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DEPARTMENT OF HEALTH

NO. 657 **12 JUNE 2020**

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO THE PRACTICE OF PHARMACY: AMENDMENT REGULATIONS, 2019

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of section 49(1)*(a)* and (3), read with section 35A of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the regulations in the Schedule.

The proposed amendments to these Regulations enable:

a) the establishment of a new category of pharmacy support personnel – pharmacy technician – with a new scope of practice;
b) the categorisation of pharmacy technicians as a type of pharmacist's assistant to enable these persons to handle medicines in accordance with the provisions of the Medicines and Related Substances Act, 1965, (Act 101 of 1965);
c) the retention of the categories of pharmacy support personnel - pharmacist's assistants (basic) and pharmacist's assistants (post-basic) - with amendments to the scope of practice;
d) two routes for the education and training and subsequent registration of pharmacy technicians – one via the Occupational Qualifications Sub-framework (OQSF), and the other via the Higher Education Qualifications Sub-framework (HEQSF);
e) registration of persons undertaking a pharmacy technician qualification which falls under the HEQSF, as a pharmacy technician (student) and completion of a traineeship whilst registered as a pharmacy technician (trainee);
f) registration of persons undertaking a pharmacy technician qualification which falls under the OQSF as a pharmacy technician (learner) and the option to exit as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) after completion of part

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qualifications. NOTE: There is no traineeship or internship required after completing these part-qualifications or the whole qualification;

g) upskilling of current pharmacist's assistants, whilst enabling those who are unable to undergo further education and training to continue to practise in the category in which they are registered.

Further information is available on the websites of the National Department of Health and the South African Pharmacy Council

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Any person wishing to comment on or make representation with regard to the proposed amendments to the Regulations is hereby invited to do so within three (3) months of the date of publication of this notice.

All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mihloti Mushwana, Director: Public Entities Governance in any one of the following ways:

(a) Hand delivered to:
Director-General: Health
National Department of Health
222 Thabo Sehume Street
Pretoria
0001

(b) By electronic mail: regulationcomments@health.gov.za

Comments received after the closing date may not be considered. Enquiries may be made to Mandie Bhembe on (012) 395 8288/8130 or regulationcomments@health.gov.za.

DR. ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH
DATE 24/03/2020

TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO THE PRACTICE OF PHARMACY MADE IN TERMS OF THE PHARMACY ACT, 1974 (ACT 53 OF 1974)

Name of Organisation / Individual:	
Date of submission:	

Comment no.	**Regulation, subregulation or paragraph**			**Comment and Rationale**	**Proposed Revised Text** **Bold underlined** – additions **[square brackets bold]** – deletions
	Reg	**Subreg**	**Par.**		
Example: 1	*4*	*(1)*	*(a)(i)*	*Provide a rationale for the comment.*	*Provide a revised text example.*

ADD MORE ROWS TO TABLE AS REQUIRED

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SCHEDULE

GENERAL EXPLANATORY NOTE:

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

Definitions

1. In this Schedule, the "Regulations" means the Regulations Relating to the Practice of Pharmacy, published under Government Notice No. R.1158 of 20 November 2000.

Amendment of regulation 1 of Regulations

2. Regulation 1 of the Regulations is hereby amended by—

(a) 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, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;";

(b) 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, in accordance with rules relating to good pharmacy practice published in terms of section 35A of the Act;";

(c) 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

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personal supervision of a tutor at a pharmacy approved by the council for purposes of such training;";

(d) substitution of the definition of "pharmacist's assistant" with the following definition:

'" **pharmacist's assistant"** means a 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';

(e) the insertion after the definition of "pharmacy student" of the following definitions:

" 'pharmacy technician' means a 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;**"**

(f) the substitution for the definition of "primary care drug therapy" of the following definition:

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" **'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;";

(g) 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;

(c) supplementary training; or

a course determined by the Council in terms of the Medicines Act;**";**

(h) the deletion of the definition of "qualification in pharmacy" after the definition of "public health facility"

(i) 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)

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or the in-service training of a pharmacist's assistant (learner basic) or pharmacist's assistant (learner post-basic);"; and

(j) 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 following regulation is hereby substituted for regulation 2 of the Regulations:

"**2. Conditions under which services or acts must be provided or performed**

The services or acts pertaining to the scope of practice of 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 specifically pertaining to the profession of a pharmacist as prescribed in regulation 3

Substitution of regulation 5 of Regulations

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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 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

6. 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

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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

7. 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 regulation 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

8. Regulation 9 of the Regulations is hereby amended by—

(a) the deletion of subregulation (1); and

(b) the substitution for subregulation (5) of the following subregulation:

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"(5) the distribution and control of stock of Schedule 1 to Schedule 5 medicines or scheduled substances; and".

Substitution of regulation 10 of the Regulations

9. 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 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."

Amendment of regulation 11 of Regulations

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10. Regulation 11 of the Regulations is hereby amended by the substitution for subregulations (5) and (6) of the following subregulations:

"(5) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances;

(6) the ordering of medicine 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 medicine or scheduled substance;".

Substitution of regulation 13 of the Regulations

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

"13. Pharmacist 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 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.

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(3) The acts referred to in subregulations 13(1) and 13(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 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 13D in Regulations

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

"13A. Pharmacy technician

(1) Subject to subregulation (3), a pharmacy technician may provide or perform the following services or acts under the direct personal supervision of a pharmacist:

(a) Assist with the manufacturing, compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance, in accordance with the Medicines Act, by performing the following functions:

(i) The weighing of materials including schedule 1 to 6 substances;

(ii) the checking and signing of the addition of materials to the mix after the pharmacist has checked each mass or volume and signed for each dispensed material in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;

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(iii) checking the identity of the bulk product and its identity label after the pharmacist has checked and signed in accordance with the Batch Manufacturing Document or prescription and in compliance with standard operating procedures;

(iv) the start-up line clearance and opening of the line as per documented procedure and detailed checklist: Provided that the pharmacist has provided the necessary signed authorisation therefor;

(v) in-process control during the manufacture of Schedule 0 to 6 medicine or scheduled substances: Provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist; and

(vi) the reconciliation of documents of Schedule 0 to 6 medicine or scheduled substances: Provided that the final release of the product is performed by a pharmacist;

(b) the packaging and re-packaging of Schedule 0 to Schedule 6 medicine or scheduled substances, in accordance with the Medicines Act, including--

(i) checking and signing the identity of the bulk product and printed packaging material in accordance with the Batch Manufacturing Document and in compliance with standard operating procedures;

(ii) start-up line clearance and opening of the packaging line in accordance with standard operating procedures and detailed checklist: Provided that the pharmacist has provided the necessary signed authorisation therefor; and

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(iii) in-process control during packaging and re-packaging of Schedule 0 to Schedule 6 medicines or scheduled substances: Provided that the pharmacist does periodic checks in accordance with standard operating procedures and that final line closure is signed off by the pharmacist;

(c) 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;

(d) picking, packing and despatch of orders for Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain Schedule 6 medicine are validated by a pharmacist prior to release thereof;

(e) the checking of orders containing Schedule 1 to Schedule 6 medicine in closed packs, prior to the packing and dispatch thereof, which have been picked by a pharmacist's assistant, as well as the supervision of such persons: Provided that this function may only be performed in a manufacturing pharmacy, wholesale pharmacy or bulk store of an institutional pharmacy;

(f) assisting with the management of stock of Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain medicine which fall into Schedule 5 and Schedule 6 are validated by a pharmacist;

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(g) the ordering and receipt of Schedule 1 to Schedule 6 medicine or scheduled substances: Provided that orders that contain Schedule 5 and Schedule 6 medicine are validated by a pharmacist;

(h) the sale of Schedule 1 and Schedule 2 medicine without the prescription of an authorised prescriber: Provided that the supply of a Schedule 2 medicine takes place in consultation with a pharmacist;

(i) 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 and 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) on the prescription of an authorised prescriber: Provided that the pharmacist interprets and evaluates the prescription;

(j) general housekeeping and administrative tasks in the pharmacy as specified by the responsible pharmacist;

(k) supervision of other pharmacist's assistants, as specified by the responsible pharmacist; and

(l) 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;

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(2) Subject to subregulation (3), a pharmacy technician may provide or perform the following services or acts under the supervision of a pharmacist who may not be physically present in a primary health care clinic or other facility as approved by the council:

(a) The ordering of Schedule 1 to Schedule 6 medicines or scheduled substances: Provided that orders that contain Schedule 6 are validated by a pharmacist;

(b) 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;

(c) receive and screen prescriptions for medicine which appears on the national Primary Health Care Essential Medicines List and which is prescribed in accordance with Standard Treatment Guidelines;

(d) the selection, manipulation or compounding of medicine prescribed, the labelling and packing of the medicine in an appropriate container;

(e) the provision of information to a patient, caregiver or the agent of a patient about medicine dispensed;

(f) 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;

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(g) 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

(h) general housekeeping and administrative tasks as specified by the supervising pharmacist.

(3) The services or acts referred to in subregulations (1) and (2) must be performed in accordance with the Act, the rules relating to good pharmacy practice published in terms of section 35A of the Act, the Medicines Act and where applicable, good manufacturing or distribution practice, as determined in terms of the Medicines Act.

13B 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 13B(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

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13C. 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 13C(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.

13D. 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.".

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Substitution of regulation 14 of Regulations

13. 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) the 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 supervision; and

(b) a pharmacist who is the 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) .

(2) A pharmacist who is a tutor of 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.".

Short Title

14. These Regulations are called the Amendment regulations relating to the practice of pharmacy, 2019 and are published for comment.