

CHAPTER 311

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[PRINCIPAL LEGISLATION]
ARRANGEMENT OF SECTIONS

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SCHEDEULE

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CHAPTER 311

THE PHARMACY ACT

An Act to establish the Pharmacy Council and to provide for the functions, management of the Council; to provide for regulation and control of the pharmacy profession and practice and to provide for other related matters.

[1st November, 2011]
[GN. No. 370 of 2011]

Act No.
1 of 2011

PART I

PRELIMINARY PROVISIONS

Short title **1.** This Act may be cited as the Pharmacy Act.

Interpretation **2.** In this Act, unless the context otherwise requires-
“advertisement” means communication, whether in a publication or by the display of any notice or by means of any catalogue, price list, letter, as a circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means or communication;
“authorised seller of medicines” means a person other than a person lawfully authorised to conduct a retail pharmacy business who may sell pharmaceutical products pursuant to section 44;
“business of a pharmacy” includes professional pharmacy practice and any activity carried on by a person in relation to medicines, medical device or herbal medicines;
“certificate” means a certificate issued by the Council under this Act;
“certificate of enrolment” means the certificate issued to a Pharmaceutical Technician under section 25;

“certificate of enlisting” means the certificate issued to a Pharmaceutical Assistant under section 29;

“certificate of registration” means the certificate issued to a Pharmacist under section 16;

“committee” means any committee established under section 8;

“Council” means the Council established under section 3;

“dispense” means the supply of medicines or medicine products in accordance with the prescription lawfully given by a medical practitioner;

“distribution” means a business of dealing in human medicines or medical devices in bulk or wholesale but does not include importers of human medicines, medical devices, food, cosmetics and veterinary medicines;

“distributor” means a person who buys medicines or medical devices from importers or local manufacturers and who sells in bulk or wholesale to retailers, and includes importers;

“herbal medicine” means any labelled preparation in a pharmaceutical dosage that contain an active ingredient and one or more substances of natural origin that are derived from plants;

“inspector” means an inspector appointed, authorised or recognised as such under this Act;

“Intern Pharmacist” means any person registered as such under section 17;

“label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of medicines, medical devices or herbal medicines;

“List” means a List of Pharmaceutical Assistants maintained under section 27;

“medicine or pharmaceutical products” means any substance or mixture of substances manufactured for treatment of diseases or for use in the diagnosis or prevention of diseases, disorders or abnormal physical or mental state or the symptoms thereof, in man or animal;

“medical device” means an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in-vitro reagent or other similar or related articles, including any component, part or accessory which is-

- (a) recognised in the Official National Form;
- (b) ular Pharmacopoeia or any of their supplement;
- (c) intended for use in diagnosis of diseases or other conditions, or in cure, mitigation, treatment or prevention of disease in man or animal; or
- (d) intended to affect the structure, any function of the body of man or animal and which does not achieve any of its principal intended purposes through chemical action within such body of man or animal and which is not dependent upon being metabolized for achievement of any of its principals intended purposes;

“medical practitioner” means a person who is registered as practitioner under the Medical, Dental and Allied Health Professionals Act;

“member” means a person appointed to be a member of the Pharmacy Council and includes the Chairman and Vice-Chairman;

“Minister” means the Minister for the time being responsible for matters relating to health services;

“pharmacy” means any approved premises wherein or from which any service pertaining to practice of a pharmacist is provided, and shall include a community pharmacy, consultant pharmacy, institutional pharmacy, or wholesale pharmacy;

“pharmacy practice” means any acts pertaining to the scope of practice of a pharmacist, pharmaceutical technician or pharmaceutical assistant as approved by the Council;

“Pharmacist” means a person registered under section 16;

“Pharmaceutical Technician” means a person enrolled under section 24;

“Pharmaceutical Assistant” means a persons enlisted under section 28;

“premises” includes a land, building, structure, basements and a vessel and in relation to any building includes a part of a building, any cartilage, forecourt or yard, and in relation to a vessel includes a ship, boat, air craft, and a carriage or receptacle of any kind, whether open or closed or place of storage used in connection with any service pertaining to practice of a pharmacist;

“prescription” means a lawfully written direction by a medical practitioner or veterinary doctor for the preparation and dispensation of a medicine by a Pharmacist;

“prescription medicine” means any medicine product required to be dispensed only upon a prescription given by medical practitioner, veterinary surgeon or any other person approved by the Minister;

“professional misconduct” means any conduct which is in breach of the Code of Conduct prescribed under this Act, done by a person who is registered, enrolled or enlisted under this Act;

“provisional certificate” means a certificate issued under section 18;

“Register” means a Register maintained under this Act;

“Registrar” means the Registrar of the Council appointed under section 12;

“retail pharmacy business” includes the retail sale of medicines products but does not include a professional practice carried by a medical practitioner or veterinarian;

“Roll” means a Roll maintained under section 23 of this Act;

“superintendent” means a Pharmacist In-Charge who supervises a pharmacy and is registered as such by the Council under this Act;

“supervisory officer” means a person appointed under section 47 to be a supervisory officer over pharmacy practice

“unfit to practice” means incapability, incompetency or unsuitability to-

- (a) continue to be registered, enrolled or enlisted in terms of the Act; or
- (b) perform acts forming part of the scope of practice of his category of registration, enrollment or enlistment as a result of a physical or mental condition;

“veterinarian” means a person registered under the Veterinary Act;

“wholesale pharmacy” means a pharmacy that buys medicines, medical devices or cosmetics from importers and sell in bulk to retail pharmacy;

“wholesaler” means a person who buys medicine, medical devices or cosmetics from importers or local manufacturers and sells in bulk to the retailer.

Cap. 319

Establishment
of Pharmacy
Council

Cap. 134

PART II

ESTABLISHMENT OF THE PHARMACY COUNCIL

3.-(1) There is hereby established a council to be known as the Pharmacy Council.

(2) The Council shall be a body corporate and-

- (a) have perpetual succession and an official seal;
- (b) in its corporate name be capable of holding, purchasing or otherwise acquiring in any other way any movable or immovable property and disposing of any of its property;
- (c) subject to the provisions of the Government Loans, Guarantees and Grants Act, have power to borrow such sums as it may require for its purpose; and
- (d) in its corporate name, be capable of suing or being sued.

(3) The Schedule to this Act shall govern the appointment of members to the Council, constitution, procedures and other matters relating to the Council.

(4) The Minister may, upon advice of the Council and by order published in the *Gazette*, amend, vary or replace all or any of the provisions of the Schedule to this Act.

Functions of Council

4. The Council shall be the sole authority for registering, enrolling and listing of Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants respectively, and shall, in addition, perform the following functions-

- (a) advise the Minister on matters relating to pharmacy practice;
- (b) safeguard and promote the provision of pharmaceutical services in compliance with norms and values, in both public and private sectors, with goals of achieving definite therapeutic outcomes for the health and quality of life of a client;
- (c) uphold and safeguard the acceptable standards of pharmacy practice in both public and private sectors;
- (d) establish, develop, maintain and control acceptable standards-
 - (i) in pharmaceutical education, training and continuing professional development;
 - (ii) for the registration of a person who provides one or more or all of the services which form part of the scope of practice of the category in which such a person is registered;
 - (iii) in the practice of the various categories of persons required to be registered under this Act; and
 - (iv) of professional conduct required for persons to be registered under this Act;
- (e) enquire into any query relating to a pharmacy practice raised by the public;
- (f) maintain and enhance the dignity of the pharmacy profession and the integrity of a person practicing the profession;
- (g) regulate standards and practices of the pharmacy profession;

- (h) promote interest in, and advancement of the pharmacy profession;
- (i) in collaboration with the Tanzania Commission for Universities and the National Accreditation Council for Technical Education, evaluate academic and practical qualifications for Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants for the purpose of registration, enrolment or enlisting under this Act;
- (j) foster cooperation between the Council and other institutions or organisations, dealing with the pharmacy profession;
- (k) ensure proper collection of fees payable under this Act;
- (l) keep and maintain Registers, Rolls and Lists for the registration, enrollment and enlisting of Pharmacists, Pharmaceutical Technicians, Pharmaceutical Assistants and Intern Pharmacists;
- (m) administer the accounts and assets of the Council or any assets to be held in trust for the benefit of the Council;
- (n) prescribe the scope of practice of the persons registered, enrolled and enlisted under this Act;
- (o) regulate activities of Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants;
- (p) ensure that training in pharmacy at any institution in Tanzania guarantees the necessary knowledge and skills needed for the efficient pharmacy practice;
- (q) pay any member of the Council, committee, staff or any person entrusted with any task under this Act, any allowance as it may determine;
- (r) determine the fees payable to the Council for services performed by the Council under this Act;
- (s) promote rational use of medicines; and
- (t) carry out any other functions as may be conferred upon the Council by any other written law.

Powers of Council **5.**—(1) The Council shall have powers to—

- (a) appoint any officer or inspector to perform any duty or act on behalf of the Council;
- (b) prescribe and determine powers and duties of officers and inspectors appointed pursuant to paragraph (a);
- (c) remove any name from the Register, Roll or List subject to such conditions as the Council may impose;
- (d) consider any matter affecting the pharmacy profession, and take any action in connection therewith as the Council may consider necessary;
- (e) delegate any of its powers to any officer, inspector or organisation;
- (f) require any person registered, enrolled or enlisted under this Act or involved in pharmacy practice or offering pharmaceutical education or training to furnish the Council with the information it requires;
- (g) inquire into any matter, complaint, charge or allegation of improper or disgraceful conduct against any person registered, enrolled, enlisted or any other person or premises registered under this Act which is brought to the attention of Council; and
- (h) approval of Institution and curriculum for the training of pharmacy education.

Pharmacy Committee and its composition

6.—(1) There shall be established a committee to be known as the Pharmacy Committee whose functions shall be to prescribe and evaluate qualifications for registration, enrolment, enlisting, evaluate application for premises registration under this Act and making recommendations to the Council.

(2) The Pharmacy Committee shall consist of a Chairman to be appointed from amongst members of the Council and four other members to be appointed by the Council.

Disciplinary Committee and its composition

7.—(1) There shall be a committee to be known as the Disciplinary Committee whose function shall be to conduct preliminary investigation into any case where it is alleged

that a registered, enrolled or enlisted person has misbehaved in his capacity as a Pharmacist, Pharmaceutical Technician, or Pharmaceutical Assistant, or should for any reason be the subject of proceeding before the Council.

(2) The Disciplinary Committee shall consist of a Chairman to be appointed from amongst members of the Council and four other members to be appointed by the Council.

(3) The procedure for conducting an inquiry under this Act shall be prescribed in the regulations.

(4) The Council may, in connection with the complaint, charge or allegation, seek information from any person, including the person against whom the complaint, charge or allegation has been lodged.

(5) In the case of a complaint, charge or allegation which forms or is likely to form a criminal case, the Council shall adjourn the holding of the inquiry until the case has been concluded by the court of competent jurisdiction.

Establishment of other committees

8.-(1) The Council may establish a number of other committees to carry out any special or general functions determined by the Council and may delegate to any of the committee any functions as the Council may consider necessary.

(2) A committee may co-opt any person as a member of its committee and any of such member so co-opted may or may not be an officer in the public service.

Meetings of committees

9.-(1) A Chairman of a committee shall convene a meeting of the committee of which he is the Chairman.

(2) The Council may, at any time, direct a Chairman of any committee to convene a meeting of his committee and the Chairman shall, as soon as practicable, comply with the directions.

(3) A committee shall keep minutes of the meetings, inform the Council of its activities and conduct its proceedings in a manner as the Council may direct.

Funds and
resources of
Council

10.—(1) The funds and resources of the Council shall consist of—

- (a) sums as may be appropriated by Parliament for the purpose of the Council;
- (b) all fees payable under this Act;
- (c) donations, grants, bequeaths, and loans as the Council may, from time to time, receive from any person or organisation;
- (d) proceeds derived from sale of Council's properties; and
- (e) any other source of income identified by the Council and legally obtained.

(2) The funds and resources of the Council shall be applied for the purposes for which the Council is established and in accordance with the directions of the Council.

(3) The Council shall keep proper accounts and other records relating to the funds and resources.

(4) The Council shall—

- (a) establish one or more separate accounts in a credible commercial bank into which all monies received by the Council shall be paid in and out;
- (b) prepare annual estimates of income and expenditure and adhere to any such estimates;
- (c) ensure that the operations of the Council are exercised in an economical and efficient manner;
- (d) manage the resources of the Council in a prudent manner;
- (e) prepare and publish an annual report which shall include—
 - (i) an account of the operations of the Council during the year covered by the report;
 - (ii) a set of audited accounts;
 - (iii) any other matters as may be prescribed;
- (f) appoint full-time and part-time staff as seems to the Council to be appropriate and necessary to ensure, that the matters referred to it in this Act are implemented;
- (g) take other action which shall advance the objects and purposes of the Council.

(5) Where the Minister is of the opinion that, the Council is not carrying out its functions in a proper and reputable manner, he shall give directives in writing to ensure that, the functions are carried out as specified.

(6) The accounts of the Council shall be audited on an annual basis by the Controller and Auditor-General or by a firm of auditors certified by the Controller and Auditor-General.

(7) The Council shall, not later than six months after the end of the financial year, submit to the Minister a copy of audited accounts and annual report and activities of the Council in respect of that year.

(8) The Minister shall, within the period of six months after the accounts have been audited, lay the audited accounts and audit report before the National Assembly.

Remuneration
of members of
Council

11.—(1) Members of the Council and the Secretariat shall be paid allowances from the funds of the Council as the Council may determine with the approval of the Minister.

(2) In determining the allowances, the Council shall make provision for reimbursement of any expenses incurred in connection with the business of the Council.

Registrar and
responsibilities

12.—(1) The Minister shall appoint a registered Senior Pharmacist in the public service to be the Registrar of the Council.

(2) The Registrar shall be the Secretary to the Council.

(3) Subject to the provisions of this Act, the Registrar shall be responsible to the Council for the administration and management of its affairs.

(4) There shall be a Deputy Registrar appointed by the Minister, who shall assist the Registrar in his day to day activities and any other functions as may be prescribed by the Council.

(5) Subject to subsection (3), in the absence of the Deputy Registrar, any other officer of the Council shall carry out the functions of the Registrar in his behalf as the Chairman of the Council may, in writing, designate.

Secretariat

13.—(1) There shall be a Secretariat of the Council which shall consist of the Registrar, Deputy Registrar and number of officers or staff as the Council may determine.

(2) The officers and staff of the Council shall be the Government employees for the performance of the functions of the Council

(3) The officer and staff of the Council shall be paid remuneration or allowances on terms as the Council may determine, subject to approval of the Minister.

PART III

REGISTRATION, ENROLMENT AND ENLISTING

OF PHARMACEUTICAL PERSONNEL

Examination and qualifications

14.—(1) The Council shall conduct professional examination for registration, enrolment or enlistment of candidates as Pharmacists, Pharmaceutical Technicians or Pharmaceutical Assistants.

(2) Where an applicant is registered, enrolled or enlisted under this Act he shall, upon payment of the prescribed fees, be entitled to practice as a Pharmacist, Pharmaceutical Technician or Pharmaceutical Assistant.

Registers of Pharmacists

15.—(1) The Registrar shall keep registers of Pharmacists in the prescribed forms.

(2) The Registrar shall, as soon as practicable and after the Council has accepted any person for registration, enter in the respective register in respect of the person, the following particulars—

- (a) his name and address;
- (b) the date of registration;
- (c) his qualifications and status of his registration; and
- (d) such other particulars as the Council may direct.

(3) The changes in the particulars registered under subsection (2) shall be entered in the register by the Registrar.

(4) The Registrar may rectify, save for any substantive error, any clerical or typographical error in the registers or other document containing extract from the registers.

Qualification for registration as Pharmacist

16.—(1) A person shall not be entitled to provide services as a Pharmacist, unless he is duly registered under this Act.

(2) A person shall be entitled, upon making an application to the Council in the prescribed manner, to be registered as a Pharmacist under this section and offer his services if he satisfies the Council that—

- (a) he holds a pharmacy degree or any other qualification recognised by the Council as being equivalent to a pharmacy degree;
- (b) he has complied with such additional requirements relating to the acquisition of practical experience as a pharmacist; and
- (c) his professional and general conduct render him fit and proper person to be registered as Pharmacist.

Internship training

17.—(1) A Pharmacist shall not be registered unless the Council is satisfied that, he has undergone internship training for a period of one year.

(2) The Council may extend the period for internship for a further period of up to two years.

Provisional registration

18.—(1) A person who is not entitled to be registered by reason only of the fact that, he has not complied with the additional requirements referred to in section 16(2)(b) shall, where, upon application in the prescribed manner, he satisfies the Council that he has secured an offer for employment or training in an institution or facility approved by the Council for the purposes of complying with the additional requirements, be entitled to be provisionally registered for a duration provided under the regulation made under this Act.

(2) A person who is provisionally registered shall be deemed to be registered as far as is necessary to enable him to be employed for the purpose stated in subsection (1), in such institution or facility approved by the Council as specified in the certificate of provisional registration.

(3) The Registrar shall maintain a separate register in which he shall enter the particulars of those persons provisionally registered.

Temporary registration

19.-(1) Where a person satisfies the Council that-

- (a) he is not ordinarily resident in Tanzania;
- (b) he is or intends to be employed in Tanzania for the express purpose of carrying out a specific assignment in research or teaching;
- (c) he is or immediately before entering Tanzania was practicing as a Pharmacist and that he is eligible for registration under section 16 of this Act; and
- (d) his professional and general conduct renders him fit and proper to be registered,

the Council may direct that he be registered under this section 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.

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

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

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

(5) Notwithstanding subsection (4), a person aggrieved by the decision of the Council may appeal to the Minister.

Certificate of registration

20. The Registrar shall, upon the registration of a Pharmacist and on payment of the prescribed fee, issue a certificate of registration in the prescribed form.

Restriction on use of title

21.—(1) A person other than a Pharmacist shall not, on or after the commencement of this Act, assume, take, exhibit or in any way make use of any title, emblem or description which suggest that he is a Pharmacist.

(2) A person who contravenes the provisions of this section commits an offence and on conviction shall be liable to a fine of not less than one million shillings or to imprisonment for a term not exceeding two years or to both.

(3) For the purpose of subsection (1), the use of any of the titles “pharmacist”, “druggist”, “pharmaceutist”, “apothecary”, “apothek”, or “pharmaceutical chemist” or any similar word or combination of words in any language, shall be deemed to suggest that, the person is or persons are pharmacists.

Application for retention in Register

22.—(1) A registered person shall, before the 31st December of each year, file information to the Council in the prescribed manner for the retention of his name in the register.

(2) An application under subsection (1) shall be accompanied by a prescribed fee.

(3) The Council may remove from the relevant register any registered person who does not comply with the provisions of subsections (1) and (2).

Roll of Pharmaceutical Technicians

23.—(1) The Registrar shall keep a Roll of Pharmaceutical Technicians in the prescribed forms.

(2) As soon as practicable and after the Council has accepted any person for enrolment, the Registrar shall enter in the Roll in respect of that person the following particulars—

- (a) his name and address;
- (b) the date of enrolment;

(c) his qualifications; and
(d) any other particulars as the Council may direct.

(3) The changes of the particulars of person enrolled under subsection (2) shall be entered in the Roll by the Registrar.

(4) The Registrar may rectify, save for any substantive error, any clerical or typographical error in the Roll or other documents containing extract from the Roll.

Enrolment of
Pharmaceutical
Technician

24.—(1) A person shall be entitled, upon making an application to the Council in the prescribed manner, to be enrolled under this section and to offer the services if the Council is satisfied that—

(a) he is a Pharmaceutical Technician who is a holder of a diploma in pharmaceutical sciences or any other qualification recognised by the Council as being equivalent to a diploma in Pharmaceutical sciences offered in Tanzania;

(b) he has complied with such additional requirements relating to the acquisition of practical experience as a Pharmaceutical Technician, as the Minister may, after consultation with the Council, prescribe by regulations made under this Act; and

(c) his professional and general conduct render him a fit and proper person to be enrolled.

(2) An applicant aggrieved by the decision of the Council under this section may appeal to the Minister within thirty days after receipt of the decision.

Certificate of
enrolment

25. Upon enrolment of a Pharmaceutical Technician and on payment of the prescribed fee, the Registrar shall issue a certificate of enrolment in the prescribed form.

Application for
retention in Roll

26.—(1) An enrolled person shall, before the 31st December of each year, file information to the Council in the prescribed manner for the retention of his name in the Roll.

(2) An application under subsection (1) shall be accompanied by a prescribed fee.

(3) The Council may remove from the Roll any enrolled person who does not comply with the provisions of subsections (1) and (2) of this section.

List of
Pharmaceutical
Assistants

27.-(1) The Registrar shall keep a List of Pharmaceutical Assistants in the prescribed form.

(2) As soon as practicable after the Council has accepted any person for enlisting, the Registrar shall enter in the List in respect of that person the following particulars-

- (a) his name and address;
- (b) the date of enlisting;
- (c) his qualifications; and
- (d) any other particulars as the Council may direct.

(3) The changes in the particulars enlisted under subsection (2) shall be entered in the List by the Registrar.

(4) The Registrar may rectify, save for any substantive error, any clerical or typographical error in the List or other documents containing extract from the List.

Enlisting of
Pharmaceutical
Assistants

28.-(1) A person shall not be entitled to provide service as a Pharmaceutical Assistant unless he is duly enlisted under this Act.

(2) A person shall be entitled, upon making an application to the Council in the prescribed manner, to be enlisted under this section and to offer his services if he satisfies the Council that-

- (a) he holds a certificate in pharmaceutical sciences or any other qualification recognised by the Council as being equivalent to a certificate in pharmaceutical sciences;
- (b) he has complied with such additional requirements relating to the acquisition of practical experience as a Pharmaceutical Assistant, as the Minister may, after consultation with the Council, prescribe by regulations made under this Act;
- (c) his professional and general conduct render him fit and proper to be enlisted.

Certificate of enlisting **29.** Upon the enlisting of a Pharmaceutical Assistant and on payment of the prescribed fee, the Registrar shall issue a certificate of enlisting in the prescribed form.

Application for retention in List **30.**-(1) An enlisted person shall, before the 31st December of each year, file information to the Council in the prescribed manner for the retention of his name in the List.

(2) An application under subsection (1) shall be accompanied by the prescribed fee.

(3) The Council may remove from the List any enlisted person who does not comply with the provisions of subsections (1) and (2).

Publication of registered, enrolled and enlisted persons **31.**-(1) The Registrar shall, by notice, cause to be published in the *Gazette*, as soon as may be practicable after registering, enrolling or enlisting the particulars entered in the Register, Roll or List in respect of each person and subject to the direction of the Council, any amendment or deletion of the particulars in the Register, Roll or List.

(2) The Registrar shall, by notice, cause to be published in the Register, Roll or Gazette, at least once each year, the particulars entered in the List in respect of all persons remaining on the Register, Roll or List at close of the previous year.

Registrar may call for information **32.** The Registrar shall, on his own motion or if requested by the Council, and where he considers it necessary for the furtherance of the objectives and purposes of this Act, require any person registered, enrolled or enlisted under this Act, by a registered letter submitted to the last known address of the person, to furnish any information relating to his practice as a Pharmacist, Pharmaceutical Technician or Pharmaceutical Assistant or any other matter which may be specified in the letter.

Publication as sufficient evidence of registration, enrolment or listing **33.**-(1) A publication under section 31 shall be sufficient evidence that the person mentioned in it is registered, enrolled or enlisted under this Act, and the deletion from the Register, Roll or List of the name of any person notified by the

publication, or the absence of the name of any person from that publication, shall be sufficient evidence that, that person is not registered, enrolled or enlisted or that the validity of his registration, enrolment or enlisting has ceased to have effect.

(2) The Registers, Rolls and Lists and their copies or extracts from them which purport to have been certified under the hand of the Registrar shall be received in a court, tribunal or any body authorised to receive as sufficient evidence of the facts stated therein.

PART IV

REGISTRATION OF PREMISES AND ISSUANCE OF PERMIT FOR BUSINESS IN MEDICINES

Registration of premises

34.—(1) A person shall not sell, dispense or supply medicinal products except in premises registered under this Act.

(2) An application for registration or renewal of registration of premises shall be made to the Council in the prescribed form, and accompanied by such fee as the Council may prescribe.

(3) The Registrar or any person in his behalf shall—

- (a) keep a register of all premises registered under this section;
- (b) register premises if he is satisfied that, the requirements to be complied with by the applicant as prescribed by the Council from time to time have been complied with; or
- (c) have powers to approve the location and name of the proposed premises.

(4) The Council may, for good cause, refuse to register or cause to be removed from the register, any premises which is or has become unsuitable for purposes for which they were registered.

(5) A person who contravenes the provisions of subsection (1), commits an offence and on conviction shall be liable to a fine not exceeding ten million shillings or imprisonment for a term not exceeding two years or to both.

Changes of business ownership or any other change

35.—(1) A business owner shall, in writing notify the Council in the case of any change of ownership of the business or the change of registered premises.

(2) Subject to subsection (1), the registration of premises under this Act shall cease to have effect upon expiration of thirty days from the date of changing the ownership of the business of medicines and related medical supplies.

Application for permits

36.—(1) A person shall not sell, dispense or supply medicinal products unless he has obtained a permit issued under this Act.

(2) An application for a permit shall be made to the Council in the prescribed form, and accompanied by a fee as the Minister may prescribe.

(3) The Council shall not issue a permit to sell medicines and related medical supplies under this section unless the Council is satisfied—

- (a) that the premises in respect of which the application relates shall be stored, meets the prescribed standards;
- (b) that the equipment are available for storing the medicines and related medical supplies;
- (c) with the suitability of the equipment and facilities which are used for distributing the medicines and related medical supplies; and
- (d) with the arrangements made or to be made for securing the safe keeping, and the maintenance of adequate records in respect of medicines and related medical supplies stored in or distributed from those premises.

(4) A separate permit under this section shall be required in respect of each set of premises in which the business is carried on.

Types of permits and revocation, suspension and cancellation of permits

37.—(1) The Registrar shall, subject to subsection (2) and upon an application made to, and on approval by the Council, issue the following pharmacy permits for—

- (a) retail;
- (b) distribution;
- (c) institutional; or

(d) any other business as the Council may deem fit for the purpose of this Act.

(2) Where the Council is satisfied that, the applicant is a fit and proper person to carry on type of business set out in subsection (1) and the premises in which the business is to be conducted meets the prescribed standards, shall issue a permit appropriate to the business subject to general or special conditions as the Council may consider to be appropriate to impose.

(3) A permit issued under subsection (1) shall be in the form and manner as set out in the regulations made under this Act.

(4) Where the Council considers that, the applicant is not fit and proper person to be issued with a permit to carry on any business specified under this section, shall refuse to issue the permit.

(5) The Council may, subject to the provisions of this Act and upon satisfaction that, the terms and conditions of issuance of permit have been violated-

(a) revoke, suspend or cancel the permit; and

(b) direct the Registrar-

(i) to notify the person whose permit has been revoked, suspended or cancelled; and

(ii) to delete the name of the person whose permit has been revoked, suspended or cancelled.

Pharmacy
practice

38. The Council shall, for the purposes of pharmacy practice, prescribe-

(a) the scope of practice of persons registered, enrolled or enlisted under this Act or the services or acts which shall, for purposes of this Act, be deemed to be services or acts pertaining to the pharmacy profession and the conditions under which the services may be provided;

(b) the services to be provided in the various categories of pharmacies, and the conditions under which the services shall be provided;

- (c) rules relating to-
 - (i) Code of Conduct for Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants registered, enrolled or enlisted under this Act;
 - (ii) Good Pharmacy Practice;
 - (iii) the services for which a Pharmacist may levy fees and guidelines for levying such fees;
- (d) the titles or trading names under which a pharmacy may be conducted; and
- (e) matters relating to the investigation and inspection of the pharmacy practice and the conduct of the business of a pharmacist.

Rational use of medicines

39.-(1) The Council shall, for purposes of rational use of medicines, prescribe roles of pharmaceutical personnel relating to-

- (a) pharmaceutical care;
- (b) accessibility, sustainability, affordability, efficacy, safety and quality of medicines;
- (c) self medications;
- (d) policy perspective changes;
- (e) pharmaceutical public health;
- (f) research and communication; and
- (g) any other act relating to appropriate use of medicines.

(2) For the purposes of ensuring the rational use of medicines, a person shall not sell by retail or supply in circumstances corresponding to retail sale or administer other than to himself, a medicine product of a description or a class specified by order made by the Minister and published in the *Gazette*, except in accordance with a prescription made by an appropriate practitioner.

(3) In this section “appropriate practitioner” means a medical practitioner, dentist, veterinarian, or any other person as the Minister, may by order published in the *Gazette*, specify.

(4) A person who contravenes the provisions of subsection (2) commits an offence and on conviction shall be liable to a fine not exceeding five million shillings or to imprisonment for term not exceeding twelve months or to both.

Minister may allow permit to be issued

40.—(1) Where public interest require and upon advice by the Council, the Minister may, notwithstanding any of the provisions of this Act relating to dispensing of medicines by order published in the *Gazette*, allow any persons or group of person to be permitted by the Council to dispense such medicines as may be specified.

(2) The Minister may, in addition to any other conditions, require an applicant for a permit to possess specified qualifications or training, as the case may be.

Exception when supplying and dispensing medicines

41.—(1) A medical practitioner, dentist or veterinary surgeon or a member of the staff of a hospital, health centre, dispensary or similar institution who has been authorised to do so by the general or special order of the Minister, on the advise of the Council, may supply or dispense a prescription medicine for the purpose of medical, dental or veterinary treatment as the case may be, subject to the following conditions:

- (a) the medicine shall be distinctly labeled with the name and address of the person by whom it is supplied or dispensed;
- (b) the following particulars shall, within twenty four hours after the medicine has been supplied or dispensed, be entered in a book used regularly for the purpose, and which shall be called the Prescription Book—
 - (i) the date on which the medicine was supplied or dispensed;
 - (ii) the name, strength and the quantity supplied;
 - (iii) the name and address of the person to whom the medicine was supplied;
 - (iv) the name and address of the person by whom the prescription was made; and
 - (v) name and address of a prescriber or prescribing health facility.

(2) Where an authorised seller of medicines supplies a prescription medicines shall enter its particulars in a Prescription Book kept in accordance with the provisions of this section.

Council to issue
dispensing
certificates

(3) A person to whom subsection (1) applies and who supplies or dispenses any prescription medicine in a manner contrary to this section, commits an offence and on conviction shall be liable to a fine of not more than one million shillings or to imprisonment, for term not exceeding six months or to both.

Restriction
on pharmacy
business and use
of title

42.—(1) The Council may, if it is in the public interest and upon an application and subject to such conditions as may be prescribed, issue a dispensing certificate to a practicing medical practitioner or dentist or veterinary surgeon to dispense medicines.

(2) Upon application to the Council pursuant to subsection (1), the Council may issue a dispensing certificate subject to conditions as it may deem necessary.

(3) The Council may, if it is satisfied that, the applicant did not or is not fulfilling any condition given, may suspend, revoke or withdraw the dispensing certificate issued under subsection (1).

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43.—(1) A person shall not carry the business of pharmacist unless that person is a pharmacist or is in association with a pharmacist.

(2) A person other than a Pharmacist shall not manufacture for sell, supply or dispense any medicine except under the immediate supervision of a Pharmacist.

(3) A permit to practice and a certificate of registration of a Pharmacist having control of the business shall be conspicuously exhibited in the premises.

(4) Where the body is an association—

- (a) a copy of the certificate of its registration under the Business Licensing Act or the Companies Act or any other charter or instrument establishing such association, shall be lodged with the Council;
- (b) the business shall be under the management of the Pharmacist in-charge who shall be a Pharmacist;

(c) in each set of premises for the retail sale of medicines, the business shall be headed by the Pharmacist in-charge.

(5) For the purpose of subsection (3), the use of any of the titles "pharmacist", "druggist", "dispensing chemist", "pharmaceutist" or "drug chemist" or a similar word or combination of words in any language, shall be deemed to suggest the owner of the business or the person having control of the business on any premises is a Pharmacist.

(6) This section shall not apply to emergency supply of medicine for use within twenty four hours to a particular person for a treatment by a qualified medical practitioner, a dentist for the purpose of medical, veterinary surgeons for veterinary treatment.

(7) A person who contravenes the provisions of this section, commits an offence and on conviction shall be liable-

- in case such person is an individual, to a fine of not less than one million shillings or to imprisonment for a term not less than six months or to both;
- in case such a person is an association, firm or body corporate, to a fine of not less than five million shillings.

Conditions for body corporate to become authorised seller of medicine and pharmaceutical products

44.-(1) A body corporate carrying on business involving sale of drugs shall be an authorised seller of medicines within the meaning of this Act, if-

- with regard to the keeping, selling, dispensing and compounding of medicines, the business is under the management of a superintendent who-
 - is a Pharmacist;
 - has signed and submitted to the Registrar a statement in writing on behalf of the body corporate stating his name and specifying whether or not he is a member of that body; and
 - is not at that time acting in similar capacity for any other body;

(b) in each set of premises for the sell of medicines, the business is carried on either under the personal supervision of the superintendent or subject to his directions under the personal control of another Pharmacist;

(c) the name and certificate of registration of the superintendent or of some other Pharmacist having control of the business is conspicuously exhibited in the premises.

(2) Where-

(a) a body corporate which is an authorised seller of drugs has been convicted of an offence under this Act; or

(b) any member of the body corporate or any of its officer or any officer employed by it in carrying on the business, has been convicted of any criminal offence, or has been guilty of misconduct which, in the opinion of the Council, renders him or would, if he were a Pharmacist, render him unfit to be on the register, the Council may inquire into the matter and may, subject to this Act, direct that-

(i) the body corporate cease to be an authorised seller of medicines, and be disqualified for a period to be specified in the directions from being an authorised seller of medicines; or

(ii) any or all of the premises of medicines and the body corporate be removed from the register of premises and be disqualified for such period as the Council may direct.

(3) The Council may, either on its own motion or on application by the body corporate concerned, direct the cessation of any disqualification imposed under this Act.

PART V

GENERAL PROVISIONS

Penalties for professional misconduct

45.—(1) Where-

- (a) a registered, enrolled or enlisted person is found by the Council to be guilty of professional misconduct;
- (b) a registered, enrolled or enlisted person is convicted by any court in Tanzania or elsewhere for an offence which, in the opinion of the Council is incompatible with the status of a Pharmacist, Pharmaceutical Technician or Pharmaceutical Assistant; or
- (c) the name of any such person has been fraudulently registered, enrolled or listed,

the Council shall direct the Registrar to-

- (i) cancel, suspend or remove his name from the Register, Roll or List;
- (ii) impose any other penalty depending on the nature and the gravity of the professional misconduct committed by such person.

(2) The Council may, defer further its decision as to the giving of a direction under the provisions of subsection (1)(c) until subsequent meeting of the Council, but-

- (a) a decision shall not be deferred under this subsection for a period exceeding one year in the aggregate; and
- (b) a person shall not be a member of the Council for the purposes of reaching a decision which has been deferred or further deferred unless he was present as a member of the Council when the decision was deferred.

(3) For the purposes of subsection (1), a person shall not be treated as guilty as mentioned under paragraph (b) of subsection (1) unless the conviction stands at a time when no appeal or further appeal is pending or may be brought in connection with that conviction.

(4) Where the Council gives a direction under subsection (1), the Council shall cause a notice of the direction to be served on the person to whom it relates.

(5) A direction of the Council under subsection (1) shall take effect-

- (a) where no appeal under this section is brought against the direction; or
- (b) where an appeal is brought and is subsequently withdrawn or struck out for want of prosecution.

(6) A person whose name is removed from a Register, Roll or List pursuant to a direction of the Council under this section shall not be entitled to be registered in that register, Roll or List again except in pursuance of a direction in that behalf given by the Council on the application of that person.

Restriction on promotion and advertisement of medicines, medical devices or herbal medicines

46.-(1) A person shall not promote and advertise medicines, medical devices or herbal medicines in a manner that is false, misleading, deceptive or that is likely to create erroneous impression regarding its character, value, quantity, composition, merit, safety or efficacy, as the case may be.

(2) A person shall not carry out any promotional activities on medicines, medical devices or herbal medicines in relation to pharmacy practice without a written approval of the Council.

(3) A person shall not advertise or sell by retail any medicines, medical devices or herbal medicines in connection with any bonus, offer or discount.

(4) Notwithstanding the provisions of subsections (1), (2) and (3), an advertisement shall not include the following:

- (a) words forming part of a sound recording or embodied in a sound-track associated with a cinematograph film;
- (b) words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service; and
- (c) anything spoken in public.

(5) A person who contravenes the provisions of this section commits an offence and, on conviction shall be liable, where such person is-

- (a) an individual, to a fine of not less than two million shillings but not exceeding ten million shillings or to imprisonment for a term of not less than six months but not exceeding three years or to both; or
- (b) a body corporate or an association, to a fine of not less than five million shillings but not exceeding fifteen million shillings.

Appointment of supervisory officers

47.-(1) The Minister may, after consultation with the Council and by notice published in the *Gazette*, appoint such registered, enrolled or enlisted persons to be supervisory officers at the district and regional levels.

(2) A person appointed in accordance with subsection (1) shall perform supervisory functions of pharmacy practice and any other functions as the Council may direct.

Cancellation or suspension of certificates

48.-(1) The Council may, subject to section 50 and if it is satisfied that the terms and conditions of registration, enrolment or enlisting have been violated-

- (a) cancel or suspend the certificate; and
- (b) direct the Registrar-
 - (i) to notify the person whose certificate has been cancelled or suspended; and
 - (ii) to remove the name of the person whose certificate has been cancelled from the Register, the Roll or the List.

(2) A person aggrieved by decision of the Council under subsection (1) may appeal to the Minister within a period of seven days.

Procedure for cancellation or suspension

49.-(1) Where a registered, enrolled or enlisted person is in violation of the terms and conditions of his registration, enrolment or enlisting, the Registrar shall, on the direction of the Council, serve to that person a notice in writing specifying the nature of default.

(2) Upon receipt of the notice under subsection (1), the person to whom the notice is served shall make representation in writing to the Registrar on the rectification of the default.

(3) Where the person under subsection (2) fails to rectify the default within the time specified in the notice or fails to make representation satisfactory to the Registrar, the Registrar shall recommend to the Council for cancellation or suspension of the certificate issued to that person.

(4) The Council shall, if it is satisfied with the recommendations made under subsection (3), direct the Registrar to cancel or suspend the Certificate of Registration, Certificate of Enrolment or Certificate of Enlisting for a period as the Council may consider appropriate.

(5) A cancellation or suspension of a certificate made under subsection (4) shall not exceed a period of twelve months.

Reinstatement to
the Register etc.

50.-(1) A person whose certificate has been cancelled or suspended shall be required to apply for reinstatement of his registration, enrolment or enlisting.

(2) An applicant for reinstatement may make an application within two years of cancellation or suspension otherwise such applicant shall be required to apply afresh as if he had never been registered.

(3) The Council may appoint a senior pharmaceutical personnel to monitor a person who has been suspended, cancelled or removed from the Register, Roll or List and such senior pharmaceutical personnel may be required by the Council to make a report or any recommendation to the Council.

Appeals

51.-(1) A person who is aggrieved by any decision of the Council under this Act, may, at any time within thirty days after receiving the notice of decision of the Council appeal to the Minister.

(2) An appeal against the decision of the Minister shall lay to the High Court.

Inspection **52.**-(1) The Council may, for the purpose of ensuring compliance with the provisions of this Act, conduct or cause to be conducted inspection in any premises or pharmacy.

(2) The Minister shall, upon advice of the Council, make regulations prescribing for-

- (a) appointment or designation, powers and qualifications of inspectors; and
- (b) conducting of inspections for the purpose of this Act.

Offences and penalties **53.** Unless otherwise exempted under this Act, a Pharmacist who uses a licence in respect of which fees are in arrears for more than one year-

- (a) for or in expectation of reward practices or holds himself out as a Pharmacist; or
- (b) without reasonable excuse takes or uses any name, title, addition or description implying that he is authorised by law to practice as a Pharmacist;
- (c) for the purpose of procuring the registration of any name, qualification or other matter-
 - (i) makes a statement which he believes to be false in a material particular; or
 - (ii) recklessly makes a statement which is false in a material particular,

commits an offence.

Indemnity of liability **54.** An Act or thing done by any member of the Council, the Registrar or any other person empowered to perform any function under this Act shall not render the member, the Registrar or that other person authorised to perform functions under this Act personally liable for the matter or things done, if done in good faith in execution or purported execution of his functions under this Act.

Regulations **55.** The Minister may, upon advice of the Council, make regulations with respect of any of the following matters or for any of the following purposes-

- (a) the manner in which additional requirements relating to practical experience referred to in sections 16, 24 or 28 may be conducted;

- (b) the conduct of inquiry by the Council, and the attendance of witnesses and production of evidence at the inquiry under this Act, including the power to take evidence on oath;
- (c) grounds for suspension or cancellation of registration, enrolment or enlisting granted under this Act;
- (d) disciplinary procedures for Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants;
- (e) the pharmacy practice;
- (f) the conduct of business of a pharmacy, including the premises, medicines and related medical supplies;
- (g) any fees payable under this Act;
- (h) the conditions of services of staff appointed by the Council;
- (i) the information to be furnished to the Registrar by Pharmacists, Pharmaceutical Technicians and Pharmaceutical Assistants who are owners or managers of pharmacies carrying on business as Pharmacists;
- (j) the minimum requirements of the curricula and the duration of the course of study for a basic degree, diploma, certificate in Pharmacy or any other certificate to be issued under this Act;
- (k) the registration of Pharmacists, enrolment of Pharmaceutical Technicians and enlisting of Pharmaceutical Assistants by the Council;
- (l) the training, education or other qualifications required for registration, enrolment or enlistment of Pharmacist, Pharmaceutical Technician or Pharmaceutical Assistant;
- (m) the persons required to be enrolled as Pharmaceutical Technicians or enlisted as Pharmaceutical Assistants and conditions under which such persons shall be required to be enrolled or enlisted;
- (n) supplementary training or refresher courses to be undertaken by any person registered, enrolled or enlisted under this Act, and control thereof;

- (o) prescribing functions, conduct and powers of supervisory officers;
- (p) promotion and advertisement of medicines, medical devices and herbal medicines;
- (q) specialties in respect of which registered persons may apply for registration; and
- (r) anything which is required or permitted to be prescribed under this Act.

Rules

56.—(1) The Council may, with approval of the Minister, make rules for the better carrying out of its functions under this Act and, without prejudice to the generality of the power conferred by this section, the Council may by such rules—

- (a) prescribe qualifications which shall be recognised as entitling the holder to registration, enrolment or enlisting under this Act;
- (b) prescribe ethics for the practice of the profession of pharmacy;
- (c) prescribe standards of professional conduct of pharmacists;
- (d) provide for and regulate the manner of giving assistance to members of the public on matters touching upon, ancillary or incidental to the practice of the profession of pharmacy; and
- (e) prescribe anything which, in the opinion of the Council is incidental or ancillary to the performance of its functions or the exercise of its powers under this Act.

(2) Rules made by the Council under this section shall be published in the *Gazette*.

Repeal and
savings
Act No.
7 of 2002

57.—(1) [Repeals the Pharmacy Act].

(2) Notwithstanding the repeal under subsection (1)—

- (a) every person who, immediately before the commencement of this Act, was registered in the Register of Pharmacists under the repealed Act, and is resident in Tanzania, shall be deemed to have been registered under this Act; and

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(b) any premises registered or business of pharmacist permitted under the repealed provisions of the Tanzania Medicine and Medical Devices Authority Act, shall be deemed to have been done under the provisions of this Act;

(c) any subsidiary legislation made or directives issued under the repealed Act, shall be deemed to have been done under the provisions of this Act.

(3) [Omitted.]

PART VI

CONSEQUENTIAL AMENDMENTS

Omitted

58.–60. [Omitted].

SCHEDULE

(Made under section 3(3))

Composition of Council

1.–(1) The Council shall consist of the following members appointed by the Minister:

- (a) a Chairman appointed from amongst persons registered as Pharmacists from private sector, have contributed towards the promotion and development of the pharmacy practice;
- (b) the Chief Pharmacist from the Ministry of Health;
- (c) representative from the Pharmaceutical Society of Tanzania;
- (d) a Principal from a public higher learning institution that offers training in pharmacy;
- (e) a representative of the Attorney General;
- (f) one enrolled or enlisted Pharmaceutical Technicians recommended from the Tanzania Pharmaceutical Technicians Association; and
- (g) one person from the public whose qualifications and experience can assist the Council and the development of the pharmacy profession.

(2). The Council may co-opt any person to attend its meetings but the person shall not have a right to vote.

Vice-Chairman	2. The members shall elect one of their numbers to be the Vice-Chairman of the Council and any member elected as Vice-Chairman shall, subject to his continuing to be a member, hold office for a term of one year from the date of his election, but shall be eligible for re-election.
Tenure of office	<p>3.—(1) A member shall, unless his appointment is terminated by the Minister, or he ceases in any other way to be a member, hold office for a period of three years and shall be eligible for reappointment.</p> <p>(2) Members appointed by virtue of their office shall cease to be members upon ceasing to hold the office entitling appointment to the Council.</p> <p>(3) A member of the Council shall cease to be a member if—</p> <ul style="list-style-type: none"> (a) the Minister, in the public interest, terminates his membership after giving written notice to the member to show cause why his membership should not be terminated; (b) ceases to hold the position entitled his appointment; (c) he fails without good cause to attend three consecutive meetings of the Council; (d) he is convicted of a criminal offence for a term of or beyond six months; (e) he becomes mentally ill; or (f) he is disqualified to practice under this Act.
Meetings of Council	<p>4.—(1) The Council shall ordinarily meet at such times and places as it deems necessary for transaction of its business, but shall meet at least once in every three months.</p> <p>(2) The Chairman or in his absence, the Vice-Chairman, may at any time call a special meeting upon a written request by a majority of the members.</p> <p>(3) The Chairman, or in his absence the Vice-Chairman, shall preside at every meeting of the Council and in the absence of both, the Chairman and Vice-Chairman, the members present shall appoint a member from amongst themselves to preside over the meeting.</p>
Absent members to be represented	5. Where a member of the Council who is a member by virtue of his office is unable for any reason to attend any meeting of the Council, he may nominate another person from his organisation to represent him in the meeting.
Quorum	6. The quorum at any meeting of the Council shall be half of the members.
Votes and decision of the Council	<p>7.—(1) Subject to subparagraph (2), matters proposed at a meeting of the Council shall be decided by a majority of the votes of the members present and voting and in the event of an equality of votes, the person presiding shall have a casting vote in addition to his deliberative vote.</p> <p>(2) A decision may be made by the Council without a meeting by circulation of the relevant papers among the members and the</p>

expression of the views of the members in writing but any member may require that the decision be deferred and the subject matter be considered at a meeting of the council.

Minutes of meeting

8.—(1) The Council shall cause to be recorded and kept minutes of all business conducted or transacted at the meeting and the minutes of each meeting of the Council shall be read and confirmed or amended and confirmed at the next meeting of the Council and signed by the person presiding and the Secretary to the meeting.

(2) The minutes purporting to be signed by the person presiding and the Secretary at a meeting of the Council shall in the absence of proof of error be deemed to be a correct record of the meeting whose minutes they purport to be.

Vacancies etc. not to invalidate proceedings

9. The Validity of any Act or proceeding of the Council shall not be affected by any vacancy among its members or by any defect in the appointment of any of them.

Council may regulate its own proceedings

10. Subject to the provisions of this Schedule, the Council may regulate its own proceedings.

Proof of documents

11. A document purporting to be under the hand of the Registrar as to any resolution of the Council or as having been issued on behalf of the Council, shall be receivable in all courts or tribunals or other bodies authorised to receive evidence and shall unless the contrary is shown, be deemed, without further proof, to be sufficient evidence of what is contained in the document.

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