

DEPARTMENT OF HEALTH

NO. 4733

19 April 2024

**PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO THE PRACTICE OF PHARMACY:
AMENDMENT REGULATIONS, 2023**

The Minister of Health hereby, in consultation with the South African Pharmacy Council, in terms of section 49(1)(a) read with section 35A of the Pharmacy Amendment Act, 1974 (Act No. 88 of 1997), makes the regulations in the Schedule.



DR. M.J PHAAHLA, MP
MINISTER OF HEALTH
DATE 11/03/2024

SCHEDULE

GENERAL EXPLANATORY NOTE:

_____ Words underlined with a solid line indicate insertions in existing enactments.

Definitions

1. In In these regulations any word or expression to which a meaning has been assigned in the Act has the meaning so assigned and, unless the context otherwise indicates—

“**Regulations**” means the Regulations Relating to the Practice of Pharmacy, published under Government Notice No. R.1158 of 20 November 2000; and

“**the Act**” means Pharmacy Act, 1974 (Act No. 53 of 1974).

Amendment of regulation 1 of Regulations

2. Regulation 1 of the Regulations is hereby amended by—
 - (a) the substitution for the definition of “Act” of the following definition:

“**Act**” means the Pharmacy Act, 1974 (Act 53 of 1974) and includes any proclamation, regulation, rule or order made under this Act.
 - (b) the substitution for the definition of “direct personal supervision” of the following definition:

“ **‘direct personal supervision’** means guidance and support provided by a pharmacist whilst physically present in a pharmacy, and in accordance with rules relating to good pharmacy practice published in terms of section 35A(b) of the Act;”;

- (c) the substitution for the definition of “indirect personal supervision” of the following definition:

“ ‘indirect personal supervision’ means guidance and support provided by a pharmacist to pharmacy support personnel in a primary health care clinic or any other facility as approved by the council, and in accordance with rules relating to good pharmacy practice published in terms of section 35A(b) of the Act;”;

- (d) the insertion after the definition of “indirect personal supervision” of the following definition:

“ ‘in-service training’ means the training undertaken by a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic) under the direct personal supervision of a tutor at a pharmacy approved by the council for purposes of such training;”;

- (e) the substitution for the definition of “pharmacist’s assistant” of the following definition:

“ ‘pharmacist’s assistant’ means a natural person registered in one of the following categories:

- (a) pharmacist’s assistant (learner basic);
- (b) pharmacist’s assistant (basic);
- (c) pharmacist’s assistant (learner post-basic);
- (d) pharmacist’s assistant (post-basic);
- (e) pharmacy technician (learner)
- (f) pharmacy technician (student);
- (g) pharmacy technician (trainee);
- (h) pharmacy technician;
- (i) pharmacy student;’

which constitute the various categories of pharmacy support personnel registered as such in terms of the Act’;

- (f) the insertion after the definition of “pharmacy student” of the following definitions:
- “ ‘pharmacy technician’ means a natural person registered as such in terms of the Act;
- ‘pharmacy technician (learner)’ means a natural person registered as such in terms of the Act;
- ‘pharmacy technician (student)’ means a natural person registered as such in terms of the Act;
- ‘pharmacy technician (trainee)’ means a natural person registered as such in terms of the Act;”
- (g) the substitution for the definition of “primary care drug therapy” of the following definition:
- “ ‘primary care drug therapy’ means diagnosing a health need, prescribing and supplying of medicine to meet the health need of a patient or group of patients or, where necessary, the referral to another health care professional by a pharmacist who has received the necessary authorisation from the council and is the holder of a permit issued in terms of the Medicines Act;”;
- (h) the insertion after the definition of “private health facility” of the following definition:
- “ ‘provider’ means any person or institution approved by and registered with the council in terms of the Act to provide education and training approved by the council for purposes of:
- (a) registration as a pharmacist;
- (b) registration as a pharmacist’s assistant (basic), pharmacist’s assistant (post-basic) or pharmacy technician;
- (c) registration of a speciality;

- (d) continuing professional development;
 - (e) supplementary training; or
 - (f) a course determined by the council in terms of the Medicines Act;”;
- (i) the deletion of the definition of “qualification in pharmacy” after the definition of “public health facility”
- (j) the insertion after the definition of “sell” of the following definitions:
- “ ‘**traineeship**’ means practical training, as determined by the council from time to time, undertaken by a pharmacy technician (trainee) in terms of a contract under the direct personal supervision of a tutor in a pharmacy approved by the council in terms of the Act for purposes of such training;”;
- “ ‘**tutor**’ means a pharmacist registered with the council as a tutor, to supervise the internship of a pharmacist intern, the traineeship of a pharmacy technician (trainee) or the in-service training of a pharmacist’s assistant (learner basic) or pharmacist’s assistant (learner post-basic);”; and
- (k) the insertion after the definition of “wholesale pharmacy” of the following definition:
- “ ‘**work-based training**’ means education and training undertaken by a pharmacist’s assistant (learner basic), pharmacist’s assistant (learner post-basic) or pharmacy technician (learner) in a pharmacy under the auspices of a provider, as part of an education and training programme approved by the council for purposes of registration as a pharmacist’s assistant (basic), pharmacist’s assistant (post-basic or pharmacy technician. ”.

Substitution of regulation 2 of Regulations

3. The Regulations are hereby amended by substitution of regulation 2 for the following:

“2. Conditions under which services or acts must be provided or performed.—

The services or acts pertaining to the scope of practice of natural persons registered in terms of the Act must be provided or performed in accordance with the Act and the Medicines Act.”

Amendment of regulation 4

4. Regulation 4 of the Regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

“(1) the acts specially pertaining to the profession of a pharmacist as prescribed in regulation 3

Substitution of regulation 5 of Regulations

5. The following regulation is hereby substituted for regulation 5 of the Regulations:

“5. Scope of practice of a pharmacist intern.— A pharmacist intern may for the purposes of education and training, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist under the direct personal supervision of a pharmacist in a pharmacy.

6. The following regulation is hereby substituted for regulation 6 of the Regulations:

“6. A pharmacist intern may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacy technician under the direct personal supervision of a pharmacist.”.

Substitution of regulation 7 of Regulations

7. The following regulation is hereby substituted for regulation 7 of the Regulations:

“7. **Scope of practice of a pharmacy student.—**

- (1) A pharmacy student who has successfully completed—
 - (a) the first year of an education and training programme approved by the council for purposes of registration as a pharmacist, and who is undergoing his or her second year of study, may perform services or acts pertaining to the scope of practice of a pharmacist's assistant (basic);
 - (b) the second year of an education and training programme approved by the council for purposes of registration as a pharmacist, and who is undergoing his or her third year of study, may perform services or acts pertaining to the scope of practice of a pharmacist's assistant (post-basic);
 - (c) the third or subsequent year of an education and training programme approved by the council for purposes of registration as a pharmacist, and who is undergoing his or her fourth or subsequent year of study, may perform services or acts pertaining to the scope of practice of a pharmacy technician.

- (2) The services or acts contemplated in subregulation (1) may only be performed under the direct personal supervision of a pharmacist in a pharmacy.”.

Substitution of regulation 8 of Regulations

8. The following regulation is hereby substituted for regulation 8 of the Regulations:

8. (1) A pharmacy student may for purposes of education and training, and under the auspices of a provider approved by the council to offer education and training for purposes of registration as a pharmacist and with whom such student is enrolled, provide the services or perform the acts prescribed in regulations 3 and 4 under the direct personal supervision of a pharmacist in a pharmacy;
- (2) The services or acts referred to in subregulation 8(1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

Amendment of regulation 9 of Regulations

9. The following regulation is hereby substituted for regulation 9 of the Regulations:

- 9. Pharmacist's assistants (basic).—A pharmacist's assistant registered in the category pharmacist's assistant (basic) may perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:**
- (1) assist with the compounding, manipulation, or preparation of a non-sterile Schedule 1 to Schedule 4 medicine or scheduled substance according to a formula and standard operating procedures;
- (2) assist with the manufacturing of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures;
- (3) the re-packaging of medicine;
- (4) the distribution and control of stock of Schedule 1 to Schedule 5 medicines or scheduled substances;

- (5) the provision of information to individuals in order to promote health;
and
- (6) general housekeeping and administrative tasks”.

Substitution of regulation 10 of the Regulations

10. The following regulation is hereby substituted for regulation 10 of the Regulations:

“10. Pharmacist’s assistant (learner basic).—

- (1) A pharmacist’s assistant (learner basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacist’s assistant (basic) and who is undertaking in-service training, may provide the services or perform the acts prescribed in regulation 9 under the direct personal supervision of a pharmacist in a pharmacy.
- (2) A pharmacist’s assistant (learner basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 9 under the direct personal supervision of a pharmacist in a pharmacy.
- (3) The services or acts referred to in subregulations 10(1) and 10(2) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.”

Substitution of regulation 11 of Regulations

11. The following regulation is hereby substituted for regulation 11 of the Regulations:

11. Pharmacist’s assistant (post-basic).—A pharmacist’s assistant registered in the category pharmacist’s assistant (post-basic) may perform the following

services or acts under the direct personal supervision of a pharmacist in a pharmacy:

- (1) the sale of Schedule 1 and Schedule 2 medicines or scheduled substances;
- (2) assist with the compounding, manipulation or preparation of a non-sterile or sterile Schedule 1 to Schedule 4 medicine or scheduled substance according to a formula and standard operating procedures;
- (3) assist with the manufacturing of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures;
- (4) the re-packaging of medicine;
- (5) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances;
- (6) the ordering of medicines and scheduled substances up to and including Schedule 6 according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicines or scheduled substance;
- (7) the reading and preparation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container following the interpretation and evaluation of the prescription by a pharmacist;
- (8) the provision of instructions regarding the correct use of medicine supplied;
- (9) the provision of information to individuals in order to promote health;
and
- (10) general housekeeping and administrative tasks”.

Substitution of regulation 13 of the Regulations

12. The following regulation is hereby substituted for regulation 13 of the Regulations:

“13. Pharmacist’s assistant (learner post-basic).—

(1) A pharmacist’s assistant (learner post-basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacist’s assistant (post-basic) and who is undertaking in-service training, may provide the services or perform the acts prescribed in regulation 11 under the direct personal supervision of a pharmacist in a pharmacy.

(2) A pharmacist’s assistant (learner post-basic) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 11 under the direct personal supervision of a pharmacist in a pharmacy.

(3) The acts referred to in subregulations (1) and (2) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.

(4) A pharmacist’s assistant (learner post-basic), may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist’s assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy.”

Insertion of regulations 13A to 13E in Regulations

13. The following regulations are hereby inserted after regulation 13 of the Regulations:

“13A. Pharmacy technician.— A pharmacy technician registered in the category pharmacy technician may provide or perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:

- (1) assist with the compounding, manipulation, or preparation of a non-sterile or sterile Schedule 1 to Schedule 6 medicine or scheduled substance, in accordance with the Medicines Act;
- (2) assist with the manufacturing of a non-sterile or sterile medicine or scheduled substance, including the start-up line clearance and opening of the line in accordance with standard operating procedures: Provided that the pharmacist has provided the necessary signed authorisation;
- (3) the packaging and re-packaging of medicine or scheduled substances, including the start-up line clearance and opening of the packaging line in accordance with standard operating procedures: Provided that the pharmacist has provided the necessary signed authorisation;
- (4) the sampling, or supervision of the sampling of medicines or scheduled substances in accordance with good manufacturing practice as determined in terms of the Medicines Act;
- (5) the checking of orders containing medicine and scheduled substances up to and including Schedule 6 in closed packs, prior to dispatch thereof, which have been picked by a pharmacist’s assistant: Provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or an institutional pharmacy;
- (6) the distribution and management of stock of Schedule 1 to Schedule 6 medicine or scheduled substances;

- (7) the ordering and receipt of a Schedule 6 medicine or scheduled substance: Provided that orders that contain a Schedule 5 and Schedule 6 medicine or scheduled substance are validated by a pharmacist;
- (8) the sale of a Schedule 1 and Schedule 2 medicine or scheduled substance without the prescription of an authorised prescriber: Provided that the supply of a Schedule 2 medicine or a scheduled substance takes place in consultation with a pharmacist;
- (9) the dispensing of Schedule 1 to Schedule 6 medicine or scheduled substances (i.e. the selection, manipulation or compounding of the medicine, the labelling and packing of the medicine in an appropriate container) on the prescription of an authorised prescriber: Provided that the pharmacist interprets and evaluates the prescription;
- (10) the provision of information to a patient, caregiver or the agent of a patient regarding the correct use of the medicine to optimise therapeutic outcomes;
- (11) general housekeeping and administrative tasks;
- (12) supervision of other pharmacist's assistants, as specified by the responsible pharmacist; and
- (13) the provision of technical support in the provision of screening tests: Provided that where an interpretation of results is required, this is done by a pharmacist.

13B. A pharmacy technician may provide or perform the following services or acts under the indirect personal supervision of a pharmacist:

- (1) the ordering of medicines and scheduled substances up to and including Schedule 6: Provided that orders that contain Schedule 6 are validated by a pharmacist;

- (2) the receipt and management of stock of Schedule 1 to Schedule 6 medicines or scheduled substances: Provided that orders received that contain Schedule 6 are validated by a pharmacist;
- (3) the receiving and screening of prescriptions for medicine which appear on the Essential Medicines List for primary health care or applicable formulary, and which is prescribed in accordance with Standard Treatment Guidelines;
- (4) the selection, manipulation or compounding of medicine prescribed and the labelling and packing of the medicine in an appropriate container;
- (5) the provision of information to a patient, caregiver or the agent of a patient about medicine dispensed;
- (6) the provision of information to a patient, caregiver or the agent of a patient about medicines which have been dispensed at a pharmacy and sent to the primary health care clinic or other facility as approved by council for supply to the patient or the patient's agent or caregiver;
- (7) the management of a dispensary or medicine room in a primary health care clinic in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act; and
- (8) general housekeeping and administrative tasks.

13C Pharmacy technician (learner).—

- (1) A pharmacy technician (learner) who is registered with a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician and who is undertaking work-based training, may provide the services or perform the acts prescribed in regulation 13A under the direct personal supervision of a pharmacist in a pharmacy.

- (2) The acts referred to in subregulation (1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.
- (3) A pharmacy technician (learner) may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy.

13D. Pharmacy technician (student)

- (1) A pharmacy technician (student) may, for purposes of education and training, and under the auspices of a provider of an education and training programme approved by council for purposes of registration as a pharmacy technician, and with whom such student is enrolled, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacy technician under the direct personal supervision of a pharmacist.
- (2) The services or acts referred to in subregulation (1) must be provided or performed in accordance with a programme developed by the provider and approved by the council in terms of the Act.
- (3) A pharmacy technician (student) may, after successful completion of the first year of study, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy.

13E. Pharmacy technician (trainee).—

- (1) A pharmacy technician (trainee) may for purposes of education and training, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacy technician under the direct personal supervision of a tutor.
- (2) The services or acts contemplated in subregulation (1) may only be performed by a pharmacy technician (trainee) as part of a traineeship.”
- (3) A pharmacy technician (trainee) may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist’s assistant registered in the category pharmacist’s assistant (post-basic) under the direct personal supervision of a pharmacist.”.

Substitution of regulation 14 of the Regulations

14. Regulation 14 is hereby amended by the substitution for regulation 14 of the following regulation:

“14. Supervision of pharmacy support personnel and pharmacist interns.—

- (1) A pharmacist may have a maximum of five pharmacy support personnel under his or her supervision: Provided that—
 - (a) a pharmacist has no more than three pharmacist’s assistants (learner basic), pharmacist’s assistants (learner post-basic), pharmacy technicians (learner), or pharmacy technicians (trainee) under direct personal supervision;
 - (b) a pharmacist who is a tutor to a pharmacist intern may have a maximum of four pharmacy support personnel under his or her supervision, of which only two may be pharmacist’s assistants (learner basic), pharmacist’s assistants (learner post-basic), pharmacy technicians (learner), or pharmacy technicians (trainee), and

- (2) A pharmacist who is a tutor to a pharmacist intern undergoing an internship at a provider of an education and training programme approved by the council for purposes of registration as a pharmacist, may act as tutor to a maximum of five such interns and no pharmacy support personnel;
- (3) a pharmacist may supervise a combination of pharmacy support personnel and interns in accordance with subregulations (1) and (2) or in accordance with guidelines as provided by council from time to time”.

Short Title

15. These Regulations are called Regulations Relating to the Practice of Pharmacy: Amendment, 2024.