

# THE UNITED REPUBLIC OF TANZANIA

# THE PHARMACY (REGISTRATION, ENROLLMENT AND ENLISTING OF PERSONS) REGULATIONS, 2005 G.N. No. 332 of 2005

# THE PHARMACY (EDUCATION AND TRAINING REGULATIONS, 2005 G.N. No. 333 of 2005

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# THE PHARMACY (REGISTRATION, ENROLLMENT AND ENLISTING OF PERSONS) REGULATIONS, 2005

Regulation

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# THE PHARMACY ACT, 2002

(No. 7 of 2002)

# REGULATIONS

(Made under section 38)

THE PHARMACY (REGISTRATION OF PHARMACISTS, ENROLLMENT OF PHARMACEUTICAL TECHNICIANS AND ENLISTING OF PHARMACEUTICAL ASSISTANTS) REGULATIONS, 2005

### PART I PRELIMINARY PROVISIONS

1. These Regulations may be cited as the Pharmacy (Registration Ci of Pharmacists, Enrollment of Pharmaceutical Technicians and Enlisting of Pharmaceutical Assistants) Regulations, 2005, and shall come into operation on the date of publication.

Citation

2. In these Regulations, unless the context otherwise requires: "Act" means the Pharmacy Act, 2002;

" Authority" means Tanzania Food and Drugs Authority, or the acronym "TFDA"; established under the Tanzania Food Drugs and Cosmetics Act, 2003;

"Council" means the Pharmacy Council established by Section 3 of the Act;

- "Committee" means a Committee established under section 7 of the Act; "certificate of enrollment" means the certificate issued to a
- Pharmaceutical Technician under section 24 of the Act, upon being enrolled by the Council;
- "certificate of enlisting" means the certificate issued to a Pharmaceutical Assistant under section 29 of the Act, upon being enlisted by the Council;
- "certificate of registration" means the certificate issued to a Pharmacist under section 18 of the Act, upon registration by the Council;

Interpretation Act No. 7 of 2002

Act No. of 2003

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- "community pharmacy" means a pharmacy where there is provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which 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, excluding institutional pharmacy;
- "continuing professional development" means the process by which pharmacists and pharmacist's assistants continuously enhance their knowledge, skills and personal qualities throughout their professional careers and encompasses a range of activities including continuing education and supplementary training;

"institutional pharmacy" means a pharmacy situated in:-

- (a) a public health facility, where there is provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which 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; or
- (b) a private health facility or any hospital, institution or facility at which provision is made for diagnostic interventions, or surgical treatment and nursing or other health care, which is not owned or controlled by the government;
- "internship" means the practical training undertaken by an intern pharmacist, pharmaceutical technician and pharmaceutical assistant in terms of a contract under the direct supervision of a registered pharmacist approved by the Council for purposes of such training or at an institution registered as a provider of a qualification in pharmacy;

"list" means a list maintained under section 27 of the Act;

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

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- "pharmacist" means a person registered under section 15 of the Act; "pharmaceutical technician" means a person enrolled under section 23 of the Act;
- "Pharmacist's Assistants from Education Training" means Pharmaceutical Technicians or Pharmaceutical Assistants;
- "pharmaceutical assistant" means a person enlisted under section 28 of the Act;
- "pharmacy owner" means any person who owns a pharmacy and who is registered as such under the Tanzania Food, Drugs and Cosmetics Act, of 2003;
- "private health facility" means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment and nursing or other health care, which is not owned or controlled by the government;
- "provider" means any person or institution approved by and registered with the Council to provide education and training for purposes of conferring a qualification in pharmacy for purposes of continuing professional development;
- "public health facility" means any hospital, institution or facility at which provision is made for diagnostic interventions, medical or surgical treatment and nursing or other health care, which is owned or controlled by the Government or government organ;
- "Registrar" means the Registrar of the Council appointed under section 11 of the Act;
- "Register" means a register maintained under section 14 of the A.
- "retail pharmacy" means a business, which consists of or includes the retail sale of drug products but, does not include a professional practice carried by a Medical Practitioner, Dentist or Veterinary Surgeon;
- "roll" means a roll maintained under section 22 of the Act;
- "supplementary training" means training approved by the Council which empowers a registered, enrolled or enlisted person to perform activities or provide services, in terms of the Act, which fall outside the scope of practice of the category in which he is registered, enrolled or enlisted; and
- "wholesale pharmacy" means a pharmacy wherein or from which services such as wholesale distribution of any medicine, or scheduled substance ,furnishing of information and advice to any

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person with regard to medicine distributed by him, promotion of public health in accordance to guidelines, initiation and conducting of pharmaceutical research and development and any other health services as may be approved by Council, are provided.

Categories of persons that may 3.-(1) The Registrar shall keep and maintain such registers for purposes of registering, enrolling and enlisting such categories of persons as follows:--

that may be registered, enrolled or enlisted

1.

- (a) Pharmacist;
- (b) Intern pharmacist;

(c) Pharmaceutical Technician; and

(d) Pharmaceutical Assistant;

(2) Each person stipulated under sub regulation (1) and any other person of whom the Council may direct to be registered enrolled or enlisted shall as the case may be, be registered, enrolled or enlisted by the Council.

#### PART II

# ESTABLISHMENT OF THE PHARMACY COMMITTEE

The Pharm- acy	4(1) There is hereby established a Committee to be known as the Pharmacy Committee.
Commit- tee composi- tion	(2) The Pharmacy Committee shall consist of a Chairman to be appointed from amongst the members of the Council and four other members to be appointed by the Council.
and its functions	(3) The functions of the Committee shall be-
	(a) to advice the Council on various matters relating to the

- (a) to advise the Council on various matters relating to the pharmacy profession;
- (b) to prescribe, maintain, develop, control and evaluate standards in training and professional conduct;

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(i.N. No. 332 (contd.)

- (c) to establish whether an applicant has sufficient skills and knowledge to practice the profession of pharmacy in Mainland Tanzania;
- (d) to set and mark examinations for pliarmadists who apply to be registered by the Council; and
- (e) to do such other things which may be prescribed by the Councilor required to be done for the furtherance of the pharmacy profession and pharmaceutical businesses in Tanzania.

#### PART III

# REQUIREMENTS AND CONDITIONS FOR REGISTRATION AS A PHARMACIST INTERN

5.-(1) Every holder of a pharmaceutical degree or any other qualification recognized by the Council as being equivalent to a pharmaceutical degree shall be required to undergo internship immediately upon completion of pharmaceutical degree course in an institution recognized by the Council for un-interrupted period of not less than twelve months or as the Council may prescribe.

(2) Internship may be carried out in rotation in the following areas, namely:-

(a) pharmaceutical industry;

(b) hospital pharmacy;

(c) community pharmacy; and

(d) in any other premises or institution approved by the Council.

(3) An intern pharmacist undergoing internship in any recognized institution, shall be required to do so under the direct supervision of a . registered pharmacist authorized by the Council.

Requirements and conditions for registration as an intern pharmacist

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(4) A Pharmacist supervising an intern pharmacist shall write a report on performance and shall submit such report to the Registrar of the Council.

(5) Notwithstanding sub-regulation (1), the pharmacist upon finishing internship shall be examined by the Council on forensic pharmacy examination.

(6) No pharmacist shall be registered by the Council unless he has qualified in forensic pharmacy examination and has worked for a period of not less than twelve months in an institution recognized by the Council.

Application for registration as an intern pharmacist 6.-(1) Any person who is not entitled to be registered by reasons only of the fact that he has not complied with additional requirements related to acquisition of practical experience as referred to under section 15 (1) (b) of the Act, shall, apply to the Council for registration as an intern pharmacist.

(2) Every application for registration under this regulation shall be accompanied with-

- (a) a duly completed application on a form approved by the Council;
- (b) a certified copy of his pharmaceutical degree;
- (c) a full academic transcript certified by the Head of an Institution or an academic body where he graduated as a pharmacist;
- (d) three recent passport size photographs endorsed at the back by public notary as a true likeness of an applicant;
- (e) a copy of current Curriculum Vitae;
- (f) a duly completed and signed contract as approved and provided by the Council for the undertaking of an internship;
- (g) evidence of the approval by the Council of the pharmacy or provider where the internship will be undertaken;
- (h) evidence of the approval by the Council of the supervisor under whom such internship will take place; and
- (i) registration fee as prescribed in the Second Schedule to these Regulations.

G.N. No. 332 (contd.)

7. Every person who complies with the requirements in regulation 5 and 6, shall be registered as an intern pharmacist and issued with a provisional registration certificate. Registration of an intern pharmacist

Removal

from the

Register

8.-(1) Except as provided for under sections 34 and 35 of the Act, the Registrar may remove from the register of an intern pharmacist the name of an intern pharmacist who:--

- (a) has completed his internship to the satisfaction of the Council;
- (b) has discontinued his internship with the consent of the Council;
- (c) no longer complies with the requirements and conditions for registration as an intern pharmacist; or
- (d) is deceased.

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9.-(1) An intern pharmacist whose name has been removed from the Register under of regulation 8 may, if applicable, restore his name to the register by:-

- (a) submitting to the Registrar-
  - a duly completed application for restoration of his name to the register on a form as approved and provided by the Council;
  - (ii) documentary evidence that he complies with the conditions under which he may be registered as an intern pharmacist;
  - (iii) documentary evidence from a supervisor to the effect he has resumed his internship; and
- (b) paying the restoration fee as prescribed in the Second chedule to these Regulations.

tion of an intern pharmacist to the register

Restora-

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(2) where the Registrar is satisfied that the applicant under this regulation is a fit and proper person to be restored to the relevant Register, he may restore the applicant's name therein.

(3) Where the Registrar is not satisfied that the applicant is a fit and proper person to be restored to the relevant register, the Registrar shall submit the application to the Council for consideration and determination.

#### PART IV

# REQUIREMENTS AND CONDITIONS FOR FULL AND TEMPORARY REGISTRATION AS A PHARMACIST

e 10.--(1) No person shall carry on business of a pharmacist without being registered by the Council.

(2) Any person shall be eligible to apply for registration to the Council if he satisfies the Council that:

- (a) he is a pharmacist who is a holder of a pharmacy degree or any other qualification recognized by the Council as being equivalent to a degree in pharmaceutical sciences offered in Tanzania;
- (b) he has complied with such additional requirements relating to the acquisition of practical experience as a pharmacist as prescribed; and
- (c) his professional and general conduct render him fit and proper person to be registered.

(3) Any person who contravenes the provisions of sub-regulation (1), commits an offence and upon conviction shall be liable to a fine of not less than three hundred thousand shillings or to imprisonment for a term of not less than six months or both.

Require ments for registration as a pharmacist

G.N. No. 332 (contd.)

11.—(1) Any Pharmacist who wishes to be fully registered shall be required to fill in and submit an application form PCF 1 set out in the First Schedule to these Regulations.

tion for full registration as a pharmacist

Applica-

(2) Every application for registration made under sub- regulation(1), shall be accompanied by a fee as prescribed in the Second Schedule to these Regulations.

(3) An application for registration made under sub-regulation (1) shall, in addition to the requirements set out under that sub- regulation, be accompanied by the following documents:-

- (a) a certified copy of his pharmaceutical degree or a qualification equivalent to a degree offered in Tanzania;
- (b) a full transcript of academic record certified by the Head of an Institution or an Academic body where he graduated as a pharmacist;
- (c) a letter for completion of internship from a supervisor or in case of those sponsored by the Ministry of Health a letter from the Chief Pharmacist therefrom that he has completed internship;
- (d) three recent passport size photographs endorsed at the back by public notary as a true likeness of an applicant; and
- (c) a letter of passing forensic pharmacy examination.

(4) Notwithstanding the provisions of sub-regulation (1), the Council may at anytime request any additional documents or information from an applicant.

12.-(1) Every pharmacist applying for full registration shall be required to undertake a forensic pharmacy examination.

(2) No forensic pharmacy examination shall be carried out unless the applicant has applied for such examination, completed at least nine months of internship and has paid examination fee as prescribed in the Second Schedule to these Regulations. Forensic Pharmacy Examination

G.N. No. 332 (contd.)

(3) The period of sitting for forensic pharmacy examination shall be in the months of March and October of each year or any other period as the Registrar may deem fit.

(4) Notwithstanding the provisions of sub-regulation (2), the Registrar may exempt to do forensic pharmacy examination any person applying for full registration who was registered from the recognized country with a reciprocal protocol.

Syllabus 13. The syllabus for the forensic pharmacy examination shall include-

forensic pharmacy examination

for

(a) the Pharmacy Act, 2002:

(b) the Regulations, guidelines and rules made under the Pharmacy Act, 2002;

(c) the Drugs and Prevention of Illicit Traffic in Drugs Act, 1995;

- (d) the International Conventions on Narcotic Drugs and Psychotropic Substances ratified by the United Republic of Tanzania:
- (e) the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made there under; and
- (f) any other relevant material which the Council may determine.

Centers for forensic pharmacy exaniination

- 14. The forensic pharmacy examination shall be conducted in the following centers, namely-
  - (a) the Pharmacy Council situated in Dar es Salaam;
  - (b) the Kilimanjaro Christian Medical Center situated in Moshi town;

(c) the Bugando Medical Center situated in Mwanza city:

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- (d) the Mbeya Referral Hospital situated in Mbeya municipal; and
- (e) any other place or center as may be determined by the Council.

15.-(1) An applicant who fails any examination may request to re- sit any part of examination or all examinations.

Re-sitting examination

(2) Every person permitted to re-sit for any examination shall be required to pay a fee as prescribed in the Second Schedule to these Regulations.

(3) Any person who fails an examination shall not be registered as a pharmacist.

16-(1) Any Pharmacist who wishes to be temporarily registered shall be required to fill in and submit the application form PCF 1 set out in the First Schedule to these Regulations.

(2) Every application for registration made under sub- regulation
 (1), shall be accompanied by a fee as prescribed in the Second
 Schedule to these Regulations.

(3) An application for registration made under sub-regulation (1) shall, in addition to the requirements set out under that regulation be accompanied by the following documents—

(a) a certified copy of his pharmaceutical degree or a qualification or equivalent to a degree offered in Tanzania;

Requirements and conditions for temporary registration as a pharmacist

G.N. No. 332 (contd.)

- (b) full transcript of academic record certified by the head of an institution or an Academic body where he graduated as a pharmacist;
- (c) evidence that he is registered as a pharmacist in the country in which the institution or examining body that awarded such qualification is situated;
- (d) evidence that he is a fit and proper person and in good standing as pharmacist with the relevant registration authority from the country where he is coming;
- (e) evidence of the practical training which he has undertaken and completed, if any;
- (f) proof that he has passed examination(s) or other evaluation as approved by the Higher Education Accreditation Councilor Pharmacy Council, if applicable;
- (g) four recent passport size photographs endorsed at the back by public notary as a true likeness of an applicant;
- (h) a certified copy of permission to reside and take up employment in Tanzania issued by the Department of immigration; and
- (i) a copy of current Curriculum Vitae.

(4) Notwithstanding the provisions of sub-regulation (3), the Council may at anytime request any additional documents or information from an applicant.

Pharmacy Committee to scrutinize applications 17.--(1) The Registrar after receiving the application form from the applicant shall table the same to the Pharmacy Committee for scrutiny and thereafter shall submit its recommendation to the Council for consideration.

(2) Where the Council is satisfied or dissatisfied with the report or recommendation forwarded to it by the Committee, it shall direct the Registrar to act upon each application accordingly.

Temporary registration

18.-(1) The Council may upon a recommendation by the Committee, grant a temporary registration to an applicant if :--

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- (a) he is not ordinarily resident in Tanzania;
- (b) he intends to be employed in Tanzania in the capacity for which he is applying for the express purpose of carrying out specific assignment in research or teaching;
- (c) he is or immediately before entering Tanzania was in practice as a Pharmacist and that he is eligible for registration under section 15 of the Act; and
- (d) his professional and general conduct renders him fit and proper person to be registered.

(2) Where the Council decides to grant a temporary registration to the applicant, it may direct that he be registered under this regulation for the duration of the specific assignment or for the period which the Council may specify, in either case the period shall not exceed twelve months but renewable.

(3) The Council may require any person applying for registration under this regulation to appear before the Pharmacy Committee and to produce documents relating to his assignment or employment.

(4) Registration of a person under this regulation shall continue only while he is engaged on the specific assignment or for the period specified by the Council and on his ceasing to be so engaged or on expiry of the period, his registration shall cease to have effect.

(5) In case of doubt as to the cessation of engagement of a person mentioned under sub regulation (3) on the specific assignment or as to the expiry of the period specified by the Council, the decision of the Council shall be final.

19. The Council may register the applicant as a pharmacist if:-

- (a) he has completed practical training to the satisfaction of the Council; or
- (b) he submits prior to such registration acceptable documentary evidence to the Registrar of the name and introduction where he has been placed to perform practical training and the date on which he will assume duty at such facility, provided that any

Registration of a pharmacist

G.N. No. 332 (contd.)

Removal of a

regis-

tered pharma-

cist from the

Register

person registered as a pharmacist in terms of this regulation shall only be entitled to practice as such:-

- (i) for the purpose of undertaking practical training for a period not exceeding twelve months; and
- (ii) subject to such further restrictions in respect of his profession to all activities as the Council may determine.

20.-(1) Except as provided for under section 34 and 35 of the Act, the Registrar may remove from the Register of pharmacists, the name of pharmacist:

(a) who no longer complies with the requirements and conditions for registration as a pharmacist;

- (b) who failed to pay annual fees; or
- (c) who is deceased.

(2) A person in respect of whose removal under sub-regulation (1) (a) (b) has been made, shall 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 has so been given.

21.-(1) A pharmacist whose name was removed from the register under regulation 20 may, if applicable, have his name restored to the Register by:-

(a) submitting to the Registrar;

- (i) a duly completed application for restoration of his name to the register on a form as approved and provided by the Council;
- (ii) acceptable documentary evidence that he complies with the conditions under which he was registered as a pharmacist; and
- (b) paying the restoration fee as prescribed in the Second Schedule to these Regulations.

Restoration of a pharmacist to the Register

G.N. No. 332 (contd.)

(2) Where the Registrar is not satisfied that the applicant is a fit and proper person to be restored to the relevant register, the Registrar shall submit the application to the Council for consideration.

## PART V

#### ENROLLING AS A PHARMACEUTICAL TECHNICIAN

22.-(1) No person shall practice a business of a pharmaceutical technician in Tanzania unless he is enrolled by the Council upon fulfillment of the conditions prescribed under section 23 of the Act.

(2) Any person who carries on the business of a pharmaceutical technician without being enrolled by the Council, commits an offence and upon conviction shall be liable to a fine of not less than three hundred thousand shillings or to imprisonment for a term not less than six months or both.

Requirements and conditions for enroliment as a pharmaceuticał Technician

23.-(1) Any pharmaceutical technician who is not entitled to be enrolled by reasons only of the fact that he has not complied with additional requirements related to acquisition of practical experience as referred to under Section 23 (1)(b) of the Act, shall, if upon application in the prescribed manner satisfies the Council that he has secured an offer for apprenticeship by a supervisor authorized by the Council for the purposes of complying with acquisition of practical experience to be enrolled under these Regulations.

Apprenticeship by a supervisor

(2) Any pharmaceutical technician enrolled under this regulation, shall be required to undergo an apprenticeship of at least nine months under the supervision of a supervisor authorized by the Council.

G.N. No. 332 (contd.)

Application for enrollment as a pharmaceutical technician 24.-(1) Any pharmaceutical technical who wishes to be enrolled under this Regulation shall be required to fill in and submit form PCF 3 to the Registrar, as set out in the First Schedule to these Regulations.

(2) Every application for enrollment made under sub-regulation (1), shall be accompanied by an enrollment fee as prescribed in the Second Schedule to these Regulations.

Additional requirement on application 25.-(1) An application for enrollment made under regulation 24 shall, in addition to the requirements set out under that regulation be accompanied by the following documents-

- (a) a certified copy of his pharmaceutical diploma or certificate as the case may be;
- (b) a full transcript of academic record certified by the Head of an institution or an Academic body where he graduated as a pharmaceutical technician;
- (c) certificate of good standing from apprenticeship supervisor;
- (d) two recent passport size photographs endorsed at the back by a public notary as a true likeness of the applicant; and
- (e) a copy of current curriculum vitae.

(2) Notwithstanding the provisions of sub-regulation (1), the Council may at anytime when it deems fit, request any additional documents or information from an applicant.

The Committee to scrutinize application forms 26.-(1) The Registrar after receiving the application form from the applicant shall table the same to the Pharmacy Committee for scrutiny and thereafter shall submit its recommendation to the Council for consideration.

G.N. No. 332 (contd.)

(2) Where the Council is satisfied or dissatisfied with the report or recommendation forwarded to it by the Committee, it shall direct the Registrar to act upon each application accordingly.

27. Every person who complies with the requirements of regulations 24 and 25 shall be enrolled as a pharmaceutical technician and be issued with enrollment certificate.

28.-(1) Except as provided for under sections 34 and 35 of the Act, the Registrar may remove from the Roll of pharmaceutical technicians, the name of a pharmaceutical technician who:-

Enrollment as a pharmaceutical technician

- (a) has not complied with the requirements for a certificate of qualification as pharmaceutical technician;
- (b) no longer complies with requirements and conditions for enrollment as a pharmaceutical technician; or
- (c) is deceased.

(2) Any person in respect of whose entry or removal under sub-regulations (1)(a) and (b) has been made, shall be notified thereof and any certificate issued in respect of the enrollment in question shall be deemed to be cancelled as from the date on which notice has so been given.

29.-(1) A pharmaceutical technician whose name was removed from the Roll under regulation 28 may, if applicable, have his name restored to the Roll by:-

Removal of a pharmaceutical technician from the Roll

- (a) submitting to the Registrar:
  - a duly completed application for restoration of his name to the roll on a form as approved and provided by the Council;
  - (ii) documentary evidence with requirements and conditions for enrollment as a pharmaceutical technician; and
- (b) paying the prescribed restoration fee.

G.N. No. 332 (contd.)

(2) Where the Registrar is not satisfied that he is a fit and proper person to be restored to the relevant register, the Registrar shall submit the application concerned to the Council for consideration.

Restoration of a pharmaceutical technician to the roll

Additional conditions for enrollment 30. Any person who holds a certificate of qualification may apply to the Registrar for enrollment as a Pharmaceutical Technician provided that he complies with the provisions of regulation 27 of these Regulations.

31. Any person with a certificate of qualification obtained outside the United Republic who applies for enrollment as a Pharmaceutical Technician shall-

- (a) submit to the Registrar:
  - a dulý completed application on a form as approved and provided by the Council;
  - (ii) a certified copy of his identity document or passport; and
    - (iii) acceptable documentary evidence of:
- (b) the certificate of qualification obtained outside the United Republic which entitles him to practice as a pharmaceutical technician in the country in which the examining body that awarded such qualification is situated;
- (c) the original copy of an evaluation of the qualification from the National Council for Technical Education;
- (d) his enrollment as a pharmaceutical technician in the country in which the examining body that awarded such qualification is situated;
- the fact that he is a fit and proper person and in good standing as pharmaceutical technician with the relevant registration authority;
- (f) an in service training, which he has undertaken and completed, if any; and
- (g) certified copy of permission to reside and take up employment in Tanzania issued by the Department of Immigration.
- (h) be a Tanzanian citizen; and

G.N. No. 332 (contd.)

Applica-

nts with

certificate of qualifi-

cation

obtained outside Tanzania

(i) pay enrolment fees as prescribed in the Second Schedule.

32.-(1) The Registrar shall submit an application that complies with the requirements of regulation 30 to Pharmacy Committee which shall submit its recommendations to the Council for consideration.

(2) Where the Council consider any recommendation submitted to it under sub -regulation (1) it may: -

(a) refuse to enroll the applicant as a pharmaceutical technician;

- (b) enroll the applicant as a pharmaceutical technician;
- (c) enroll the applicant as a Pharmaceutical Technician in the category of apprenticeship under an approved supervisors in an approved institution:

Provided that prior to approving an application for enrollment under regulation 24 the Council may require that the applicant to pass an examination(s) determined by the Council.

33. A person enrolled under regulation 27 shall prior to enrollment in the category of pharmaceutical technicians comply with the requirements relating to the apprenticeship specified under regulation 23.

Phannacy commitee to scrutinize application under Regulation 31 - Compliance with requirements under Regulation 23

22

G.N. No. 332 (contd.)

#### PART VI

# ENLISTMENT OF A PHARMACEUTICAL ASSISTANT

Require ments and condition for enlisting as a pharmaceutical assistant 34.-(1) No person shall practice a business of a pharmaceutical assitant in Tanzania unless he is enlisted by the Council upon fulfillment of the conditions prescribed under section 28 of the Act.

(2) Any person who carries on the business of pharmaceutical assistant without being enlisted by the Council, commits an offence and upon conviction shall be liable to a fine of not less than three hundred thousand shillings or to imprisonment for a term not less than six months or both.

Enlasting of pharmaceutical assistant for apprenticeship 35.-(1) Any pharmaceutical assitant who is not entitled to be enlisted by reasons only of the fact that he has not complied with additional requirements related to acquisition of practical experience as referred to under section 28 (1) (b) of the Act, shall, if upon application in the prescribed manner satisfies the Council that he has secured an offer for apprenticeship by a supervisor authorized by the Council for the purpose of complying with acquisition of practical experience, be enlisted under these Regulations.

(2) Any pharmaceutical assistant enlisted under this Regulation shall be required to undergo an apprenticeship of at least six months under the supervision of a supervisor authorized by the Council.

Application enlisting as a pharceutical assistant 36.-(1)Any pharmaceutical assistant who wishes to be enlisted under this Regulation shall be required to fill in and submit form to the Registrar PCF 5 as set out in the First Schedule to these Regulations

(2) Every application for enlisting made under sub-regulation (1) shall be accompanied by a fee prescribed under the Second Schedule to these Regulations.

Additional requirements on application 37.-(1) An application for enlisting made under regulation 32 shall, in addition to the requirements set out under that regulation be accompanied by the following documents-

(a) a certified copy of his pharmaceutical certificate;

G.N. No. 332 (contd.)

- (b) a full transcript of academic record certified by the Head of an Institution or An academic body where he graduated as a pharmaceutical assistant;
- (c) a certificate of good standing by an apprenticeship supervisor authorized by the Council;
- (d) two recent passport size photographs endorsed at the back by an authorized public notary as a true likeness of the applicant;
- (e) a copy of current curriculum vitae.

(2) Notwithstanding the provisions of sub-regulation (1), the Council may at anytime request any additional documents or information from an applicant.

38. A person who applies for enlisting as a pharmaceutical assistant shall-

Documents to be submitted to the Registrar

Enlisting

Removal

pharmaceutical

assistant

from the

list

ofa

of pharmaceuti-

cal assistants

- (a) submit to the Registrar:
  - (i) a duly completed application form as approved and provided by the Council; and
  - (ii) a certified copy of his identity document or passport; and
- (b) pay enlistment fee as prescribed in the Second Schedule.

39. Every person who complies with the requirements of regulation 34 shall be enlisted as a pharmaceutical assistant and shall be issued with certificate of enlisting.

40.-(1) Except as provided for under sections 35 and 36 of the Act, the Registrar may remove from the list the name of a pharmaceutical assistant who:-

 (a) has not complied with the requirements for a certificate of qualification as pharmaceutical assistant;

G.N. No. 332 (contd.)

- (b) no longer complies with requirements and conditions for enlisting as a pharmaceutical assistant; or
- (c) is a deceased.

(2) A person in respect of whose removal as contemplated in sub-regulations (1)(a) and (b) has been made, shall be notified of and any certificate issued in respect of the enlisting in question shall be deemed to be cancelled as from the date on which notice has so been given.

Restoration of a pharmaceutical assistant to the list 41.-(1) A pharmaceutical assistant whose name is removed from the list under regulation 40 may, if applicable, have his name restored to the list by:-

- (a) submitting to the Registrar:
  - a duly completed application for restoration of his name in the list of pharmaceutical assistant on a form as approved and provided by the Council; and
  - (ii) acceptable documentary evidence to the effect that he has complied with requirements and conditions for enlisting as a pharmaceutical assistant;
- (b) paying the restoration fee as prescribed in the Second Schedule to these Regulations.

(2) Where the Registrar is not satisfied that the applicant is a fit and proper person to be restored to the list, the Registrar shall submit the application to the Council for consideration.

# PART VII

## APPEAL

Appeal 42.-(1) against (a) to refusal to (a) to register a: or w removal en of name from the Register

42.-(1) Any person aggrieved by the Council's decision-

) to refuse to register him or to enter in the appropriate register any degree, diploma, certificate or additional qualification which he desires, and maintains to be entitled, to have so entered in terms of the provisions of the Act; or

G. N. No. 332 (contd.)

(b) to remove from the Register his name or any degree, diploma, certificate or additional qualification which he maintains to be entitled to have entered in the register in terms of the provisions of the Act,

may, after notice to the Council and within a period of two months after the date of such decision, appeal against such decision to the High Court.

(2) The High Court may:-

- (a) dismiss an appeal;
- (b) if it is of the opinion that the Council has not acted in accordance with the provisions of the Act, make an order reversing or modifying the Council's decision;
- (c) remit the matter to the Council for further consideration; or
- (d) make such other order as it may deem appropriate.

43. The Registrar shall, at intervals to be determined by the Council and in accordance with the instructions and under the authority of the Council, cause copies of the Registers, or of supplementary lists showing all alterations, additions, revisions and deletions made since the last publication of the complete Registers, to be published in the Gazette.

44. A copy of the last published issue of a register or any supplementary list purporting to be published under the authority of the Council shall be *prima facie* proof, in all legal proceedings, of the facts therein recorded, and the absence of the name of any person from such copy shall be proof, until the contrary is proved, that person is not registered according to the provisions of the Act, provided that in the case of any person whose name-

(a) does not appear is such copy, or whose name has been added to the Register after the date of the last published issue thereof, a certified copy under the hand of the Registrar of the entry of the name of such person in the Register, shall be proof that such person is registered under the provisions of the Act; Publication of registers

Register as a proof

G.N. No. 332 (contd.)

Issue of

duplicate registra-

tion

certificate, extract

from the

register

certificate by the

Registrar

OF

(b) has been removed from the Register since the date of the last published issue thereof and has not been restored thereto, a certificate under the hand of the Registrar that the name of such person has been removed from the Register shall be proof that such person is not registered according to the provisions of the Act.

45.-(1) Where the Registrar is satisfied-

(a) of proof submitted by the registered person concerned, that a registration certificate has been destroyed; or

(b) by virtue of an affidavit submitted by the registered person concerned, that a registration certificate has been lost, he may issue a duplicate registration certificate to that person upon payment of the fee prescribed in the Second Schedule.

(2) The Registrar may issue a certified extract from the Register or a certificate under his hand as provided to any person upon payment of the fee prescribed in the Second Schedule.

# PART VIII MISCELLANEOUS PROVISIONS

Continuing Education Programme

46.-(1) It shall be a duty of every registered pharnlacist, enrolled pharnlaceutical technician and enlisted pharnlaceutical assistant to attend a Continuing Education Programme organized by the Council at least once in a year.

(2) A pharmacist, pharmaceutical technician or pharmaceutical assistant, as the case may be, attending a continuing education programme course organized under sub-regulation (1), shall be required to pay a fee determined by the Council.

(3) The Council may suspend a pharmacist, phamaceutical technician or a pharmlaceutical assistant who fails to attend such a course.

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G. N. No. 332 (contd.)

47.-(1) A pharmacist who wishes to supervise an apprentice pharmaceutical technician or pharmaceutical assistant shall:

- have minimum working experience as pharmacist of at least five years;
- (b) be of good standing; and
- (c) have no professional disciplinary action taken against him.
   (2) Any person intending to become an apprentice supervisor for

an apprentice pharmacist's assistant shall be required:

- (a) to apply to the Council in a prescribed manner; and
- (b) to pay the fee provided under the Second Schedule of these Regulations.

(3) Upon satisfying the Council, the applicant shall be authorized in writing and issued with a certificate for that purposes provided by the Council.

48. In order to practice pharmacy in Tanzania the applicant shall be Language required to have satisfactory knowledge of Kiswahili or English or both.

49.-(1) Any person who-

- (a) procures or attempts to procure registration, enrollment or enlisting by making or producing any false or fraudulent statement or document;
- (b) deliberately makes or causes to be made any falsification in any matter relating to registration, enrollment and enlisting;
- (c) assists or aids any other person to be registered, enrolled or enlisted illegally,

commits an offence and on conviction shall be liable to a fine of five hundred thousands shillings or to imprisonment for a term not less than twelve months or both.

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Offences

Qualification for apprentice pharmacists' assistants supervisor

G.N. No. 332 (contd.)

(2) any person who commits an offence in the course of practice as a pharmacist, a pharmaceutical technician or a pharmaceutical assistant shall not be allowed to practice in any other lesser grade in this profession.

General penalty

50. Any person who commits an offence under these Regulations and where no specific penalty has been provided shall, on conviction be liable to a fine not exceeding two hundred thousand shillings or imprisonment for a term not less than three months or both.

**PCFI** 

#### FIRST SCHEDULE

#### (Made Under Section 11(1))

#### THE UNITED REPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

#### APPLICATION FOR REGISTRATION AS A PHARMACIST

The Registrar Pharmacy Council P. O. Box 77150 Dar es Salaam

Address	
I hereby declare to the best of my know circumstances, which I am aware of wh *Provisional/ *Temporary/ *Full register	vledge, belief and information that there are no hich would disqualify me from registration as a ered Pharmacist.
I hereby apply to be considered register I enclose the following authenticated co	red as a phannacist. opies of my certificates:-
Date.	Signature
NOTE: * Delete whichever is inapplicable.	

G. N. No. 332 (contd.)

PCF2

#### THE UNITED REPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

#### APPLICATION FOR RETENTION OF A NAME IN THE REGISTER AS A PHARMACIST

The Registrar Pharmacy Council P. O. Box 77150 Dar es Salaam

<b>,</b>	
Address	· • • • • •
****	*****

I hereby declare to the best of my knowledge, belief and information that there are no circumstances, which I am aware of which would disqualify me from retaining my name in the register. My qualification(s) is/are

Date ..... 2004

Signature .....

PCF3

#### THE UNITED REPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

### APPLICATION FOR ENROLLMENT AS A PHARMACEUTICAL TECHNICIAN

The Registrar Pharmacy Council P. O. Box 77150 Dar es Salaam

,	
Address	
	••••

G. N. No. 332 (contd.)

I hereby declare to the best of my knowledge, belief and information that there are no circumstances which I am aware of which would disqualify me from enrollment. My qualification (s) is/are:-

hereby apply to be considered for \*temporary/\*full enrollment as a pharmaceutical technician.

I enclose the following authenticated copies of my certificates:-

Date .....

Signature .....

NOTE: Delete whichever is inapplicable.

PCF4

#### THE UNITED RÉPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

#### APPLICATION FOR RETENTION OF THE NAME IN THE ROLL AS A PHAR-MACEUTICAL TECHNICIAN

The Registrar Pharmacy Council P. O. Box 77150 Dar es Salaam

1,	
Address	

I hereby declare to the best of my knowledge, belief and information that there are no circumstances, which I am aware of which would disqualify me from retaining my name in the roll. My gualification(s) is/are

Date.

Signature .....

G. N. No. 332 (contd.)

PCF5

#### THE UNITED REPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

# APPLICATION FOR ENLISTING AS A PHARMACEUTICAL ASSISTANT

The Registrar Pharmacy Council P. O. Box 77150 Dar es Salaam

1		 	
Address	····, · · · · · · · · · · · · · · · · ·	 	

hereby declare to the best of my nowle lge, belief and information that there are no circumstances, which I am aware of which would disqualify me from enlisting. My qualification(s) is/are

hereby apply to be considered for \* provisional / \*full enlisting as a pharmaceutical assistant. I enclose the following authenticated copies of my certificates: -

Date .....

Signature .....

N.H. \* Delete whichever is inapplicable

PCF6

#### THE UNITED REPUBLIC OF TANZANIA

#### THE PHARMACY COUNCIL

## APPLICATION FOR RETENTION OF A NAME IN THE LIST AS A PHARMA-CEUTICAL ASSISTANT

The Registrar
Pharmacy Council
P. O. Box 77150
Dar es Salaam

I	 	 
Address	 	 
. Y	 1	

G. N. No. 332 (contd.)

I hereby declare to the best of my knowledge, belief and information that there are no circumstances, which I am aware of which would disqualify me from retaining my name in the list. My qualification(s) is/are

Date .....

Signature .....

#### SECOND SCHEDULE

(Under Regulations 6(2), 9(C), II(h), 12(2),16(2),17(2), 20(2),21(2),26(2), 27(4),30(2),34(2),42(2),47(c) and 49(2)

			Fee		
	Registration fee (payable with duly completed				
(i)	Pharmacist Intern (Provisional Registr	ration)	\$ 75		
	Pharmaceutical Technician (Provision	al)	\$ 30		
(iii)	Pharmaceutical Assistant (Provisional	)	\$ 20		
(iv)			\$ 50		
(v)	Pharmaceutical Assistant (Enlisting)		\$ 30		
(vi)	Pharmacist -Full		\$ 150		
	-Temporary		\$ 500		
Ann	ual fees (Payable on the dates as indi	cated below)			
(i)	Pharmacy Intern (Provisional registrat	tion extension	) \$ 25		
(ii)	Pharmaceutical Technician		\$ 15		
(iii)	Pharmaceutical Assistant		\$ 10		
(iv)	Pharmacist -Full		\$ 75		
Res	toration fees		- E		
Oth	er Fees				
The follo	owing fees are payable for:				
(i) Fore	ensic Pharmacy Examination	\$ 25			
(ii) Du	plicate certificate (course,				
regi	stration, enrollment, enlisting or				
cert	ificate extracts)	\$,50			
Dar es S	alaam	Anna N	A. ABDALLAH,		
	,2005		ster for Health		
	appl (i) (ii) (iii) (iv) (v) (v) (vi) (vi) (	<ul> <li>application form)         <ul> <li>Pharmacist Intern (Provisional Registration (Provisional Registration)</li> <li>Pharmaceutical Technician (Provisional (Provisi))))))))))))))</li></ul></li></ul>	<ul> <li>application form)         <ul> <li>Pharmacist Intern (Provisional Registration)</li> <li>Pharmaceutical Technician (Provisional)</li> <li>Pharmaceutical Assistant (Provisional)</li> <li>Pharmaceutical Technician (Enrollment)</li> <li>Pharmaceutical Assistant (Enlisting)</li> <li>Pharmacist -Full</li></ul></li></ul>		

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

# THE PHARMACY (EDUCATION AND TRAINING) REGULATIONS, 2005 ARRANGEMENT OF REGULATION

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- 5. General requirements and conditions for internship
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- 7. Conditions for commencing internship
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- 9. Period for practical training
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- 13. Cession of contract
- 14. Approval of the contract of cession
- 15. Delegation of training by approved supervisor
- 16. Supervisor to submit assessment forms to Registrar
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# Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

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# STANDARDS OF EDUCATION AND TRAINING OF PHARMACEUTICAL ASSISTANTS

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G.N. No. 333 (contd.)

## THE PHARMACY ACT, 2002

### (No.7 of 2002)

# REGULATIONS

# (Made under section 38):

## THE PHARMACY (EDUCATION AND TRAINING) REGULATIONS, 2005

### PARTI

## 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.

Interpret ation 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 armacist in terms of a contract under the direct supervision of a carmacist 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.

(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.

(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-

(a) in accordance with the terms of a contract:

- (b) in a community phamacy 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.

course for a qualification in pharmacy

General requirements and conditions for internship

Internship

G.N. No. 333 (contd.)

7. No person shall commence an internship unless-

- Conditions for commencing internship
- (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.

Restriction to employ an intern pharmacist 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.

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Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

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-

- (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.

Recognition of partial completion 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.

Recognition of internship undertaken at a provider

> Completion of additional practi-

cal

training

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 imprison;
- (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

(t) 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.

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

(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 detennined 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:-
  - 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

G.N. No. 333 (contd.)

- (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.

16. The supervisor shall-

(a) submit to the Registrar:

- assessment forms as approved and provided by the (i) Council on the progress of the an intern pharmacist during the period of internship; and
- an affidavit at the end of the period of internship stating (ii) 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.

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

Supervisor to submit assessment form to the Registrar

Pre-reg-

istration

tion

(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 pharmacy entitling pharmacists to registration

### 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.

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.

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.

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.

Unit standards for pharmaceutical technicians

Learning programs for pharmaceutical technicians

Certificate of qualification

Entry requirements for obtaining a certificate of qualification

(2) Not withstanding 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 Councilor National Council for Technician Education and on payment of the evaluation fee prescribed in the Fifth Schedule.

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.

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 phannacy approved by the Council for purposes of such training; and
- (b) under the guidance of a supervisor approved by the Council.

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

i'reenrolment additional practical training duration

General requirements and conditions for preenrolment additional practical training

Preenrolment additional practical training for pharmaceutical technician

G.N. No. 333 (contd.)

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

27.-(1) A supervisor may delegate the actual pre-emolment additional practical training of a pharmaceutical technician 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- 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-emolment 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.

29.-(1) No pharmacist shall undertake to act as a supervisor to more than three pharmaceutical technicians 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.

Delegation of preenrolment additional practical training of pharmaceutical technician

Restriction to employ pharmaceutical technicians

Supervision of pharmaceutical technician undergoing preenrolment additional practical training

G.N. No. 333 (contd.)

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.

50

Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

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

(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.

(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.

39. The pre-enlisting additional practical training referred to under regulation 38 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.

Certificate of qualification

Entry require-" ment for obtaining certificate of qualification by a pharmaceutical assistants

Evaluation prior to enlisting

Preenlisting additional practical training duration

General requirements and conditions for preenlisting additional practical training

G.N. No. 333 (contd.)

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

additional practical training for a pharmaceutical assistant

- (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 preenlisting additional practical training of pharmaccutical assistants

Restriction to employ pharmaceutical assistant

Supervisor of pharmaceutica: assistant undergoing preenlisting additional practical training 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.

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.

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

Council may

impose

tion

examination or evalua-

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

(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 enlisting

G.N. No. 333 (contd.)

### 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 Approval 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.

(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.

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.

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. Approval as a supervisor

Council committee or Inspector to inspect and submit report

Applicant pharmacists to cooperate with inspector

Pharmacy or provider to be inspected frequently

as

provider

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

### PART VI

## APPROV AL OF PROVIDERS OF PHARMACY EDUCATION AND TRAINING

Application for approval 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 F fth Sch dule 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 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

- (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.

Restoration to the Register

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

- (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.

Inspection of providers

Minimum criteria and conditions for approval

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 institutions 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.

58

Pharmacy (Education and Training) Regulations

G.N. No. 333 (contd.)

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.

of courses for purposes of continuing professional development

Approval

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.

Approval of a new academic program

65. There shall be paid such fees as prescribed under the Fifth Schedule to these Regulations, namely:-

(a) by providers of pharmacy education and training for:

- (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.
- (b) by a supervisor for:-
  - (i) application to be a supervisor;
  - (ii) evaluation of application; and
  - (iii) restoration.

Fees

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

#### 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:-

- 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 (ii) Assessors	\$ 1000 \$ 30
B:	Renewal fees (Payable on the dates as indicated (i) Pharmacy Education Provider (payable every 3) (ii) Assessor (payable every year)	\$ 300 \$ 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

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