which have been prepared and are in a patient ready pack e.g. in the case of down-referrals. He/she may also perform Phase 2 of the dispensing process for prescriptions containing Schedule 5 medicines.
- 4.6 A pharmacy technician or a pharmacist's assistant (post basic) may not receive verbal instructions e.g. a telephonic prescription from an authorised prescriber for a new prescription for a patient.
- 4.7 A pharmacist may supervise a maximum of 3 pharmacy support personnel, inclusive of qualified personnel and those who are undergoing training. A pharmacist may supervise a combination of pharmacy support personnel with different role types.

5. Supervision of pharmacy support personnel in community and institutional pharmacy

A pharmacy, as defined in the Pharmacy Act, 53 of 1974, must be conducted under the continuous personal supervision of a pharmacist. A pharmacist must be physically present in the pharmacy. Therefore pharmacy support personnel may only work in a pharmacy under the supervision of a pharmacist who is physically present in the pharmacy.

The pharmacist involved in the supervision of pharmacy support personnel in a pharmacy must ensure that he/she is at all times available to supervise the activities taking place in the pharmacy. The pharmacist must perform random checks of all activities taking place in the pharmacy. The following approach must be used in the dispensing of prescriptions where pharmacy technicians or pharmacist's assistants: post-basic are involved –

- 5.1 All prescriptions coming into a pharmacy must be triaged by a pharmacist;
- 5.2 Prescriptions which contain medicines which fall into Schedules 1 and 2 may be dispensed by a pharmacy technician or a pharmacist's assistant (post basic) under the direct personal supervision of a pharmacist (Phases 1, 2 and 3 of the dispensing process).
- 5.3 Any prescription which contains medicines which fall into Schedule 3 and higher must be evaluated and interpreted by a pharmacist (Phase 1 of the dispensing process).
- 5.4 After a prescription has been evaluated by a pharmacist, the pharmacist must indicate that this function has been performed by him/her e.g. by initialling on the prescription.
- 5.5 Data capturing may be done by a pharmacy technician or a pharmacist's assistant (post basic) with authorisation by a pharmacist.
- 5.6 The preparation of all prescriptions may be done by the pharmacy technician or the pharmacist's assistant (post basic) (Phase 2). The pharmacy technician or the

pharmacist's assistant (post basic) must indicate that he/she prepared the prescription.

- 5.7 All calculations relating to the patient's dosage or the volume of liquids to be supplied must be validated by a pharmacist before dispensing takes place.
- 5.8 The pharmacist must decide which patients require counselling by a pharmacist e.g. patients with complicated regimens, the first time supply of chronic medicine, patients with co-morbidities, patients with adherence problems etc. (Phase 3 of the dispensing process).
- 5.9 A pharmacy technician or a pharmacist's assistant (post basic) may explain the benefits of generic substitution to a patient as required in terms of Section 22F of the Medicines and Related Substances Act 101 of 1965. A pharmacist must, however, be involved in the final substitution decision as to which medicine should be dispensed for the patient in cases where such a choice must be made.
- 5.10 In the case of prescriptions containing Schedule 5 and 6 medicines the pharmacist must be involved in the dispensing process.

6. Supervision of pharmacy support personnel in manufacturing and wholesale pharmacy

The pharmacist involved in the supervision of pharmacy support personnel in a manufacturing or wholesale pharmacy must ensure that he/she is at all times available to directly supervise the activities taking place in a pharmacy. The pharmacist must randomly check all activities taking place in a pharmacy. The following approach must be used:

- 6.1 A manufacturing or a wholesale pharmacy must be conducted under the supervision of a pharmacist who is physically present in the pharmacy.
- 6.2 The pharmacist must be involved at all critical stages in the manufacturing, packaging and distribution process. Pharmacist involvement is needed but is not limited to the control of scheduled substances, the conducting of independent dispensing checks, the conducting of mix checks, line clearance and product release onto the market. Pharmacists must also be responsible for dealing with product complaints and product recalls.
- 6.3 Pharmacy support personnel may be involved in the performance of 'non-critical' functions so that pharmacists can focus on the 'critical' functions required to produce products in line with the Good Manufacturing Practice (GMP) guidelines.
- 6.4 These 'non-critical' functions must be identified and formally agreed upon by the responsible pharmacist of the manufacturing or wholesale pharmacy and the pharmacists responsible for each area of the pharmacy and then suitably documented and measured.

7. Supervisory support at a primary health care clinic

A pharmacy technician or a pharmacist's assistant (post basic) may work under indirect supervision in a dispensary in a primary health care clinic. Supervisory support must be provided by a pharmacist who is not necessarily physically present at all times in the primary health care clinic.

When working in a primary health care clinic with supervisory support of a pharmacist, the pharmacy technician or the pharmacist's assistant (post basic) may dispense prescriptions which contain medicines as contained in the Primary Health Care Essential Medicines List and which are prescribed in accordance with the Standard Treatment Guidelines. In addition he/she may dispense prescriptions which are in accordance with such other protocols which may be approved by the Pharmacy and Therapeutics Committee of the province, municipal or other competent authority under which the primary health care clinic falls provided that such protocols are publicly available.

A pharmacist may only provide supervisory support to a pharmacy technician or a pharmacist's assistant (post basic) working in the dispensary in a primary health care clinic which falls under the jurisdiction of the same competent authority e.g. district or metropolitan council by whom he/she is employed. In cases where a pharmacist has been seconded from one authority to another he/she may support pharmacy technicians or pharmacist's assistants: post-basic working in primary health care clinics falling under the jurisdiction of the authority to whom he/she has been seconded.

The pharmacist involved in providing supervisory support to a pharmacy technician(s) or a pharmacist assistant(s) post-basic working in the dispensary in a primary health care clinic must ensure that he/she is at all times available to provide the necessary support either telephonically or by physically visiting the clinic to support activities taking place in the clinic.

- 7.1 The pharmacist who undertakes supervisory support of pharmacy technicians or pharmacist's assistants post-basic whilst not physically present in the dispensary in a primary health care clinic must visit the pharmacy technician(s) or pharmacist's assistant(s): post-basic at the primary health care clinic at least once a month. Visits must be documented.
- 7.2 No indirect supervision of a pharmacy technician(s) or a pharmacist's assistant(s) post-basic may take place outside the boundaries of the district authority or metropolitan council where the pharmacist providing supervisory support is employed.
- 7.3 The pharmacist providing supervisory support must ensure that written and up-dated protocols and Standard Operating Procedures are available describing clearly the responsibility of the pharmacy technician or the pharmacist's assistant (post basic).
- 7.4 The pharmacy technician or the pharmacist's assistant (post basic) must report to the facility manager (line function), and the pharmacist who provides supervisory support to the pharmacy technician or the pharmacist's assistant (post basic), will provide professional supervision of the pharmacy technician or the pharmacist's assistant.
- 7.5 The pharmacist providing supervisory support must be available at all times when the clinic is open either telephonically by means of a land line or cellular phone or by electronic means.
- 7.6 In the case of patients with co-morbidities, consultation with a pharmacist should take place when a prescription is dispensed. Such consultation could take place telephonically or electronically.

- 7.7 In-service training must be provided to update the pharmacy technician or the pharmacist's assistant (post basic) about developments relevant to his/her practice.
- 7.8 Clearly documented referral to primary health care clinic procedure shall be in place at primary health care clinics where the prescription is prepared at a pharmacy and sent to a primary health care clinic or other site for collection. (e.g. a community pharmacy)
- 7.9 A mechanism of monitoring and evaluating the pharmaceutical service provided at the primary health care clinic must be in place.