

GOVERNMENT NOTICE No. 333 published on 28/10/2005

THE PHARMACY (EDUCATION AND TRAINING)
REGULATIONS, 2005
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THE PHARMACY ACT, 2002

(No.7 of 2002)

REGULATIONS

(Made under section 38):

THE PHARMACY (EDUCATION AND TRAINING) REGULATIONS, 2005

PART I

PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Pharmacy (Education and Training) Regulations, 2005 and shall come into force on the date of publication.

**Interpretation
Act No.7
of 2002**

2. In these Regulations, unless the context otherwise requires:

"Act" means the Pharmacy Act, 2002;

"additional qualification" means a qualification obtained as part of continuing professional development, which is recognized by Council for purposes of registration;

"assessor" means any pharmacist appointed by Council in accordance with criteria determined by Council to measure outcomes of pharmacy education and training and includes National Council for Technical Education and Higher Education Accreditation Council;

"certificate of approval" means a certificate issued by Council to a person or institution that complies with the criteria determined by Council for the approval of providers;

"certificate of qualification" means a documentary evidence of a qualification required for enrolment of a pharmaceutical technician or enlisting of a pharmaceutical assistant;

"community pharmacy" means a pharmacy serving a certain community wherein there is provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, and they shall include but not limited to dispensing, furnishing information and advice to any

person with regard to medicine, determining patient compliance, evaluation of patient's medicine related needs and provision of pharmacist initiated therapy;

"contract" means a contract approved by Council which stipulates the conditions of an internship of an intern pharmacist or the in-service training of a pharmaceutical technician and pharmaceutical assistant;

"continuing professional development" means any additional training undertaken which does not lead to a new qualification;

"health facility" means any hospital, pharmacy, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment, pharmaceutical and nursing or other health care;

"pre- enrolment or enlisting additional practical training" means the training undertaken by a pharmaceutical technician and a pharmaceutical assistant under the direct supervision of a pharmacist approved by Council for purposes of such training;

"internship" means the additional practical training undertaken by an intern pharmacist in terms of a contract under the direct supervision of a pharmacist approved by Council for purposes of such training or at an institution registered as a provider of a qualification in pharmacy;

"institutional pharmacy" means a pharmacy situated in - a health facility wherein or from which there is provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs; and they shall include but not limited to dispensing, furnishing information and advice to any person with regard to medicine, determining patient compliance, evaluation of patient's medicine related needs and provision of pharmacist initiated therapy;

"manufacturing pharmacy" means a pharmacy involved in the production, preparation, processing, compounding, formulating, filling, refining, reprocessing, packaging, re-packaging and labeling of products regulated under the Tanzania Food, Drugs and Cosmetics Act, 2003;

"intern pharmacist" means a person registered as such under section 16 of the Act and who is undergoing additional practical training;

"qualification in pharmacy" means a qualification prescribed for purposes of registration as a pharmacist;

4.-(1) The course for a degree qualification in pharmacy shall extend over a minimum period of four years.

course
for a
qualifi-
cation in
pharma-
cy

(2) Where the course for a degree qualification in pharmacy includes practical training to the satisfaction of the Council of not less than one year or periods of not less than one year in the aggregate as part of the undergraduate studies, under the supervision of the provider, such course shall extend over a minimum period of five years.

5.-(1) Any person who holds a qualification in pharmacy shall prior to registration as a pharmacist, undertake an internship to the satisfaction of the Council for a period of not less than one year or periods of not less than one year in the aggregate.

General
require-
ments and
conditions
for intern-
ship

(2) Notwithstanding sub-regulation (1) the Council may exempt a person partially or in full from the requirement under sub-regulation (1) on submission of documentary evidence to the satisfaction of the Council that such person has undertaken practical training for a period of not less than one year or periods of not less than one year in the aggregate as part of undergraduate studies under the supervision of a person or an institution registered as a provider of a qualification in pharmacy.

6. The internship referred to in regulation 5 shall be undertaken-

Intern-
ship

- (a) in accordance with the terms of a contract;
- (b) in a community pharmacy or institutional pharmacy, approved by the Council for the purpose of such training, manufacturing pharmacy, or at a provider and approved by the Council for the purposes of such training;
- (c) manufacturing pharmacy and at community pharmacy or institutional pharmacy;
- (d) a provider and at community pharmacy or institutional pharmacy;
- (e) under the direct guidance of a supervisor.

Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

Condi-
tions for
com-
mencing
intern-
ship

7. No person shall commence an internship unless-

- (a) he is duly registered as an intern pharmacist under the Regulations relating to registration, enrollment and enlisting of persons;
- (b) a contract is entered into between the supervisor and the prospective intern pharmacist;
- (c) the pharmacy or institution registered as a provider at which the internship will take place has been approved by the Council; and
- (d) the supervisor has been approved by the Council.

Restric-
tion to
employ
an intern
pharma-
cist

8. No pharmacist, pharmacy or institution registered as a provider shall employ an intern pharmacist or treat such person as an intern pharmacist or in any other capacity which may imply or lead such person to believe that he is undertaking an internship, unless the requirements specified in regulations 6 and 7 have been complied with and such pharmacist, pharmacy or institution is registered as a provider as such and has been notified by the Registrar in writing thereof.

Period of
practical
training

9. The internship undertaken at an institution registered as a provider or in a manufacturing pharmacy shall include as part of such internship a period of not less than 6 months of practical training as determined by Council at a community or institutional pharmacy approved by Council for such training provided that-

- (a) the supervisor shall make the necessary arrangements for and keep the necessary records of such training; and
- (b) such periods of practical training shall be done on a basis of periods each of which shall be at least 5 consecutive days in a week in such approved community or institutional pharmacy.

10. No internship undertaken at an institution registered as a provider shall be recognized under the Act, unless the prospective supervisor has submitted to the Registrar—

Recogni-
tion of
intern-
ship
under-
taken at
a
provider

(a) full particulars of the proposed post-graduate study or research to be undertaken by the prospective intern pharmacist and the post-graduate study or research has been approved by Council; and

(b) acceptable documentary evidence that the prospective intern pharmacist is registered at such institution for the post-graduate study or research referred to in paragraph (a), which post-graduate study or research will lead to the awarding by such institution of at least a master's degree;

(c) a documentary proof that the provisions of regulation 9 shall be complied with.

11. Where an intern pharmacist, undergoing an internship at a community or an institutional pharmacy registered as a provider, discontinues his studies or research for any reason, or ceases to be registered at that provider, he shall receive recognition only for the period of practical training duly completed at a community or institutional pharmacy referred to in regulation.

Recogni-
tion of
partial
comple-
tion of
practical
training

12. The internship of an intern pharmacist at an institution registered as a provider, shall be regarded to be completed upon successful completion of the required period of practical training referred to in regulation 9 and the submission of acceptable documentary evidence to the Registrar that the intern pharmacist has satisfied the requirements of the institution for the awarding of at least a master's degree.

Comple-
tion of
addition-
al practi-
cal
training

Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

Cession
of
contract

13.-(1) A contract may be ceded in the event of:

- (a) the death of a supervisor, conviction of a supervisor for a serious offence, suspension or the removal of his name from the register of pharmacists;
- (b) conviction of a supervisor for an offence attracting a sentence of a period of not less than six months imprisonment;
- (c) the discontinuation of practice of the supervisor or the resignation of the supervisor from the pharmacy or provider approved for the internship of the an intern pharmacist;
- (d) the closure of the pharmacy or provider approved for the internship of the an intern pharmacist;
- (e) mutual consent between the supervisor and the intern pharmacist for a reason which is acceptable to the Registrar; or
- (f) for any other reason that the Council may deem fit.

(2) Where upon the occurrence of any event stipulated under sub-regulation (1), the intern pharmacist undertakes internship under another supervisor, the period of internship undertaken by the intern pharmacist under the original supervisor shall be recognized by the Council for the purposes of internship.

Approval
of the
contract
of
cession

14.-(1) An intern pharmacist intending to cede a contract to another supervisor shall within fourteen days before such cession occurs submit to the Registrar:

- (a) a duly completed application form as approved and provided by the Council;

- (b) a duly completed and signed contract of cession for the conducting of an internship approved and provided by the Council;
- (c) acceptable documentary evidence—
 - (i) of the approval by the Council of the pharmacy or provider where the internship of the an intern pharmacist shall be undertaken after cession of the contract;
 - (ii) of the approval by the Council of the supervisor under whose direct supervision such internship shall take place;
 - (iii) where applicable, that he is registered at an institution approved as a provider for a course of study which will lead to the awarding of at least a master's degree; and

(2) Where the contract cedes for reasons stated in regulation 13(d) and (e), an intern pharmacist shall pay the cession fee as shall be determined by the Council.

15.—(1) No pharmacist shall act as a supervisor to more than one an intern pharmacist.

(2) Notwithstanding sub-regulation (1)—

- (a) a supervisor practicing in a pharmacy in which other pharmacists practice on a full-time basis may act as supervisor to more than one an intern pharmacist, in which event he shall delegate the actual practical training of all such additional an intern pharmacists to such other pharmacists, provided that:—
 - (i) the responsibility for the effective practical training of all such an intern pharmacists shall remain with the supervisor;
 - (ii) the supervisor informs the Council in writing of such delegation or of any changes to such delegation; and

Delegation of training by an approved supervisor

- (iii) the internship is conducted in accordance with the provisions of these Regulations; and
- (b) a supervisor may act as supervisor to a second an intern pharmacist when a an intern pharmacist already under training with such supervisor has completed his ninth month of internship; or
- (c) a supervisor in an institution approved by the Council as a provider may, with the prior approval of the Council, act as a supervisor to more than one an intern pharmacist.

Supervi-
sor to
submit
assess-
ment
form to
the
Registrar

16. The supervisor shall—

- (a) submit to the Registrar:
 - (i) assessment forms as approved and provided by the Council on the progress of the an intern pharmacist during the period of internship; and
 - (ii) an affidavit at the end of the period of internship stating that the training has been completed satisfactorily in accordance with the Council's requirements for an internship and that the an intern pharmacist is a fit and proper person to be registered as a pharmacist;
- (b) if applicable, submit to the Registrar an affidavit at the end of the period of internship referred to in regulation 9 to confirm that the prescribed minimum period of six months has been completed satisfactorily in accordance with the Council's requirements for an internship at an institution registered as a provider of a qualification in Pharmacy or in a manufacturing pharmacy.

Pre-reg-
istration
examina-
tion

17.—(1) The Council may, before registering a pharmacist under the Act, impose a pre-registration examination or evaluation as a pre-requisite for registration;

(2) where a person requiring registration fails a pre-examination or evaluation, the Council may require;

- (a) such person to be re-evaluated or re-examined at a time and date as may be determined by the Council; or

(b) such person's period of practical training to be extended by an additional period or periods as the Council may determine.

(3) No person shall undergo a pre-registration examination or evaluation unless he pays pre-registration examination or evaluation fee prescribed in the Fifth schedule.

18. A person who complies with requirements relating to registration prescribed in the Pharmacy (Registration of Pharmacists, Enrollment of Pharmaceutical Technicians and Enlisting of Pharmaceutical Assistants) Regulations 2005 shall be entitled to be registered.

Qualifica
tion in
pharma-
cy enti-
tling
pharma-
cists to
registra-
tion

PART III

STANDARDS OF EDUCATION AND TRAINING OF PHARMACEUTICAL TECHNICIANS

19. The unit standards for a certificate of qualification for a pharmaceutical technician shall be as set out in the Second Schedule to these Regulations.

Unit
standards
for phar-
maceuti-
cal tech-
nicians

20. A provider shall provide learning programs for purposes of conferring a certificate of qualification in accordance with a curriculum that ensures the required outcomes of the unit standards as set out in the Second Schedule to these Regulations.

Learning
programs
for phar-
maceuti-
cal tech-
nicians

21. A provider who holds a certificate of approval shall be entitled to provide education and training for purposes of conferring a certificate of qualification.

Certifi-
cate of
qualifi-
cation

22.--(1) The minimum entry requirements for admission to a learning programs to obtain a certificate of qualification for a pharmaceutical technician shall be the entry assumptions as determined by providers and approved by National Council for Technician Education or the Higher Education Accreditation Council.

Entry
require-
ments
for
obtaining
a certi-
ficate of
qualifi-
cation

(2) Notwithstanding sub-regulation (1), the provider may admit a pharmaceutical technician to a learning program to obtain a certificate of qualification by the recognition of prior learning obtained by such person upon the provision by such person of documentary evidence of competency and skills acquired to the satisfaction of the provider.

Evaluation prior to enrolment

23.-(1) The Council may, when it deems necessary, arrange for an evaluation prior to enrolment as a pharmaceutical technician.

(2) The evaluation arranged under sub-regulation (1) shall be conducted in accordance with a procedure as determined by the Council or National Council for Technician Education and on payment of the evaluation fee prescribed in the Fifth Schedule.

Pre-enrolment additional practical training duration

24. A person who wishes to be enrolled shall before enrollment be required to undergo an additional practical training for a minimum period of nine months.

General requirements and conditions for pre-enrolment additional practical training

25. The pre-enrolment additional practical training referred to in regulation 24 shall be undertaken—

- (a) at a community pharmacy, institutional pharmacy, provider, manufacturing pharmacy or wholesale pharmacy approved by the Council for purposes of such training; and
- (b) under the guidance of a supervisor approved by the Council.

Pre-enrolment additional practical training for pharmaceutical technician

26. No person shall commence pre-enrolment additional practical training unless:—

- (a) he is duly qualified as pharmaceutical technician in accordance with these Regulations;
- (b) the pharmacy at which the pre-enrolment additional practical training will take place has been approved by Council for such pre-enrollment training;
- (c) the supervisor has been approved by Council; and

- (d) a contract has been entered into between the supervisor and the respective person.

27.-(1) A supervisor may delegate the actual pre-enrolment additional practical training of a pharmaceutical technician to another pharmacist practicing in a full-time capacity in the same pharmacy.

Delegation of pre-enrolment additional practical training of pharmaceutical technician

(2) Notwithstanding sub-regulation (1), where the supervisor delegates the actual pre-enrolment additional practical training of the pharmaceutical technician to a pharmacist, the supervisor shall be responsible to ensure that the pre-enrolment additional practical training shall be completed in accordance with the provisions of these Regulations and that Council is informed in writing of such delegation.

28. No pharmacist, pharmacy or institution registered as a health facility shall employ any person as a pharmaceutical technician or treat such person in any other capacity which may imply or lead such person to believe that he is undertaking a period of pre-enrolment additional practical training, unless the provisions of regulations 25 and 26 have been complied with and such pharmacy and pharmacist is registered and have been notified by the Registrar in writing thereof.

Restriction to employ pharmaceutical technicians

29.-(1) No pharmacist shall undertake to act as a supervisor to more than three pharmaceutical technicians undergoing pre-enrolment additional practical training.

Supervision of pharmaceutical technician undergoing pre-enrolment additional practical training

(2) Notwithstanding sub-regulation (1), the Council may approve a written application for an increase in the ratio as stipulated in sub-regulation (1): provided that—

- (a) each application is treated on its own merit;
- (b) the motive for such application is to the satisfaction of the Council; and
- (c) any increase in the ratio approved by Council shall apply in that specific circumstance or situation only and be subject to such conditions as Council may determine.

Provider
to submit
notification to
Registrar

30. Any provider shall submit to the Registrar upon successful assessment of a pharmaceutical technician, a notification of final examination results.

Council
may
impose
assessment or
evaluation

31.—(1) The Council may, before enrolling pharmaceutical technician impose a pre-enrolment examination or evaluation as a prerequisite for enrollment.

(2) Where person requiring enrolment fails pre-requisite examination or evaluation, the Council may require:—

- (a) such person to be re-evaluated or re-examined at a time and date as may be determined by Council; or
- (b) such person's period of practical training to be extended by an additional period or periods as the Council may determine.

Certificate of
qualification
entitling
pharmaceutical
technician to
enrollment

32. Certificate of qualification shall entitle the holder thereof to enrollment as a pharmaceutical technician and as the case may be, in terms of the Act if that pharmaceutical technician if he has complied with the requirements for pre-enrollment training in terms of these Regulations.

PART IV

STANDARDS OF EDUCATION AND TRAINING OF PHARMACEUTICAL ASSISTANTS

Unit
standards
for pharmaceutical
assistants

33. The unit standards for a certificate of qualification for a pharmaceutical assistant shall be as set out in the Third Schedule to these Regulations.

Learning
programs
for pharmaceutical
assistants

34. A provider shall provide learning programs for purposes of conferring a certificate of qualification in accordance with a curriculum that ensures the required outcomes of the unit standards set out in the Third Schedule to these Regulations.

35. A provider shall be required to provide education and training for the purposes of conferring a certificate of qualification.

Certificate of qualification

36.-(1) The minimum entry requirements for admission to a learning program to obtain a certificate of qualification for a pharmaceutical assistant shall be the entry assumptions as determined by providers and approved by the National Council for Technician Education or the Higher Education Accreditation Council.

Entry requirement for obtaining certificate of qualification by a pharmaceutical assistants

(2) Notwithstanding sub-regulation (1), the provider may admit a pharmaceutical assistant to a learning program for purposes of obtaining a certificate of qualification by the recognition of prior learning obtained by such person upon the provision by such person of documentary evidence of competency and skill acquired to the satisfaction of the provider.

37.-(1) The Council may, when it deems necessary, arrange for an evaluation prior to enlisting as a pharmaceutical assistant.

Evaluation prior to enlisting

(2) The evaluation arranged under sub regulation (1) shall be conducted in accordance with the procedure determined by the Council or the National Council for Technician Education and payment of evaluation fee prescribed in the Fifth Schedule.

38. A person who wishes to be enlisted shall, before enlisting, be required to undergo an additional practical training for a minimum period of six months.

Pre-enlisting additional practical training duration

39. The pre-enlisting additional practical training referred to under regulation 38 shall be undertaken: -

General requirements and conditions for pre-enlisting additional practical training

(a) at a community pharmacy, institutional pharmacy, provider, manufacturing pharmacy or wholesale pharmacy approved by the Council for purposes of such training; and

(b) under the guidance of a supervisor approved by the Council.

Pre-enlisting additional practical training for a pharmaceutical assistant

40. No person shall commence pre-enlisting additional practical training unless:-

- (a) he is duly qualified as a pharmaceutical assistant in accordance with these Regulations;
- (b) the pharmacy at which the pre-enlisting additional practical training will take place has been approved by the Council for such training;
- (c) the supervisor has been approved by the Council; and
- (d) a contract has been entered into between the supervisor and the respective person.

Delegation of pre-enlisting additional practical training of pharmaceutical assistants

41.-(1) A supervisor may delegate the actual pre-enlisting additional practical training of a pharmaceutical assistant to another pharmacist practicing in a full time capacity in the same pharmacy.

(2) Notwithstanding sub-regulation (1), where the supervisor delegates the actual pre-enlisting additional practical training of a pharmaceutical assistant to a pharmacist, the supervisor shall be responsible to ensure that the pre-enlisting additional practical training is completed in accordance with the provisions of these Regulations and that the Council is informed in writing of such delegation.

Restriction to employ pharmaceutical assistant

42. No pharmacist, pharmacy or institution registered as a health facility shall employ any person as a pharmaceutical assistant or treat such person in any other capacity which may imply or lead such person to believe that he is undertaking a period of pre-enlisting additional practical training, unless the provisions of regulations 40 and 41 have been complied with, and such pharmacy and pharmacist are registered and have been notified in writing by the Registrar.

Supervisor of pharmaceutical assistant undergoing pre-enlisting additional practical training

43.-(1) No pharmacist shall undertake to act as a supervisor to more than two pharmaceutical assistants who are undergoing pre-enlisting additional practical training.

(2) Notwithstanding sub-regulation (1), the Council may approve a written application for an increase in the ratio as stipulated in sub-regulation (1), provided that:-

- (a) each application shall be treated on its own merits;
- (b) the motive for such application is to the satisfaction of the Council;
- (c) any increase in the ratio approved by the Council shall apply in that particular circumstance or situation only and be subject to such conditions as the Council may determine.

44. A provider shall submit to the Registrar upon the successful assessment of a pharmaceutical assistant, a notification of final examination results.

Provider
to submit
notification
to
Registrar

45.-(1) The Council may before enlisting a pharmaceutical assistant, impose a pre-enlisting examination or evaluation as a pre-requisite for enlistment.

Council
may
impose
examination
or
evaluation

(2) Where a person requiring enlisting fails an examination or evaluation imposed under this regulation, the Council may require:-

- (a) such person to be re-evaluated or re-examined at a time and date as may be determined by Council;
- (b) such person's period of practical training to be extended by an additional period or periods as the Council may determine.

46. A certificate of qualification shall entitle the holder thereof to be enlisted as a Pharmaceutical Assistant under the Act if a pharmaceutical assistant has complied with the requirement of pre-enlisting training under these Regulations.

Certificate of
qualification
entitling
pharmaceutical
assistant
to enlist-
ing

PART V

APPROVAL OF SUPERVISOR AND PREMISES FOR PURPOSES OF
EDUCATION AND TRAINING

Application for approval as a supervisor or provider

47.-(1) A pharmacist who wishes to be appointed as a supervisor, shall submit to the Registrar application in the prescribed form for:

- (a) the approval of the supervisor under whom an internship or pre-enrollment or pre-enlisting additional practical training is contemplated; and
- (b) the approval of the pharmacy or provider at which an internship or pre-enrolment or pre-enlisting additional practical training is contemplated.

(2) Upon acceptance by the Registrar of the application made under sub-regulation (1), the applicant shall pay an evaluation fee set out in the Fifth Schedule to these Regulations.

(3) A supervisor who wishes his name to be retained in the Register, shall pay a retention fee set out in the Fifth Schedule to these Regulations.

Approval of premises/ pharmacy or provider

48.-(1) Upon receipt of the application and the fee referred to in regulation 47, the Registrar shall within fourteen days cause a Council Committee to be appointed, appoint inspectors to inspect the pharmacy or provider.

(2) The Council Committee, inspectors appointed under sub-regulation (1), shall be composed of three members and shall be:-

- (a) registered pharmacists who are conversant with the practice of pharmacy and who have experience of a period of not less than three years;
- (b) persons who have no direct or indirect beneficial interest in the pharmacy or provider to be inspected.

(3) Notwithstanding sub-regulation (2), where the Council Committee, inspectors are appointed to inspect a provider, the team leader of such committee or inspectors shall be a person who has qualification of at least a masters degree in Pharmacy.

49.-(1) Upon receipt of the application for approval as a supervisor and the fee referred to under regulation 47, the Registrar shall arrange for the examination or evaluation prior to the approval of a pharmacist as a supervisor.

Approval
as a
supervi-
sor

(2) Where the pharmacist satisfies the Council on the examination or evaluation conducted under sub-regulation (1), the Council shall approve and appoint the pharmacist to be a supervisor under whom an internship or pre- enrolment or pre-enlisting additional practical training can be conducted.

(3) Where the pharmacist fails an examination or evaluation, the Council may require such pharmacist upon payment of the prescribed fee re- evaluated at a time and date as the Council may determine.

50. The Councilor inspectors, appointed under regulation 48 shall within fourteen days of the receipt of the Registrar's request, satisfy itself by a physical inspection of such pharmacy or provider so as to satisfy himself as to whether or not it conforms to the minimum criteria determined by the Council for the training of intern pharmacists, pharmaceutical technicians and pharmaceutical assistants and shall, within seven days, submit to the Registrar a written report on a form approved and provided by Council.

Council
commit-
tee or
Inspector
to
inspect
and
submit
report

51. The applicant who applied for approval to act as supervisor shall be required to co-operate with the committee or inspectors appointed by the Council and provide the necessary assistance to enable them carry out inspection.

Applica-
nt phar-
macists
to coop-
erate
with
inspector

52. A pharmacy or provider may be inspected whenever an application is made for an internship or pre-enrollment or pre-enlisting additional training to be undertaken at such pharmacy or provider.

Pharma-
cy or
provider
to be
inspected
frequent-
ly

Inspector's remuneration

53. An inspector appointed by the Council shall be remunerated by the Council as the Council may determine.

PART VI

APPROVAL OF PROVIDERS OF PHARMACY EDUCATION AND TRAINING

Application for approval as provider

54. Any person who applies for approval as provider by the Council shall submit to the Registrar:-

- (a) a duly completed application form approved by the Council together with an acceptable documentary evidence;
- (b) a fee as prescribed in the Fifth Schedule to these Regulations.

Inspection of a provider

55. The Council may arrange for an inspection of a provider prior to the approval as a provider.

Approval of providers

56.-(1) The Council may approve providers of education and training for purposes of:-

- (a) conferring a qualification in pharmacy or a certificate of qualification;
- (b) additional qualifications or supplementary training; or
- (c) continuing professional development.

Cancellation of approval

57.-(1) The Council may at any time cancel an approval as a provider where:-

- (a) the provider has failed to meet the approval criteria of the Council;
- (b) the provider has failed to discharge its duties and responsibilities as a provider; or

- (c) the provider has failed to comply with the provisions of the Act or these Regulations.

(2) The Registrar shall strike the name of each cancelled provider from the Register.

58. Where the name of the provider has been deleted from the Register under regulation 57, the Council may on application in the prescribed manner and upon payment of the fee prescribed in the Fifth Schedule direct the Registrar to restore the name of such provider in the Register.

Restora-
tion to
the
Register

59.-(1) The approval of providers under regulation 56 shall be subject to:-

Mini-
mum cri-
teria and
condi-
tions for
approval

- (a) minimum criteria for the approval of providers as determined and published by the Council;
- (b) such conditions and for such period or periods of time as the Council may determine; and
- (c) satisfaction of conditions set by the National Council for Technical Education or the Higher Education Accreditation Council.

(2) Subject to the provisions of sub regulation (1):-

- (a) providers of education and training for purposes of conferring a certificate of qualification or for purposes of continuing professional development may be approved for a maximum period of three years; and
- (b) providers of education and training for purposes of conferring a qualification in pharmacy may be approved for a maximum period of five years.

60.-(1) The Council shall inspect providers to measure compliance with the requirements determined by the Council for the provision of pharmacy education and training at least every three years or at intervals as determined by the Council, from time to time.

Inspec-
tion of
providers

Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

(2) A person appointed by the Council to perform inspection referred to in regulation 55 shall:—

- (a) be conversant with pharmacy education and training;
- (b) not have a direct or indirect beneficial interest in the provider to be inspected; and
- (c) where applicable, provide documentary evidence to the satisfaction of the Registrar of expert knowledge in an area being evaluated.

(3) A person appointed to inspect a provider shall, within fourteen days from the date of such inspection, submit a written report to the Registrar of his finding.

(4) A person appointed to inspect a provider shall be remunerated by the Council as determined by the Council from time to time.

Council
may vary
amend or
withdraw
provider's
approval

61.-(1) The Council may vary, amend or withdraw the approval of provider if the provider fails to comply with the Council's terms and conditions for his approval.

(2) The Council shall not vary, amend or withdraw the approval of a provider unless the Council has:—

- (a) accorded or afforded such provider an opportunity to furnish reasons why the approval should not be withdrawn or amended; and
- (b) Given due notice to the provider.

PART VII

MISCELLANEOUS PROVISIONS

Approved
institu-
tions

62. The institutions as set out in the Fourth Schedule to these Regulations, shall be deemed to be approved and registered to provide education and training for a qualification in pharmacy at the commencement of these Regulations.

- | | |
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| <p>63. The Council may, upon application and payment of the fee prescribed in the Fifth Schedule to these Regulations approve courses for purposes of continuing professional development, subject to such conditions as the Council may determine.</p> | <p>Approval of courses for purposes of continuing professional development</p> |
| <p>64. The Council may, upon application by the provider and payment of a fee prescribed in the Fifth Schedule to these Regulations approve a new academic program, subject to such conditions as the Council may determine.</p> | <p>Approval of a new academic program</p> |
| <p>65. There shall be paid such fees as prescribed under the Fifth Schedule to these Regulations, namely:-</p> | <p>Fees</p> |
| <p>(a) by providers of pharmacy education and training for:</p> <ul style="list-style-type: none"> (i) the application to be a provider; (ii) evaluation of application for purposes of approval as a provider; (iii) the approval of continued professional development; (iv) the approval of a new academic program; (v) registration of the provider; (vi) renewal of registration after every three years; (vii) restoration in case of deletion of the name from the Register. | |
| <p>(b) by a supervisor for:-</p> <ul style="list-style-type: none"> (i) application to be a supervisor; (ii) evaluation of application; and (iii) restoration. | |

- (c) by a person lodging a notice of appeal against:-
 - (i) a decision regarding registration;
 - (ii) a decision against suspension or cancellation; and
 - (iii) an objection by a person other than the provider.
- (d) by any person for:-
 - (i) issuing a duplicate certificate; and
 - (ii) entrance to the professional examination for the purpose of registration as a pharmacist per paper;

Minister
may
amend
Schedules

66. The Minister may amend any of the Schedule to these Regulations.

FIRST SCHEDULES

(Under regulation 3)

UNIT STANDARDS FOR PHARMACISTS

Holder of the qualification will be able to apply knowledge, skills and understanding in a wide and unpredictable variety of contexts with substantial personal responsibility, responsibility for work of others and responsibility for allocation of resources, policy, planning, execution and evaluation.

The following unit standards are prescribed for pharmacists in terms of Section 4 (d), (c), (i) and (j) of the Act:-

- (a) organize the manufacturing, compounding and packaging of pharmaceutical products;
- (b) organize the procurement, storage and distribution of pharmaceutical products;
- (c) dispense and ensure the optimum use of medicine prescribed to the patient;

- (d) provide pharmacist initiated care to the patient and ensure the optimum use of medicine;
- (e) provide education and information on health care and medicine;
- (f) promote community health and provide related information and advice;
- (g) design, undertakes or participates in research to ensure the optimal use of medicine.

SECOND SCHEDULE

(Under regulation 19)

UNIT STANDARDS FOR PHARMACEUTICAL TECHNICIANS

Holder of the qualification will be able to apply skills and knowledge in a broad range of work activities, most of which are non-routine.

The following unit standards are prescribed for pharmaceutical technician in terms of Section 4 (d),(e),(i) and (j) of the Act:-

- (a) provision of health advice, information on pharmacy products directly to the consumer;
- (b) provision of pharmacy products in hospital pharmacy;
- (c) pharmacy marketing;
- (d) stock control;
- (e) manufacturing/compounding of pharmaceutical products;
- (f) packaging and/or pre-packing of pharmaceuticals;
- (g) control and distribution of finished pharmacy products;
- (h) collect information for research purposes.

THIRD SCHEDULE

(Under regulation 33)

UNIT STANDARDS FOR PHARMACEUTICAL ASSISTANT

Holder of the qualification will be able to apply skills in a range of activities, some of which are non-routine and be able to assume operational responsibilities.

The following unit standards are prescribed for pharmaceutical assistants in terms of Section 4(d), (e) (i) and (j) of the Act:-

- (a) issuing of pharmacy products and information to consumers;
- (b) stock control;
- (c) manufacturing/compounding of pharmaceutical products;
- (d) packaging and/or pre-packing of pharmaceuticals;
- (e) control and distribution of finished pharmacy products;
- (f) collect information for research purposes.

FOURTH SCHEDULE

(Under regulation 62)

APPROVED INSTITUTIONS IN TANZANIA WHICH PROVIDE
EDUCATION AND TRAINING

The following institutions in the Mainland Tanzania shall be regarded to be providers approved and registered to provide education and training for purposes of conferring qualification in pharmacy:-

- (a) School of Pharmacy Muhimbili University College of Health Sciences; University of Dar es Salaam;
- (b) School of Pharmaceutical Sciences Muhimbili University College of Health Sciences; University of Dar-es-Salaam;
- (c) School of Pharmaceutical Technicians; St. Augustine University Bugando Mwanza;
- (d) School of Pharmacy Kilimanjaro, Moshi.

FIFTH SCHEDULE

(Under regulation 14(2), 17(3), 23(2), 32(2), 47(2,3), 49(3), 58, 63, 64, 65)

	Approved fee
A: Registration fee (payable with duly completed	
(i) Pharmacy Education	\$ 1000
(ii) Assessors	\$ 30
B: Renewal fees (Payable on the dates as indicated	
(i) Pharmacy Education Provider (payable every 3)	\$ 300
(ii) Assessor (payable every year)	\$ 30
C: Restoration fees	
Restoration fee should be published by order of the	\$ 500
D: Other Fees	
(1) Provider of pharmacy education and training	
(2) Any person lodging a Notice of Appeal in terms	
(3) Any person for:-	
Application fee for supervisor	\$ 20
Registration fees for supervisor	\$ 30
Retention fees for supervisor	\$ 30

Dar-es- Salaam,
....., 2005

ANNA M. ABDALLAH, (MP.)
Minister for Health