

DEPARTMENT OF HEALTH

NO. 656

12 JUNE 2020

PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)
REGULATIONS RELATING TO THE REGISTRATION OF PERSONS AND THE
MAINTENANCE OF REGISTERS: AMENDMENT REGULATIONS, 2019

The Minister of Health intends, in consultation with the South African Pharmacy Council, in terms of section 14 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

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.

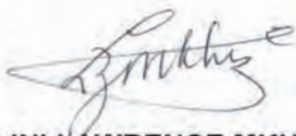
All such comments and representations must be submitted in writing using the format outlined in the attached template (available on www.health.gov.za), marked for the attention of Ms Mhloti Mushwana, Director: Public Entities Governance in any one of the following ways:

- (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

GENERAL EXPLANATORY NOTE:

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

SCHEDULE**Definitions**

1. In this Schedule the "the Regulations" means the Regulations Relating to the Registration of Persons and the Maintenance of Registers published under Government Notice No. 1160 of 20 November 2000.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by—
- (a) the deletion of the definition of "certificate of qualification" after the definition of "certificate of approval"
- (b) the substitution for the definition of "**continuing professional development**" of the following definition:
- "continuing professional development" means the process by which persons registered under this Act maintain and enhance their competence throughout their professional careers, and encompasses a range of activities including continuing education and supplementary training;"
- (c) 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);

(f) pharmacy technician (trainee);

(g) pharmacy technician; or

(h) pharmacy student;

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

- (d) the insertion after the definition of "**pharmacist's assistant**" of the following definitions:

" 'pharmacy technician' means a person registered as such in terms of the Act;

'pharmacy technician (learner)' means a person registered as such in terms of the Act;

'pharmacy technician (student)' means a person registered as such in terms of the Act;

'pharmacy technician (trainee)' means a person registered as such in terms of the Act;";

- (e) the substitution for the definition of "**provider**" 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
- a course determined by the Council in terms of the Medicines Act;”;
- (f) the deletion of the definition of “**qualification in pharmacy**” after the definition of provider;
- (g) the deletion of the definition of “**retail pharmacy**”
- (h) the insertion after the definition of “**supplementary training**” of the following definition:
- “**“traineeship”** means practical training, as determined by 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 council for purposes of such training;”;
- (i) the substitution for the definition of “**tutor**” of the following definition:
- “**“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
- (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 the Regulations

3. The following regulation is hereby substituted for regulation 2 of the Regulations:

"Categories of persons that may be registered

2. For purposes of registration in terms of the Act, there shall be the following categories of persons:

- (a) Pharmacy student;
- (b) Pharmacist intern;
- (c) Pharmacist;
- (d) Specialist pharmacist;
- (e) Pharmacist's assistant (learner basic);
- (f) Pharmacist's assistant (basic);
- (g) Pharmacist's assistant (learner post-basic);
- (h) Pharmacist's assistant (post-basic);
- (i) Pharmacy technician (student);
- (j) Pharmacy technician (learner);
- (k) Pharmacy technician (trainee);
- (l) Pharmacy technician;
- (m) Pharmacy owner;
- (n) Responsible pharmacist;
- (o) Nominee;
- (p) Tutor;
- (q) Provider;
- (r) Assessor; and
- (s) Moderator.

who must be registered by council in registers kept for these categories."

Substitution of regulation 3 of the Regulations

4. The following regulation is hereby substituted for regulation 3 of the Regulations:

"Requirements and conditions for registration as pharmacy student

3. Any person registered with a provider to undertake an education and training programme approved by the council for purposes of registration as a pharmacist, must register with the council as a pharmacy student at the commencement of the first year of study: Provided that no person shall be registered as a pharmacy student with the council unless he or she complies with the provisions of regulation 4."

Amendment of regulation 4 of the Regulations

5. Regulation 4(1) of the Regulations is hereby amended by—

- (a) the substitution for paragraph (b) of the following paragraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable study permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and"

- (b) the substitution for paragraph (c) of the following paragraph:

"(c) acceptable documentary evidence from the provider concerned that he or she has been admitted to the first or subsequent year of study for an education and training programme approved by the council for purposes of registration as a pharmacist; and"

Amendment of regulation 6 of the Regulations

6. Regulation 6(1) of the Regulations is hereby amended by the substitution for paragraph (a) of the following paragraph:

"(a) who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist"

Amendment of regulation 7 of the Regulations

7. Regulation 7 of the Regulations is hereby amended by the substitution for paragraph (b) of sub-regulation (1) of the following paragraph:

"(b) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted for the first or subsequent year of an education and training programme approved by the council for purposes of registration as a pharmacist; and"

Amendment of regulation 8 of the Regulations

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

8. Requirements and conditions for registration as a pharmacist intern.—Any person who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist must register as a pharmacist intern with the council: provided that no person shall be registered as a pharmacist intern, unless he or she complies with regulation 9.

Amendment of regulation 9 of the Regulations

9. Regulation 9(1) of the Regulations is hereby amended by—

(a) the substitution for paragraph (b) of the following paragraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and"

(b) the substitution for paragraph (d)(iii) of the following paragraph:

"(d)(iii) from the provider concerned, that he or she has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist; and"

Substitution of regulation 10 of the Regulations

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

"10. A person who complies with the requirements in regulation 9 must be registered as a pharmacist intern and issued with a registration certificate by the registrar."

Amendment of regulation 13 of the Regulations

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

13. Requirements and conditions for registration as a pharmacist. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, and —

(1) offered in the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 14;

(2) offered outside the Republic may apply to the registrar for registration as a pharmacist: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 17.

Amendment of regulation 14 of the Regulations

12. Regulation 14 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

“14. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, which is offered in the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist which is offered in the Republic, and who applies for registration as a pharmacist must—”

(b) the substitution for paragraph (1)(b) of the following paragraph:

“(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and”;

(c) the substitution for paragraphs (1)(c)(i) and 1(c)(ii) of the following paragraphs:

“(c)(i) he or she has successfully fulfilled the requirements of an education and training programme approved by the council for purposes of registration as a pharmacist;

- (ii) he or she has completed an internship: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of the council that he or she has undertaken practical training as part of his or her undergraduate studies under the supervision of a provider of an education and training programme approved by the council for purposes of registration as a pharmacist; and "

Amendment of regulation 15 of the Regulations

13. Regulation 15 of the Regulations is hereby amended by the substitution for the words preceding sub-regulation (1) of the following words:

"15. Any person who complies with the requirements in regulation 14 must be registered as a pharmacist and issued with a registration certificate by the registrar: Provided that any person registered as a pharmacist in terms of this regulation shall be entitled only to practise as such—"

Amendment of regulation 17 of the Regulations

14. Regulation 17 of the Regulations is hereby amended by—

- (a) the substitution for the preamble of the following paragraph:

"17. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist, which is offered outside the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist which is offered outside the Republic, and who applies for registration as a pharmacist must—"

(b) the substitution for paragraph (b) of sub-regulation (1) of the following paragraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

(c) the substitution for subparagraph (i) of paragraph (c) of sub-regulation (1) of the following subparagraph:

"(i) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated; "

(d) the substitution for subparagraph (ii) of paragraph (c) of sub-regulation (1) of the following subparagraph:

"(ii) the fact that he or she is registered as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

Amendment of regulation 18 of the Regulations

15. Regulation 18 of the Regulations is hereby amended by the substitution for sub-regulation (1) of the following sub-regulation:

"(1) register the applicant in one of the categories of pharmacist's assistant under such conditions as the council may determine from time to time; or"

Amendment of regulation 23 of the Regulations

16. Regulation 23 of the Regulations is hereby amended by the substitution for sub-regulation (2) of the following sub-regulation:

"(2) submit acceptable documentary evidence to the registrar that he or she has satisfied all the requirements as published in regulations made in terms of the Act;".

Substitution of regulation 24 of the Regulations

17. The following regulation is hereby substituted for regulation 24 of the Regulations:

"24. A pharmacist who complies with the requirements of regulation 23 and applicable regulations relating to specialities must be registered as a specialist pharmacist and be issued with a registration certificate by the registrar, indicating his or her specialty."

Substitution of regulation 28 of the Regulations

18. The following regulation is hereby substituted for regulation 28 of the Regulations:

"Requirements and conditions for registration as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic) or pharmacy technician (learner)"

28. Any person registered with a provider to undertake 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 must register with the council at the commencement of such learning programme: Provided

that no person will be registered with the council as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic) or pharmacy technician (learner), as the case may be, unless he or she complies with the provisions of regulation 29."

Amendment of regulation 29 of the Regulations

19. Regulation 29 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"29. Any person who applies for registration as a pharmacist's assistant in the category pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be, must —"

(b) the substitution for paragraph (b) of sub-regulation (1) of the following paragraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work or study permit as applicable, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and"; and

(c) the substitution for paragraph (c) of sub-regulation (1) of the following paragraph:

"(c) acceptable documentary evidence

(i) from the provider concerned that he or she has been registered for an education and training programme approved by the council for purposes of registration in the category pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician, as the case may be;

(ii) of approval by the council of the pharmacy where in-service training will be undertaken, and the tutor under whom the training will take place, where in-service training is a requirement of the

education and training programme referred to in subregulation 29(c)(i); and"

Substitution of regulation 30 of the Regulations

20. The following regulation is hereby substituted for regulation 30 of the Regulations:

"30. Any person who complies with the requirements of regulation 29 must be registered in the category pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner), as the case may be, and issued with a registration certificate by the registrar."

Repeal of regulation 31 of the Regulations

21. Regulation 31 of the Regulations is hereby repealed.

Amendment of regulation 32 of the Regulations

22. Regulation 32 is hereby amended by-

(a) the substitution for sub-regulation 32 (1) of the following paragraph:

32. Removal from the register.— (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacist's assistants (learner basic), pharmacist's assistants (learner post-basic) or pharmacy technician (learner), as the case may be, the name of a pharmacist's assistant—

(a) who has complied with the requirements 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 as the case may be;

(b) who no longer complies with the requirements and conditions for registration as a pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be; or

(c) who is deceased.

Substitution of regulation 33 of the Regulations

23. The following regulation is hereby substituted for regulation 33 of the Regulations

33. Restoration to the register.—A pharmacist's assistant (learner basic), pharmacist's assistant (learner post-basic), or pharmacy technician (learner) as the case may be, whose name was removed from the register in terms of regulation 32 may, if applicable, have his or her name restored to the register by—

(1) submitting to the registrar:

(a) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council; and

(b) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted to 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 and".

(2) paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register. If the registrar is not satisfied that he or she is a fit and proper person

to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Amendment to regulation 34 of the Regulations

24. The following regulation is hereby substituted for regulation 34 of the Regulations:

“34. Requirements and conditions for registration as a pharmacist’s assistant (basic) or pharmacist’s assistant (post-basic). Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist’s assistant (basic) or pharmacist’s assistant (post-basic), and —

(1) offered in the Republic may apply to the registrar for registration as a pharmacist’s assistant (basic) or pharmacist’s assistant (post-basic) provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 35;

(2) offered outside the Republic may apply to the registrar for registration as a pharmacist’s assistant (basic) or pharmacist’s assistant (post-basic): provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 37.”

Amendment of regulation 35 of the Regulations

25. Regulation 35 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

“35. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a

pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered in the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered in the Republic, and who applies for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) must—"

- (b) the substitution for paragraph (b) of sub-regulation (1) of the following subparagraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

- (c) the substitution for paragraph (c) of sub-regulation (1) of the following paragraph:

"(c) acceptable documentary evidence that he or she has successfully fulfilled the requirements of an education and training programme approved by the council for purposes of registration in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and has completed any in-service training required; and"

Substitution of regulation 36 of the Regulations

26. The following regulation is hereby substituted for regulation 36 of the Regulations:

"36. Any person who complies with the requirements of regulation 35 must be registered as a pharmacist's assistant in the category pharmacist's assistant (basic) or pharmacist's assistant (post-basic), as the case may be, and issued with a registration certificate by the registrar."

Amendment of regulation 37 of the Regulations

27. Regulation 37 of the Regulations is hereby amended by—

(a) the substitution for the preamble of the following paragraph:

"37. Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered outside the Republic. — Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic), which is offered outside the Republic, and who applies for registration as a pharmacist's assistant (basic) or pharmacist's assistant (post-basic) must—"

(b) the substitution for paragraph (b) of sub-regulation (1) of the following paragraph:

"(b) a certified copy of—

(i) his or her identity document or passport; and

(ii) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

(c) the substitution for subparagraph (i) of paragraph (c) of sub-regulation (1) of the following subparagraph:

"(i) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacist's assistant in the country in which the institution or examining body that awarded such qualification is situated; "

(d) the substitution for subparagraph (ii) of paragraph (c) of sub-regulation (1) of the following subparagraph:

"(ii) the fact that he or she is registered as a pharmacist's assistant in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;"

Repeal of regulation 43 of the Regulations

28. Regulation 43 of the Regulations is hereby repealed.

Insertion of Chapter IXA and regulations 56A to 56R

29. The following Chapter and regulations are hereby inserted in the Regulations after regulation 56 of the Regulations:

"CHAPTER IXA

Requirements and conditions for registration as pharmacy technician (student)

56A. (1) Any person registered with a provider to undertake an education and training programme approved by the council for purposes of registration as a pharmacy technician, may register with the council as a pharmacy technician (student) at the commencement of the first year of study: Provided that no person shall be registered as a pharmacy technician (student) with the council unless he or she complies with the provisions of 56B."

56B. Any person who applies for registration with the council as a pharmacy technician (student) must—

(a) submit to the registrar:

- (i) a duly completed application on a form approved and provided by council;
 - (ii) a certified copy of his or her identity document or passport;
 - (iii) a certified copy of a study permit, in the case of a student who is not a South African citizen or a permanent resident in the Republic of South Africa; and
 - (iv) acceptable documentary evidence from the provider concerned that he or she has been admitted to the first or subsequent year of study of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and
- (b) pay the registration fee as determined by the council.

56C. Any person who complies with the requirements in regulation 56B must be registered as a pharmacy technician (student) and issued with a registration certificate by the registrar.

Removal from the register

56D. (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacy technician (students) the name of a student who—

- (a) has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician;
- (b) no longer complies with the requirements and conditions for registration as a pharmacy technician (student): Provided that a student who interrupts his or her studies may, on making written application annually to the registrar, have his or her name retained on the register of pharmacy technician (students) for a period

not exceeding one year from the end of the year in which he or she interrupts his or her studies; or

(c) is deceased.

(2) A person whose name has been removed as contemplated in sub-regulation (1)(a) and (b), must be notified of the removal, and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56E. A pharmacy technician (student) whose name is removed from the register in terms of regulation 56D may, if applicable, have his or her name restored to the register—

(a) by submitting to the registrar—

- (i) a duly completed application for restoration of his or her name to the relevant register on a form as approved and provided by the council; and
- (ii) acceptable documentary evidence from the provider concerned to the effect that he or she has been re-admitted to an education and training programme approved by the council for purposes of registration as a pharmacy technician; and

(b) by paying the prescribed restoration fee; and

if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Requirements and conditions for registration as pharmacy technician (trainee)

56F. Any person who has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician, may register as a pharmacy technician (trainee) with the council: provided that no person may be registered as a pharmacy technician (trainee), unless he or she complies with regulation 56G.

56G. Any person who applies for registration as a pharmacy technician (trainee) must—

(a) submit to the registrar:

(i) a duly completed application on a form as approved and provided by council;

(ii) a certified copy of his or her identity document or passport;

(iii) a certified copy of a work permit, in the case of a person who is not a South African citizen or a permanent resident in the Republic of South Africa;

(iv) a duly completed and signed contract approved and provided by council for the undertaking of a traineeship; and

(v) acceptable documentary evidence—

(aa) of the approval by the council of the pharmacy where the traineeship will be undertaken;

(bb) of the registration of the tutor under whom such traineeship will take place;

(cc) from the provider concerned, that he or she has complied with the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and"

(b) pay the registration fee as determined by council.

56H. A person who complies with the requirements in regulation 56G must be registered as a pharmacy technician (trainee) and issued with a registration certificate by the registrar.

Removal from the register

56I. (1) Subject to sections 23, 24 and 39 of the Act, the registrar may remove from the register of pharmacy technicians (trainee) the name of a pharmacy technician (trainee)—

- (a) who has completed his or her traineeship to the satisfaction of the council;
- (b) who has not completed his or her traineeship to the satisfaction of the council;
- (c) who has discontinued his or her traineeship with the consent of the council;
- (d) who no longer complies with the requirements and conditions for registration as a pharmacy technician (trainee); or
- (e) who is deceased.

(2) A person whose name is removed in terms of sub-regulations (1)(a) to (d), must be notified thereof and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56J. A pharmacy technician (trainee) whose name is removed from the register in terms of regulation 56I, may, if applicable, have his or her name restored to the register—

- (a) by submitting to the registrar—

- (i) a duly completed application for restoration of his or her name to the register on a form as approved and provided by council;
 - (ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacy technician (trainee); and:
 - (iii) acceptable documentary evidence from a tutor to the effect that he or she has resumed his or her traineeship; and
- (b) by paying the prescribed restoration fee; and
- if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision.

Requirements and conditions for registration as pharmacy technician

56K. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician, and —

- a) offered in the Republic may apply to the registrar for registration as a pharmacy technician: provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 56L.
- (b) offered outside the Republic may apply to the registrar for registration as a pharmacy technician: Provided that he or she shall not be so registered unless he or she complies with the provisions of regulation 56N.

Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered in the Republic

56L. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered in the Republic, and who applies for registration as a pharmacy technician must—

(a) submit to the registrar:

- (i) a duly completed application on a form approved and provided by council;**
- (ii) a certified copy of his or her identity document or passport;**
- (iii) a certified copy of a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;**
- (iv) evidence of successful fulfillment of the requirements of an education and training programme approved by the council for purposes of registration as a pharmacy technician;**
- (v) proof of completion of a traineeship: provided that the council may exempt him or her partially or in full from this requirement on submission of documentary evidence to the satisfaction of the council that he or she has undertaken work based training under the supervision of a provider of an education and training programme approved by the council for purposes of registration as a pharmacy technician; and**
- (vi) acceptable documentary evidence that he or she has passed an examination or other evaluation as determined by council, if applicable; and**

(b) pay the registration fee as determined by the council.

56M. A person who complies with the requirements of regulation 56L must be registered as a pharmacy technician and issued with a registration certificate by the registrar.

Applicants who have successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered outside the Republic

56N. Any person who has successfully completed an education and training programme approved by the council for purposes of registration as a pharmacy technician which is offered outside the Republic, and who applies for registration as a pharmacy technician must—

(a) submit to the registrar:

(i) a duly completed application on a form as approved and provided by council;

(ii) a certified copy of—

(aa) his or her identity document or passport; and

(bb) a suitable work permit, should such person not be a South African citizen or a permanent resident in the Republic of South Africa; and

(iii) acceptable documentary evidence of—

(aa) the qualification obtained outside the Republic which entitles him or her to practise as a pharmacy technician in the country in which the institution or examining body that awarded such qualification is situated;

(bb) the fact that he or she is registered as a pharmacy technician in the country in which the institution or examining body that awarded such qualification is situated, should such person not be a South African citizen or a permanent resident in the Republic of South Africa;

(cc) the fact that he or she is a fit and proper person and in good standing as a pharmacy technician with the relevant registration authority; and

(dd) the practical training which he or she has undertaken and completed, if any; and

(b) pay the registration fee as determined by council.

56O. (1) The registrar must submit an application that complies with the requirements of regulation 56N to the council for evaluation, and the council may—

(a) refuse to register the applicant as a pharmacy technician;

(b) register the applicant as a pharmacy technician; or

(c) register the applicant in any other category of pharmacist assistant.

(2) The council may prior to approving an application for registration in terms of sub-regulation (1)(b), require that the applicant pass an examination or other evaluation determined by the council.

56P. A person registered in terms of regulation 56N must be issued with a registration certificate by the registrar.

Removal from the register

56Q. (1) Except as provided for in terms of sections 23, 24 and 39 of the Act, the registrar may remove from the register the name of a pharmacy technician—

- (a) who no longer complies with the requirements and conditions for registration as a pharmacy technician; or
- (b) who is deceased.
- (2) A pharmacy technician whose name is removed in terms of sub-regulation (1)(a), must be notified of such removal and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice is given.

Restoration to the register

56R. A pharmacy technician whose name is removed from the register in terms of regulation 56Q may, if applicable, have his or her name restored to the register—

- (a) by submitting to the registrar:
 - (i) a duly completed application for restoration of his or her name to the register on a form as approved and provided by the council;
 - (ii) acceptable documentary evidence that he or she complies with the conditions under which he or she may be registered as a pharmacy technician; and
 - (b) paying the prescribed restoration fee; and
- if the registrar is satisfied that he or she is a fit and proper person to be restored to the relevant register: Provided that if the registrar is not satisfied that he or she is a fit and proper person to be restored to the relevant register, the registrar must submit the application concerned to the council for a decision."

Substitution of regulation 71 of the Regulations

- 30.** The following regulation is hereby substituted for regulation 71 of the Regulations:

"71. The council may inspect premises in which the business of a pharmacy is carried out and may provide the pharmacy owner or the responsible pharmacist with a written report of the findings of such inspection, if it is found that such pharmacy does not comply with the prescribed requirements or is, in the opinion of the council, unsuitable for the conduct of a pharmacy business."

Substitution of regulation 91 of the Regulations

32. The following regulation is hereby substituted for regulation 91 of the Regulations:

"Requirements and conditions for registration of providers of pharmacy education and training

91. Only providers who comply with the minimum criteria for the approval of providers of pharmacy education and training as determined and published by council, shall be entitled to offer pharmacy education and training for purposes of registration as a pharmacist, pharmacist's assistant (basic), pharmacist's assistant (post-basic) or pharmacy technician, registration of a speciality, continuing professional development, supplementary training or courses determined by the Council in terms of the Medicines Act."

Insertion of regulation 91A

33. The following regulation is hereby inserted after regulation 91 of the Regulations:

"91A. No person or provider shall offer any education and training using the words "pharmacy", "pharmacist", "pharmaceutical" or any such other words which may imply the profession of pharmacy or pharmacy support personnel, unless such provider has been registered and such education and training have been approved by council."

Substitution of regulation 96 of the Regulations

34. The following regulation is hereby substituted for regulation 96 of the Regulations:

"96. Any pharmacist approved by the council as an assessor of pharmacy education and training must register with the council: Provided that no person must be registered as an assessor unless he or she complies with the provisions of regulation 97."

Substitution of regulation 98 of the Regulations

35. The following regulation is hereby substituted for regulation 98 of the Regulations

"98. An assessor who complies with the requirements of regulation 97 must be issued with a registration certificate by the registrar, subject to such conditions as may be determined by council."

Short Title

36. These Regulations are called the Amendment Regulations relating to the Registration of persons and the maintenance of registers, 2020 and are published for comment.

**TEMPLATE FOR COMMENT ON THE AMENDMENTS TO THE REGULATIONS RELATING TO THE
REGISTRATION OF PERSONS AND THE MAINTENANCE OF REGISTERS, 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