

THE SENATE FEDERAL REPUBLIC OF NIGERIA

PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022

(HB. 334)

A BILL FOR AN ACT TO REPEAL THE PHARMACISTS COUNCIL OF NIGERIA ACT CAP. P17, LAW OF THE FEDERATION OF NIGERIA, 2004, AND ENACT THE PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022 TO REGULATE THE STANDARD OF TRAINING AND PRACTICE OF PHARMACY; AND FOR RELATED MATTERS, 2022

FIRST READING
SECOND READING
THIRD READING AND PASSAGE

WEDNESDAY, 23RD MARCH, 2022 TUESDAY, 21ST JUNE, 2022 TUESDAY, 21ST JUNE, 2022

PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022



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Commencement

ENACTED by the National Assembly of the Federal Republic of Nigeria-

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PART I-ESTABLISHMENT OF THE PHARMACY COUNCIL OF NIGERIA

Establishment of the Pharmacy Council of Nigeria

- 1. (1) There is established the Pharmacy Council of Nigeria (in this Act referred to as "the Council").
- (2) The Council -
- (a) is a body corporate with perpetual succession and a common seal;
- (b) may sue or be sued in its corporate name; and

Cap. L15, LFN 2004

(c) may acquire, hold or dispose of any property, movable or immovable, subject to the provisions of the Land Use Act, for the purpose of performing any of its functions under this Act.

Composition of the Council.

- 2. (1) The Council shall consist of -
- (a) a Chairman, who shall be a pharmacist with not less than 25 years post registration experience;
- (b) the head of Food and Drug Services Department of the Federal Ministry of Health or his representative, who shall be a registered pharmacist;
- (c) the President of the Pharmaceutical Society of Nigeria;
- (d) the Director responsible for Pharmaceutical Services of each State Ministry of Health including the Federal Capital Territory;
- (e) the Deans of the recognised faculties or schools of pharmacy in Nigerian Universities who shall be Pharmacists;
- (f) the head of Pharmaceutical Services of the Armed Forces of Nigeria:
- (g) the Director-General of the National Institute of Pharmaceutical Research and Development or his representative who shall be a pharmacist;
- (h) eight members, who shall have at least 10 years post qualification experience to represent the geopolitical zones of the Federation, on the recommendation of Pharmaceutical Society of Nigeria through the Minister;

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- (i) three members who shall be registered pharmacy technicians in good standing with the Council with at least 10 years post-registration experience;
- (j) the Registrar of the Council who shall be a member and the Secretary to the Council; and
- (k) the Director-General of National Agency for Food and Drug Administration and Control (NAFDAC) or his representative who shall be a registered pharmacist.
- (2) The Chairman and members of the Council shall be paid such emoluments, allowances and benefits as the President may direct in line with the recommendations of the Revenue Mobilisation, Allocation and Fiscal Commission.
- 3. (1) The Chairman and other members of the Council other than the Registrar, shall -

Appointment and tenure of members of the Council.

- (a) be appointed by the President on the recommendation of the Minister;
- (b) hold office on part time basis for a term of four years; and
- (c) be eligible for re-appointment on satisfactory performance for a further term of four years and no more.
- (2) The office of the Chairman or a member of the Council shall become vacant where-
- (a) his term of office expires;
- (b) he resigns his appointment as a member of the Council by a notice in writing under his hand addressed to the President; or
- (c) he dies.
- (3) The President may, on the recommendation of the Minister, remove the Chairman or a member of the Council on any of the following grounds where –
- (a) he has been absent from the Council meetings for four consecutive times without the permission of the Council;
- (b) he is incapable of carrying out his duties due to mental or physical infirmity;
- (c) he has been declared bankrupt or he makes compromise with his creditors;
- (d) he has been convicted of a felony or any offence involving fraud or dishonesty;
- (e) he is guilty of gross misconduct relating to his duties;
- (f) the President is satisfied that it is not in the interest of the Council or of the public for the person to continue in office; or
- (g) in the case of an ex-officio member, he ceases to hold the office on the basis of which he became a member of the Council.
- (4) Where a member of the Council ceases to hold office before the date that his term of office has expired, the body or person by whom he was appointed shall immediately appoint a person to fill Senate Bill Page 2 of 36

the vacancy for the residue of the term.

(5) The provisions of the First Schedule to this Act shall have effect with respect to the proceedings of the Council and other matters mentioned in it.

Functions and powers of the Council.

- 4. (1) The Council shall in the public interest -
- (a) administer the provisions of this Act;
- (b) regulate the standard of pharmacy practice and business in Nigeria;
- (c) determine the standard of knowledge and skills to be attained by persons seeking to become registered members of the pharmacy profession and review such standards;
- (d) determine and set standards for the degree courses in faculties of pharmacy in Nigerian universities;
- (e) establish requirements and standards for registration of intern pharmacists for internship and any other experiential training to enable a person obtain practical experience in the practice of pharmacy;
- (f) establish requirements for the grant of licence to intern pharmacists to undergo internship training and engage in the practice of pharmacy in an approved institution under the direct supervision of registered pharmacists;
- (g) establish and maintain a register of persons entitled to practice as members of the pharmacy profession and publish the list of members;
- (h) inspect, approve, licence and regulate the registration and practice or operations in all pharmaceutical premises where drugs, medicines and poisons are manufactured, imported, exported, distributed, stored, dispensed or sold in Nigeria, based on Good Pharmaceutical Practice Standards (GPP);
- (i) establish and maintain a register of premises used for the manufacture, storage, importation, exportation, distribution, sale and dispensing of drugs, poisons, medicines, and medical devices and accessories;
- (j) regulate, formulate, publish and review the code of conduct, ethics and practice of the pharmacy profession and code of conduct for pharmacy technicians, patent medicine vendors and pharmaceutical marketers;
- (k) determine and set standards for the training of pharmacy technicians in schools and colleges of health technology approved by the Council;
- (I) determine the standards of knowledge and skills to be attained by persons seeking to become pharmacy technicians and patent medicine vendors, and review such standards;
- (m) establish requirements for continuing education and development for pharmacists, pharmacy technicians, patent medicine vendors and other cadres in practice in institutions and centres recognised by it, including the determination of acceptable continuing educational and developmental courses;
- (n) register, licence, regulate and control the practice of pharmacists, pharmacy technicians or such

other cadres as may be recognised by the Council in Nigeria;

- (o) register, licence, regulate and control the activities of patent and proprietary medicines vendors and satellite medicine facilities, pharmacies, pharmaceutical manufacturing, importation, exportation, storage, distribution of pharmaceutical products and veterinary products in Nigeria;
- (p) regulate and control the practice of pharmaceutical marketing and representations;
- (q) regulate and control Pharmacy practice in all its aspects and ramifications; and
- (r) do such other things that are necessary to ensure the efficient performance of the functions conferred on the Council under this Act.

PART II- REGISTRAR AND OTHER STAFF OF THE COUNCIL

Appointment, functions and tenure of the Registrar of the Council.

- **5.** (1) There shall be a Registrar appointed by the Council who is a registered pharmacist of at least 20 years post-registration experience.
- (2) The Registrar shall be -
- (a) the chief executive and accounting officer of the Council;
- (b) member and secretary to the Council and the secretary to the Disciplinary Tribunal;
- (c) responsible for the execution of policies, decisions and directives of the Council and the administration of the Council;
- (d) responsible for keeping and maintaining the registers under this Act; and
- (e) subject to the supervision and control of the Council.
- (3) The Registrar shall hold office -
- (a) for a term of four years from the date of his appointment and is eligible for re-appointment for another term of four years and no more; and
- (b) on such other terms and conditions as may be specified in his letter of appointment.
- (4) The office of the Registrar shall become vacant where -
- (a) his term of office expires;
- (b) he resigns his appointment as Registrar by a notice in writing under his hand addressed to the Council;
- (c) he is incapable of carrying out his duties due to mental or physical infirmity;
- (d) he has been declared bankrupt or he makes compromise with his creditors;
- (e) he has been convicted of a felony or any offence involving fraud or dishonesty;

- (f) he is guilty of gross misconduct relating to his duties;
- (g) he dies; or
- (h) the Council is satisfied that it is not in the interest of the Council or of the public for the Registrar to continue in office.

Other staff of the Council.

- **6.** (1) The Council shall appoint directly or on Secondment from other Government Ministries, Departments and Agencies such number and category of employees as it may require in the effective discharge of its duties and performance of its functions under this Act.
- (2) The Council may have power to appoint, promote and discipline staff of the Council.
- (3) The Council shall make rules and regulations in line with Public Service Rules relating to the conditions of service of employees of the Council, including rules providing for the appointment, promotion, advancement, determination of appointment and discipline of the employees.
- (4) The members of staff of the Council shall be public officers as defined in the Constitution of the Federal Republic of Nigeria, 1999.
- (5) Service in the Council shall be pensionable service under the Pension Reform Act provided that nothing in this section shall exclude the Council from employing staff on non-pensionable terms and conditions.

Zonal and state offices.

7. The Council shall have the power to establish zonal and state offices to enhance its operations and the performance of its functions under this Act.

Co-operation with other bodies.

8. The Council may cooperate with relevant organizations and authorities involved in public health related issues in the performance of its functions under this Act.

PART III - FINANCIAL PROVISIONS

Fund of the Council.

- 9. (1) There is established for the Council a fund (in this Act referred to as "the Fund") which shall consist of —
- (a) budgetary and extra budgetary allocations received from the Government of the Federation, grants and annual subventions;
- (b) all money held immediately before the commencement of this Act by the Pharmacists Council of Nigeria;
- (c) gifts, loans, endowment, grants-in-aids, testamentary disposition, bequest or other voluntary contributions where the terms and conditions attached are not inconsistent with the functions of the Council;
- (d) all foreign aids and monetary assistance received by the Council under any agreement or arrangement with any international body or organization with the approval of the Government of the Federation;
- (e) fees, charges for publications and services rendered by the Council; and

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- (f) such other money received by the Council from investments and other sources.
- (2) The Council may apply the Fund established under subsection (1) for -
- (a) payment of the costs of administration, charges and expenses of the Council:
- (b) discharging the cost of maintaining the head office and other offices of the Council:
- (c) the development and maintenance of any property vested in or owned by the Council;
- (d) the payment of the allowances and other benefits of members of the Council or any committee set up by it;
- (e) payment of emoluments, allowances, benefits and other entitlements of the Registrar and other staff of the Council;
- (f) payment for all purchases made by the Council and the training of members of its staff;
- (g) provision of scholarships, bursaries and awards for specialised training of members of staff of the Council:
- (h) payment to publicise and promote the activities of the Council;
- (i) payment to various stakeholders involved in regulatory activities of the Council;
- (j) payments for the support of national and international scientific and professional organisations;
- (k) maintaining general financial reserves subject to general or specific directives that may be given by the President;
- (I) payment of annual and other subscriptions and contributions to national and international scientific and professional organisations;
- (m) the payment of all consultancies, legal fees and costs of contracts awarded by the Council; and
- (n) any other expenditure as may be approved by the Council, in connection with all or any of its functions and powers under this Act.
- 10. (1) The Council may invest any or all money in its Fund, not immediately required for its current expenditure in —
- Investment of the Fund of the Council.
- (a) securities created, issued by or on behalf of the Federal Government, as may be approved by the Council;
- (b) the purchase or improvement of any land in any part of the Federation; or
- (c) any venture in Nigeria as may be approved by the Minister, including investment in stocks quoted at the Nigerian Stock Exchange.
- (2) In the exercise of its power of investment under subsection (1), the Council may, vary any investments and may deposit any money not invested with any bank approved by the Council in line with government regulations.

11. The Council may with the approval of the President and in line with applicable laws, policies and regulations, borrow such sums by way of loan, overdraft or from any other source, as may be required for the performance of its functions and meeting its obligations under this Act and any interest payable on money so borrowed shall be paid out of the Fund of the Council.

Power to borrow.

Power to accept gifts,

- 12. (1) The Council may accept gifts of land, money or other property on such terms and conditions, if any, as may be specified by the persons or organizations making the gift.
- (2) The Council shall not accept any gift if the conditions attached by the persons or organizations offering the gift are inconsistent with the functions of the Council under this Act.

Annual estimates.

- 13. (1) The Council shall, not later than 30 September of each financial year, prepare and submit to the Minister for onward transmission to the National Assembly, an estimate of its income and expenditure for the next succeeding year.
- (2) Notwithstanding the provisions of subsection (1), the Council may, where necessary due to unforeseen circumstances, submit supplementary or adjusted statements of estimated income and expenditure to the Minister for onward transmission to the National Assembly for approval.

Accounts, records and audit.

- 14. (1) The Council shall keep proper and regular accounts and other records of money received and paid by the Council and for other purposes for which money have been received or paid, and of its assets, credits and liabilities in respect of each year and shall cause its accounts to be audited on or before 31 March of the following year to which the accounts relate, by a firm of auditors appointed from the approved list of auditors, and in accordance with guidelines, supplied by the Auditor-General for the Federation.
- (2) The Council shall do all things necessary to ensure that all payment of its funds and bank accounts are correctly made and properly authorized and that adequate control is maintained over its assets.
- (3) Where the accounts and the financial statements of the Council have been audited in accordance with the requirement of this Act, the Council shall immediately forward a copy of the audited financial statements to the Minister together with any report or observations made by the auditors and the Auditor-General for the Federation on the statement of accounts.
- (4) The remuneration of the auditor shall be paid out of the Fund of the Council.

Annual reports.

15. The Council shall, not later than 30 June of each year, prepare and submit to the Minister and the Auditor—General for the Federation, a report on the activities and administration of the Council during the preceding year and shall include in the report a copy of the audited accounts of the Council for the year and the auditor's report thereon.

PART IV - REGISTERS OF PHARMACISTS, PHARMACY TECHNICIANS, PREMISES, SATELLITE MEDICINE FACILITIES AND PATENT MEDICINES SHOPS

16. (1) The Registrar shall in accordance with rules made by the Council, keep and maintain-

Keeping and maintaining registers.

(a) a register of pharmacists, where the names, addresses, qualifications and other particulars of all persons who are entitled to be enrolled as provisional members or members of the profession who apply to the Council to be so registered shall be entered;

- (b) the register of pharmacy technicians where the names, addresses, qualifications and such other particulars of all persons who are entitled to be enrolled as pharmacy technicians who apply to the Council to be so registered shall be entered;
- (c) the registers of premises used by pharmacists, pharmacy technicians and patent medicine vendors, or any other person licensed by the Council for the manufacture, production, exportation, importation, stocking for research or any other purposes, storage, distribution, sale or dispensing of drugs and medicines, medical devices and accessories and the provision of other pharmaceutical products shall be entered; and
- (d) any other register that the Council may require to be kept.
- (2) The register of pharmacists provided under subsection (1) (a) shall consist of two parts, one for
- (a) provisional members; and
- (b) members.
- (3) The register of the pharmacy technicians provided under subsection (1) (b) shall consist of -
- (a) the names of pharmacy technicians;
- (b) matters relating to pharmacy technicians; and
- (c) particulars of the location where medicines are sold or distributed by pharmacy technician or satellite medicine facility.
- (4) A register of premises referred to under subsection (1) (b) shall contain -
- (a) the names and addresses of premises to which the entries relate and to which members carry on pharmacy business;
- (b) the type of pharmaceutical practice being carried on at the premises;
- (c) the name of the pharmacist or person, company, firm or body lawfully carrying on the business;
- (d) the name of the approved vendor of medicines and location where the medicines are being sold; and
- (e) such other matters relating to the premises as may be specified by the Council.
- 17. (1) Subject to the provisions of this Act, the Council may make rules with respect to the forms, contents, parts and procedures for keeping and making of entries in any of the registers provided under this Part.

Rules for keeping and maintainin g registers.

- (2) The rules made under subsection (1) shall, in particular make provision for -
- (a) regulating the making and processing of applications for enrolment of provisional

members or members and the registration of premises under this section;

- (b) the notification to the Registrar of any change in those particulars by the person -
- (i) to whom any registered particulars relate; or
- (ii) carrying on a pharmacy practice at any registered premises;
- (c) the procedure for the acceptance and registration of additional qualification to the earlier qualification held by him which is in relation to the profession;
- (d) specifying the fees, including any annual subscription, to be paid to the Council in respect of -
- (i) entry of names in the register of pharmacists or the registration of premises in the register of premises; and
- (ii) entry of names in the register of pharmacy technicians or the registration of satellite medicine facilities, patent medicines vendors or shops;
- (e) authorizing the Registrar to refuse to enter a name or premises in a register until any fees specified for the entry has been paid or until the premises comply with the requirements of this Act or of rules made on that behalf which are for the time being in force; and
- (f) specifying any other thing not mentioned under this provisions which the Council considers necessary or expedient.
- (3) A document signed by the Registrar stating that, on a specified date, specified persons or premises were or were not registered under this Act shall be admissible in a proceeding as evidence of such registration or non registration.

18. The Registrar shall -

Correction of entries in the registers.

- (a) correct any entry in the registers of pharmacists, premises, pharmacy technicians, satellite medicines facilities and patent medicines shops in accordance with the Council's directions or order of court;
- (b) make or update any necessary alteration in the registers of pharmacists, pharmacy technicians, satellite medicines facilities, licensed patent medicines shops and the registers of premises as may be necessary or expedient;
- (c) remove from the registers of pharmacists, pharmacy technicians, satellite medicines facilities and patent medicines shops or the registers of premises, the name of any registered person who is dead or premises which has ceased to be used for the purpose for which it was registered; and
- (d) remove from the register of premises any premises that its registration has become void under the provisions of this Act.

19. (1) Where the Registrar -

Removal of names from the registers.

(a) sends by registered post, e-mail or other recognized means of communication to any person, a

letter addressed to him at the address on the register of pharmacist, pharmacy technician, satellite medicines facilities and medicines vendor, enquiring whether the registered particulars relating to him or to the premises at which he carries on pharmacy practice are correct and the Registrar receives no reply to the letter within a period of six months from the date of posting or sending it, and

- (b) considers it necessary upon the expiration of that period of six months, sends in the like manner to the person in question, a second similar letter and receives no reply within three months from the date of posting or sending it, the Registrar may remove the name and particulars of that person or any registered premises where that person carries on a pharmacy practice from the register of pharmacists, pharmacy technicians, satellite medicines facilities and patent medicines vendors or the registers of premises or both.
- (2) The Council may direct the Registrar to restore to the appropriate register any name, premises or particulars removed from the register under subsection (1).
- 20. The Registrar shall cause -
- (a) the list of licensed pharmacists, pharmacy technicians, satellite medicines facilities, patent medicines vendors and licensed premises to be printed, published and gazetted not later than two years from the commencement of this Act;
- (b) to be updated, printed and published, each of the lists referred to under paragraph (a), in each subsequent year;
- (c) a print of each edition of the list of licensed pharmacists, pharmacy technicians, satellite medicines facilities and medicines vendors and the lists of premises and of each document or corrections to be deposited at the principal office of the Council; and
- (d) the documents so deposited in line with the provisions of paragraph (c), open to members of the public at all reasonable times for inspection.
- **21.** (1) A document purporting to be a print of an edition of any list published under section 20 of this Act by authority of the Registrar, or prints of an edition of such list, and of the lists of corrections to that edition so published in the current year and of lists of corrections to that edition so published, shall, without prejudice to any other mode of proof, be admissible in any proceedings as evidence showing that —
- (a) any other person or premises specified in the document; or
- (b) the documents read together, as being licensed,

was so licensed at that date of the edition or of the list of corrections of licensed persons or premises and that any person or premises not so specified was not so licensed at that date.

(2) Where in accordance with subsection (1), the name of any person or any premises is in any proceedings shown to have been or not to have been licensed in the register of pharmacists or the register of premises at a particular date, the person or the premises shall unless the contrary is proved, be taken for the purposes of those proceedings as having at all material times thereafter

Publication of list of pharmacists, pharmacy technicians, premises, satellite medicines facilities and patent medicines shops

Print of an edition of a register as admissible evidence.

PART V -INSPECTION AND REGISTRATION OF PREMISES

22. (1) Any place used for the purpose of dispensing, selling, compounding, distribution, storage, stocking, retailing, wholesale, manufacturing, importation, exportation of drugs and poisons, scientific offices or any other form of pharmaceutical activities shall be inspected and registered in accordance with the provisions of this Act and in case of manufacturing facility such GMP activities conducted by the NAFDAC are not included.

Inspection and registration of premises.

- (2) Where an application is made under subsection (1) and it appears to the Registrar that the premises to which the application relates do not comply with the requirements of this Act, the Registrar may refuse to register the premises and state the reasons for the refusal in writing.
- (3) The applicant may within 30 days after the service of notice of refusal by the Registrar under subsection (2), give notice to the Registrar of his desire to be heard or make representation in writing to the Registrar with respect to the notice of refusal.
- (4) The Registrar before making any determination under subsection (3) shall –
- (a) where the applicant has given notice of his desire to be heard, afford the applicant an opportunity of appearing before and being heard by a person appointed by the Registrar for the purpose; or
- (b) where the applicant has made representations in writing, consider the representations of the applicant in determining whether the premises is suitable for registration or otherwise.
- (5) Where a determination is made under subsection (4) that the premises is -
- (a) suitable for registration, the Registrar shall cause the details of the premises to be entered into the register subject to the provisions of section 23 of this Act; or
- (b) unsuitable for registration, the Registrar shall not enter the premises in the register; and shall notify the applicant of his decision accordingly.
- (6) Where the applicant is dissatisfied with the decision under subsection (5) (b), he may within 14 days after being notified of the decision make application in writing to the Council stating the grounds of his dissatisfaction and the reliefs sought.
- (7) The Council shall consider and determine the application made under subsection (5) within three months of the receipt of the application or such extended period as it may deem necessary in any particular case.
- (8) Where the Council under subsection (6), determines that the premises is -
- (a) suitable for registration, the Registrar shall enter the premises in the register, subject to the provisions of section 23 of this Act; or
- (b) unsuitable for registration, the Registrar shall not enter the premises in the register, and shall

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notify the applicant of the decision, in writing.

- (9) Where the Registrar is of the view that a licence should be suspended, revoked, withdrawn, canceled or restored, the holder of such licence shall, by notice, be required to give reasons within 14 days of receipt of such notice why the licence should not be suspended, revoked, withdrawn or cancelled and if the –
- (a) Registrar is satisfied by the reasons so given, such licence shall not be suspended, revoked, withdrawn or cancelled; or
- (b) reason given is not satisfactory, the Registrar shall notify his decision to suspend, revoke, withdraw or cancel same to the holder and in such case, the holder of the licence shall within 14 days appeal to the Council.
- (10) An application shall be made to the Registrar for his approval for change, variation or modification in a licence in respect of Superintendent Pharmacist, structure of premises, location of premises ,scope and areas of practice or any other change or variation that may affect the licence.
- 23. (1) The Council shall prescribe the fees for the registration and retention of premises.

Payment of fees in respect of registration and retention of premises.

- (2) The Council may vary the fees provided under subsection (1).
- (3) A person shall not operate premises where drugs, poisons, medicines, medical devices and medical accessories are sold, dispensed, distributed, manufactured, stored, imported or exported unless he has paid the prescribed fees and is duly licensed by the Council.
- 24. (1) Where any premises has been entered in the register of premises, a retention fee of an amount prescribed by the Council in respect of the type of pharmacy practice being carried on at the premises, shall be payable to the Council every subsequent year by the person carrying on the pharmacy practice in the premises.

Payment of retention fees.

- (2) A retention fee shall become due on the first day of January of each year.
- (3) Where the person carrying on pharmacy practice at any premises entered in the register of premises fails to pay the retention fee in respect of any year by 31 March, the Council may close the premises and remove the name from the register of premises.
- (4) Where the person in default of payment of retention fees under subsection (2), pays before the end of the year in default, together with additional sum, the Registrar shall restore the name of the premises to the register and the restoration shall be deemed to have had effect as from the date on which the premises were removed from the register of premises.
- 25. The Registrar shall keep record of the names of registered persons who are in default of the payment of the annual subscription for a period of more than six months and take such actions including the removal of the names of the defaulters from the appropriate register as the Council may direct or require.

Records of annual subscription defaulters.

Application for retention of name of all premises.

- 26. (1) A person who carries on practice of pharmacy whether online or on sight shall, in the month of January in each year deliver to the Registrar, an application for renewal or retention of name of the premises at which his practice is located or where he carries on his practice for a prescribed fee.
- (2) An application for renewal or retention of premises under subsection (1) shall state the name of the superintendent pharmacist under whose control the practice is being carried on.
- 27. (1) A person shall not own or operate a retail or community pharmacy practice unless the person is registered as a pharmacist under this Act.

Operating a retail, community pharmacy or pharmaceutical company.

- (2) The Council may approve satellite pharmacy owned by licensed pharmacists who have a minimum of 10 years post-registration experience provided that such satellite pharmacy is affiliated to a registered pharmaceutical premises for the purpose of regulation and control.
- (3) A company owned by Nigerians or foreign company shall not own or operate a chain retail or community pharmacy unless such a company has Nigerian pharmacist or pharmacists on board of directors who shall solely or jointly own not less than 40% shares of the company.
- (4) A corporate body shall not operate a pharmaceutical company for the purpose of manufacture, importation, exportation, storage, distribution or wholesale business without having as a member of the board of directors, at least a registered pharmacist who shall be a shareholder of the company.
- (5) A person or corporate body shall not own or operate a private pharmacy in a public health facility.
- (6) A pharmacist who makes a false statement under subsection (3) commits an offence and is liable on conviction to a fine equivalent to the value of the shares he claimed to own or a term of imprisonment for two years or both.

Failure to renew license.

- 28. (1) A licensee who fails to renew its license by 31 January in each year shall in addition to the prescribed fee, pay a fine equivalent to 50% of the applicable fee.
- (2) A licensee who fails to renew the license of its premises by 31 March in each year shall be considered to be operating in violation of the provisions of this Act and shall be liable to closure by the Council.
- **29.** (1) Every pharmaceutical premises is under the direct supervision of a Superintendent Pharmacist.

Requirement for Superinten dent Pharmacist

- (2) Where a premises is operated without a Superintendent Pharmacist for a continuous period of 30 days, the registration of the premises license shall lapse at the expiration of that 30 days.
- (3) Every pharmacy whether in public or private hospital shall be under the supervision and control of a Superintendent Pharmacist.
- **30.** (1) A body corporate shall notify the Council of any change in its company's profile, profile of Pharmacist Director, ownership, type of business being done on the premises and name of the company not later than 60 days of its occurrence.

Notification of change in company's profile

(2) A body corporate shall conspicuously display the original of the Superintendent Pharmacist's annual license and certificate of registration of the premises.

Appointment of Pharmaceu tical

- 31. (1) The Council shall appoint licensed pharmacists as Pharmaceutical Inspection Officers.
- tical Inspection Officer

of

- (2) A person appointed by the Council as Pharmaceutical Inspection Officer may for the purposes of section 32 of this Act enter at any reasonable time, any premises –
- (a) where pharmaceutical activities are carried on; or
- (b) on or in relation to which he has reasonable cause to believe that an offence with respect to this Act has been committed.

Powers
Pharmaceutical
Inspection Officer.

- 32. (1) A Pharmaceutical Inspection Officer may –
- (a) require the superintendent pharmacist on the premises to furnish him with any information in his possession concerning the pharmaceutical activities being carried on in the premises; or
- (b) inspect and seal premises where drugs are sold or dispensed, in violation of any provisions of the Act.
- (2) A Pharmaceutical Inspection Officer appointed by the Council in the course of his duty and on production of his identity card if so requested, may —
- (a) open and examine while in the premises any container or package which he reasonably believes may contain anything which may help in his investigation; or
- (b) examine any book, computer, document, prescription, register of poison or dangerous drugs or other records, electronic or printed found on the premises which the pharmaceutical inspection officer reasonably believes may contain any information relevant to the enforcement of this Act and make copies or extracts from it.
- (3) A Pharmaceutical Inspection Officer who uses to his advantage or discloses to a third party any information obtained in the course of his duties under this Act other than for investigative and prosecutorial purposes, commits an offence.
- (4) Any person who willfully delays, cause to be delayed or obstruct or cause to be obstructed a Pharmaceutical Inspection Officer in the exercise of any of the powers conferred upon him under this Act, commits an offence.
- (5) The owner or person in-charge of any premises entered into by a Pharmaceutical Inspection Officer shall render all reasonable assistance within their powers to the Pharmaceutical Inspection Officer and shall make available to him all such information as he may reasonably require for the purpose of the Act.
- (6) A person operating any pharmaceutical business on any premises has a duty to provide information on the owner when requested by an inspector and to produce to the inspector all books kept in accordance with this Act.

and registration of hospital pharmacies

- **33.** (1) Pharmacies in public and private hospitals and clinics shall be subject to inspection, registration and annual licensure by the Council.
- (2) There shall be a superintendent pharmacist in every public and private hospital, clinic and healthcare institution where drugs are dispensed.
- (3) The Council may grant exemptions on the application of subsections (1) and (2) or prescribe supervisory roles to cover pharmaceutical services in underserved areas, on such terms as the Council may prescribe.

PART VI - REGISTRATION OF PHARMACISTS

Registration pharmacists.

of

- **34.** (1) A person shall not hold any appointment as a pharmacist or practice as a pharmacist in Nigeria unless he is registered and licensed with the Council under the provisions of this Act.
- (2) A registered pharmacist is entitled to practice as a pharmacist in any part of Nigeria provided he is licensed to practice.

Registration

provisional member or a member,

- **35.** (1) A person admitted to membership of the pharmacy profession in Nigeria under the provisions of this Act may be registered as —
- (a) a provisional member; or
- (b) a member.
- (2) A person is entitled to be enrolled as a provisional member where he-
- (a) has completed a degree course of study in a faculty of pharmacy in a recognized university;
- (b) has submitted a written application in the form prescribed by the Council and has paid the prescribed registration fee;
- (c) has sworn to the pharmacist oath;
- (d) is of good character;
- (e) has not been convicted in the last 10 years in Nigeria or elsewhere of any criminal offence involving fraud or dishonesty; and
- (f) meets other requirements for registration as a provisional member of the profession as may be prescribed by the Council.
- (3) A person is entitled to be registered as a member of the profession if in addition to holding the qualifications and satisfying all the conditions set out in subsection (2), he –
- (a) has submitted a written application in the form prescribed by the Council and paid the prescribed registration fees;
- (b) has completed the statutory continuous internship training for not less than one year in an institution approved by the Council and has obtained from the institution a certificate of

experience in that regard; and

- (c) meets any other requirements for registration as a member of the profession as may be prescribed by the Council.
- **36.** A Nigerian citizen who qualified as a pharmacist in an approved institution outside Nigeria shall be registered as a pharmacist under this Act, where he –

Registration of Nigerian citizen who qualified outside Nigeria.

- (a) holds a qualification in pharmacy awarded by an approved or recognised university outside Nigeria which qualification for the time being, is acceptable to the Council for the purpose of this Act;
- (b) holds a certificate of registration as a pharmacist, acceptable to the Council;
- (c) has completed in Nigeria the statutory internship course of training and obtained certificate specified in section 35 (3) (b) of this Act, where applicable;
- (d) has received instructions in pharmacy for a period specified by the Council in an institution in Nigeria approved by the Council for that purpose, and has passed an examinations as the Council may prescribe, including an examination in forensic pharmacy;
- (e) is of good character;
- (f) has not been convicted in the last 10 years in Nigeria or elsewhere of any criminal offence involving fraud or dishonesty;
- (g) submits a duly completed application in writing in the prescribed form and paid the prescribed registration fees; and
- (h) meets any other requirements for registration as a member of the profession as may be prescribed by the Council.
- 37. (1) A person who is not a citizen of Nigeria may be registered as a pharmacist under this Act if the country of which he is a citizen grants reciprocal registration facilities to Nigerian citizens and where he -

Registration of non-Nigerian pharmacists.

- (a) holds a requisite qualification recognized by the Council;
- (b) has passed the Council's examination in law and ethics governing the practice of pharmacy in Nigeria and such other examinations as the Council may prescribe;
- (c) has acquired the requisite experience in accordance with section 35 (3) (b) of this Act;
- (d) has been resident in Nigeria for not less than 12 calendar months immediately preceding the date of his application for registration; and
- (e) meets all other requirements for registration as may be prescribed by the Council.
- (2) An applicant applying for registration under this section shall in addition to evidence of qualification, satisfy the Council that he —

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- (a) is of good character;
- (b) has not been convicted in the last 10 years in Nigeria or elsewhere of any criminal offence involving fraud or dishonesty;
- (c) submits a duly completed application in writing in the prescribed form; and
- (d) has paid the prescribed fee for registration.

Payment of practicing fees.

- **38.** (1) A person shall not practice as a pharmacist in any year unless he has paid to the Council the appropriate practicing fees prescribed by the Council which shall be due in January of each year as prescribed by the Council.
- (2) The Council shall disburse or distribute the aggregate amount collected as practicing fees as follows –
- (a) 70 % to the Pharmaceutical Society of Nigeria; and
- (b) 30 % to the Council.
- (3) A pharmacist with at least 40 years post registration experience or who has attained the age of 65 years is exempted from the payment of practicing fees.
- (4) A registered pharmacist who fails to pay the prescribed practicing fee by 31 March of every year shall in addition to the fee, pay a fine of a sum which is equivalent to 50 % of the applicable fee within the year.
- (5) A registered pharmacist who has paid his practicing fee in any year as prescribed in subsection (1) or who is exempted from payment of practicing fee under subsection (3), is entitled to a practicing licence for that year authorising him, subject to any enactment or regulation in force applicable to him to –
- (a) import, export, mix, compound, prepare, dispense, sell, procure and distribute drugs and poisons, herbal medicines, veterinary drugs and health supplements, chemicals and home use Invitro Diagnostics (IVDs);
- (b) monitor pharmaceutical products;
- (c) perform other duties related to -
- (i) Drug Utilisation Review (DUR);
- (ii) Pharmaceutical Care (PC);
- (iii) Collaborative Drug Therapy Management (CDTM); and
- (d) any other pharmaceutical activities.

(6) The Council may vary the practicing fees prescribed in subsection (1) provided that any variation of the practicing fee shall not come into force unless confirmed at the Annual General Meeting of the Pharmaceutical Society of Nigeria.

PART VII - TRAINING AND INTERNSHIP OF PHARMACISTS

39. (1) An institution shall not award any degree in pharmacy unless such institution and the course of study are approved by the Council.

Approval of Institutions and pharmacy degree courses.

- (2) The Council may approve -
- (a) any course of training intended for persons seeking to become or who are already pharmacists and which in the opinion of the Council is designed to confer appropriate knowledge and skills; and
- (b) any qualification with attendant course content which in the opinion of the Council affords the candidate sufficient knowledge and skill to practice as a pharmacist.
- (3) The Council may withdraw any approval given under subsection (1) in respect of any course, qualification or institution provided that before such approval is withdrawn, the Council shall –
- (a) give notice of such proposed withdrawal to the affected institution;
- (b) give the institution an opportunity to make representation to the Council in respect of the proposed withdrawal; and
- (c) take into account any representations made to it under paragraph (b) of this subsection as regards the proposed withdrawal.
- (4) A course, qualification or an institution shall not be treated as approved under this section during any period that the approval is withdrawn by the Council under this section.
- (5) The withdrawal of an approval under subsection (3) shall not prejudice the registration or eligibility for registration of any person who by virtue of the approval was registered or was eligible for registration either unconditionally or subject to obtaining a certificate of experience as an intern pharmacist immediately before the approval was withdrawn.
- (6) The giving or withdrawal of an approval under this section shall have effect from the date the Council may signify in an instrument and the Council shall —
- (a) publish such instrument in the Federal Government Gazette; and
- (b) before its publication in the Federal Government Gazette, send a copy of the instrument to the Minister.
- **40.** (1) The Council shall assess the nature of instructions given to persons undergoing professional degree course of training in pharmacy in an approved institution.

(2) The Council may constitute external assessors or visitation teams to evaluate degree examinations or course of training in approved institutions.

Supervision and assessment of institutions, instructions and degree examinations.

- (3) The external assessors or visitation teams shall submit a report to the Council on the approved institutions visited and the report may disclose –
- (a) the adequacy of the instructions given to persons attending the degree course of training in pharmacy or the facilities for such instructions;
- (b) the adequacy of the professional pharmacy degree examinations;
- (c) any other matter relating to the institutions and examinations on which the Council may direct; and
- (d) that external assessors or visitation team shall not in the performance of its functions under this section interfere with the holding of any degree examination.
- (4) The Council may, on the receipt of a report made under this section by a visitation team or external assessors, demand for a clarification from the institutions visited.

Intern pharmacists trained in Nigeria.

- 41. (1) A person seeking to undergo training as an intern pharmacist under this Act shall be -
- (a) a graduate and have received a first degree in pharmacy from a recognized university approved by the Council; and
- (b) duly registered as a provisional member.
- (2) An intern pharmacist shall within six weeks of commencing his training as an intern notify the Council in the prescribed form of the -
- (a) identity of the institution approved by the Council, where he is undergoing his internship;
- (b) particulars of the registered pharmacist approved by the Council to supervise his work; and
- (c) date when the internship commenced.
- (3) An intern pharmacist shall immediately notify the Council of the occurrence of any change in the particulars mentioned in subsection (2) (a) and (b).
- (4) One year period of internship training shall be calculated from the date of the notification referred to in subsection (2).
- (5) An intern pharmacist, after the one year internship training shall be required to pass a preregistration examination to qualify for full registration as a pharmacist.
- **42.** (1) An institution or facility shall not be used for internship placement for the purposes of section 39 of this Act, unless approved by the Council in writing.
- Approval of institution: for internship placement
- (2) The Council shall approve an institution for the purpose of subsection (1) where it is satisfied that —
- (a) the institution or facility provide a conducive environment to the learning of the practice of pharmacy by intern pharmacists; and

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- (b) all intern pharmacists undergoing the training at the institution at any particular time are exposed to all facets of the practice of pharmacy available at the institution or facility.
- (3) The Council may make rules or guidelines for internship placement.

Supervision of Intern pharmacists.

- **43.** (1) An intern pharmacist in an approved institution under section 40 (1) of this Act shall be under the direct supervision of a licensed pharmacist who must have practiced for a period as Council may specify by regulations.
- (2) A Pharmacist serving as a supervisor of an intern pharmacist shall notify the Council in the prescribed form of the date of commencement of the internship by the intern pharmacist.

PART VIII - TRAINING AND REGISTRATION OF PHARMACY TECHNICIANS

44. (1) An institution shall not award pharmacy technician certificate unless the institution and the course of study are approved by the Council.

Training and registration of pharmacy technician.

- (2) A person shall not be qualified to work as a pharmacy technician in any part of Nigeria unless he is duly registered and issued with an annual permit by the Council as a pharmacy technician.
- (3) A person shall not be registered by the Council as a pharmacy technician unless he has -
- (a) undergone a course of training for pharmacy technicians in a school of health technology or any other institution approved by the Council;
- (b) been converted from pharmacy assistant to pharmacy technician before the commencement of this Act or holds a certificate issued by a recognised institution approved by the Council; or
- (c) undergone a course of training in a foreign institution recognised by the Council for a specified period of time and has also undergone a mandatory six months orientation programme in a school of health technology or any other institution recognised by the Council for that purpose.
- (4) A person who is registered as a pharmacy technician under subsection (2) shall work under the direct supervision and control of a registered pharmacist.
- (5) A supervising Pharmacist shall not assign to a pharmacy technician any duty which is required under the provisions of this Act to be performed only by a pharmacist.
- (6) A person who does not possess the qualifications specified in subsection (2) or who has not registered as a pharmacy technician or deemed to have been so registered, shall not work or perform any function as a pharmacy technician at any place of work in any part of Nigeria.
- (7) A person shall not -
- (a) use or bear the title "pharmacy technician" in connection with any work or function performed by him at any place of work in any part of Nigeria, if he is not registered as a pharmacy technician in accordance with the provisions of this Act;
- (b) use or bear the title "pharmacy technician" in connection with his work or duty, in circumstances likely to suggest that he possesses any of the qualifications specified in subsection

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- (2) for pharmacy technicians but that person does not possess or that he has been registered or deemed to be registered as a pharmacy technician under this Act, when he is not so registered; and
- (c) work as a pharmacy technician in any year unless he has paid in respect of that year the prescribed annual permit renewal fee before 31 March.
- (8) Any person who violates the provisions of subsection (5) and (6) commits an offence and is liable on conviction to a fine of N500,000.00 or imprisonment for a term of two years or both.

PART IX - PROFESSIONAL DISCIPLINE

45. (1) There is established the Pharmacy Council of Nigeria Investigating Panel (in this Act referred to as "the Panel") charged with the responsibilities for —

Establishment of the

- (a) conducting a preliminary investigation into any case where it is alleged that a person registered under this Act as a pharmacist, pharmacy intern or a provisional member has committed an act in that capacity amounting to a professional misconduct or infamous conduct in a professional respect, or is for any other reason the subject of proceedings before the Tribunal; and
- (b) deciding whether the case should be referred to the Tribunal.
- (2) The Panel shall be appointed by the Council and shall consist of four members of the Council and one other person who is not a member of the Council, but who is a registered pharmacist appointed by the Council.

Establishment of the Tribunal.

- 46. (1) There is established the Pharmacy Council of Nigeria Disciplinary Tribunal (in this Act referred to as "the Tribunal") which shall be charged with the responsibility of considering and determining any case referred to it by the Panel established under section 45 of this Act.
- (2) The Tribunal shall consist of the Chairman of the Council and six other members appointed by the Council.

Second Schedule

- (3) The provisions of the Second Schedule to this Act apply to the Panel and the Tribunal respectively.
- (4) Without prejudice to the provisions of this section, the Council may make regulations for the discipline of pharmacy technicians and medicine vendors.
- **47.** (1) For the purpose of this Part, professional misconduct or infamous conduct in a professional respect include –

Meaning of professional misconduct or infamous conduct.

- (a) the publication or circulation of false, misleading or deceptive statements concerning the practice of pharmacy;
- (b) divulging or revealing to unauthorised persons, a patient or another practitioner's information, or the nature of professional pharmacy services rendered, without the patient's express consent,

or without order or direction of a court;

- (c) selling, giving away, or disposing of accessories, chemicals, drugs, medicines or devices which have been obtained illegally, when the pharmacist knows or ought to have known of their having been obtained illegally or their intended use in illegal activities;
- (d) manufacturing, importing, exporting, procuring, compounding, mixing, preparing, dispensing, selling, distributing of medicines, chemicals, drugs, poisons, devices or accessories in an unlicensed premises;
- (e) dispensing, selling, distributing, giving away or disposing accessories, chemicals, drugs, poisons, medicines or devices to unauthorized persons;
- (f) engaging in conduct likely to deceive, defraud or harm the patient or the public, or demonstrating a willful or careless disregard for the health, welfare or safety of a patient or the public or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist;
- (g) knowingly failing to maintain a complete and accurate records of all drugs and medicines produced, received, dispensed or disposed of in compliance with the requirements of all enactments, regulations and rules for the time being in force;
- (h) practicing the profession without being licensed; or
- (i) obtaining any money by fraud, misrepresentation or deception.
- (2) Without prejudice to the provisions of subsection (1), the Council may make rules prescribing other acts or omissions which shall constitute professional misconduct or infamous conduct in professional respect under this Act.

Penalties professional misconduct.

48. (1) Where -

- (a) a pharmacist is found by the Tribunal to be guilty of professional misconduct or infamous conduct in any professional respect;
- (b) a pharmacist is convicted by any court or tribunal in Nigeria or elsewhere having power to award imprisonment, of an offence which in the opinion of the Tribunal is incompatible with his status as a pharmacist; or
- (c) the Tribunal finds that the name of any person has been fraudulently registered under this Act, the Tribunal may give a direction –
- (i) reprimanding that person,
- (ii) ordering the Registrar to suspend him from practice,
- (iii) ordering the Registrar to strike out his name off the appropriate register,
- (iv) ordering the person to pay a fine as may be specified in the direction, or
- (v) ordering the Registrar to remove from the register of premises, any premises entered in the register of premises, at which the pharmacy practice in question is carried out by a registered person.

for

- (2) The Tribunal may defer its decision under subsection (1) provided, that --
- (a) no decision shall be deferred for more than an aggregate period of three months; and
- (b) a member of the Tribunal shall not sit for the purpose of reaching a decision which has been deferred unless he was present when the decision to defer was taken.
- (3) Where the Tribunal gives a direction under subsection (1), the Tribunal shall cause a notice of the direction to be served on the person to whom it relates.
- (4) A person to whom a direction under subsection (1) relates may, at any time within 30 days from the date of service on him of the notice of direction, appeal against the direction to the Court of Appeal and the Tribunal may appear as respondent to the appeal and, for the purpose of enabling directions to be given by the Court of Appeal as to the costs of the appeal and of proceedings before the Tribunal, the Tribunal shall be considered to be a party to the appeal, whether or not it appears on the hearing of the appeal.
- (5) A direction of the Tribunal under subsection (1) shall take effect where -
- (a) no appeal under subsection (4) is brought against the direction within the time limit for such an appeal, on the expiration of that time;
- (b) an appeal under subsection (4) is brought against the direction, but it is withdrawn or struck out for want of prosecution, from the date of the withdrawal or striking out of the appeal; or
- (c) such an appeal is brought and is not withdrawn or struck out, if and when the appeal is dismissed.
- (6) A person whose name is struck out of any register kept under this Act or suspended from practice in pursuance of a direction of the Tribunal shall not be entitled to be re-registered in that register or reinstated to practice, except in pursuance of a direction given by the Tribunal or an appellate court.
- (7) A pharmacist who in respect of any year practices the profession without paying his annual practicing fee commits a misconduct and is liable –
- (a) in the case of a first offender, to a fine of twice the prescribed practicing fee, and
- (b) in the case of a second or subsequent offender, to a fine of not less than 10 times the prescribed practicing fees, and if the pharmacist is in the employment of any person, the employer commits an offence punishable in the like manner as the pharmacist where it is proved that the pharmacist's failure to pay the prescribed fees was with the knowledge, consent or connivance of the employer.
- **49.** For the purpose of section 48 (1) (b) of this Act, a person shall not be treated as convicted unless as at the time the conviction is subsisting, the time stipulated for appeal has lapsed and no appeal is pending in an appellate court.

When a person shall be treated as convicted.

When a person is deemed to practice as a pharmacist.

- 50. For the purpose of this Act, a person shall be considered to practice as a pharmacist if he -
- (a) engages himself in the practice of pharmacy or holds himself out to the public as a pharmacist;
- (b) renders professional service or assistance in or about matters of principle or detail relating to pharmacy; or
- (c) renders any other service which may, by regulations made by the Council, be designated as service constituting practice as a licensed pharmacist.
- **51.** Criminal proceedings shall not oust the jurisdiction of the Tribunal from determining any case of misconduct or infamous conduct in a professional respect.

The jurisdiction of the Tribunal.

PART X - OFFENCES AND PENALTIES

General offences.

- **52.** (1) A person who knowingly makes a false statement for the purpose of procuring the registration of any name, premises, qualification or any other matter under this Act, commits an offence.
- (2) A person who is not a registered pharmacist, an intern pharmacist, pharmacy technician, satellite medicines facility, vendor or pharmaceutical representative under this Act, but practices as such or holds himself out as being so registered or practice in that capacity whether for reward or not, or takes or uses any name, title, addition or description implying that he is so registered and authorised by law to so practice, commits an offence under this Act.
- (3) A person who commits an offence under this section is liable on conviction, in the case of -
- (a) subsection (1), to a fine not less than N500,000.00 or imprisonment for a term not exceeding one year or both; or
- (b) subsection (2), to a fine not less than N1,000,000.00 or imprisonment for a term not exceeding two years, or both.
- (4) A body corporate that violates the provisions of this section commits an offence and is liable on conviction, in the case of -
- (a) subsection (1), to a fine not less than N2,000,000.00 and the directors or principal officers of the body corporate are liable to a fine not less than N250,000.00 or imprisonment for a term not exceeding two years or both; or
- (b) subsection (2), to a fine not less than N5,000,000.00 and the directors or principal officers of the body corporate are liable to a fine not less than N500,000.00 or imprisonment for a term not exceeding three years or both.
- (5) Where an offence under this Act which has been committed by a body corporate is proved to have been committed with the consent, connivance or collusion of or to be attributable to any neglect on the part of a director, manager, secretary or any other similar officer of the body corporate or any person who was purporting to act in any capacity, the officer and the body

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corporate commits an offence and are liable to be proceeded against and punished accordingly.

- (6) In relation to a body corporate carrying on pharmacy business, subsection (4) shall have effect as to a person who, not being an officer of the body corporate at the time of the commission of the offence –
- (a) is the Superintendent Pharmacist, or
- (b) at any premises where the business is carried on, is the pharmacist who acts under the directions of the Superintendent Pharmacist, or as if he were such an officer of the body corporate as mentioned in the preceding subsection.

53. Any person who -

Obstruction of a Pharmaceutical Inspection Officer and breaking of seal.

- (a) obstructs, resists, or attempts to obstruct or resist a Pharmaceutical Inspection Officer in the execution of his duty under this Act,
- (b) makes any statement to a Pharmaceutical Inspection Officer in the course of his duties which the person knows or has reasonable cause to believe to be false or misleading,
- (c) without the authority of the Pharmaceutical Inspection Officer removes, alters or interferes in anyway with any article seized under this Act, or
- (d) breaks the Council's seal or lock, commits an offence and is liable on conviction to a fine of N2,000,000.00 or imprisonment for a term of two years or both.

54. (1) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, a pharmacy which is not registered under this Act, commits an offence and is liable on conviction to a fine of \$2,500,000.00 or imprisonment for a term of two years or both.

- (2) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, a pharmacy in which a person not licensed as a pharmacist or not registered as an intern pharmacist or in which an intern pharmacist who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicines, drugs or poison commits an offence and is liable on conviction to a fine of \$2,500,000.00 or imprisonment for a term of two years or both.
- (3) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, a satellite medicine facilities outlet or patent and patent medicines vendors shop which is not registered under this Act commits an offence and is liable on conviction to a fine of \$\pm\$500,000.00 or imprisonment for a term of at least than 6 months or both.
- (4) A person who knowingly and with intent to defraud –
- (a) makes a false or fraudulent claim, either for himself or another person, in any application, affidavit or statement presented to the Council or any proceeding before the Council, or
- (b) fills, compounds or dispenses prescriptions or medicines without holding a valid licence as a

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Operating a pharmacy without registration pharmacist or not registered as an intern pharmacist or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist, commits an offence and is liable on conviction to a fine of N250,000.00 or imprisonment for a term of one year or both.

General penalty.

- 55. (1) A person who commits an offence under this Act for which no specific penalty is provided is liable on conviction to a fine of at least ₱500,000.00 or imprisonment for a term of two years or both.
- (2) A body corporate that commits an offence under this Act for which no specific penalty is provided is liable on conviction to a fine of at least \(\frac{4}{2}\),000,000.00.

Arrest, investigation and prosecution of criminal cases.

- **56.** Subject to the provisions of the Constitution of the Federal Republic of Nigeria, 1999 and the Administration of Criminal Justice Act, a police officer or other relevant law enforcement agencies shall have power under this Act to —
- (a) arrest and investigate offenders; or
- (b) prosecute cases.

Seizure.

- **57.** (1) Any medicine, drug, poison or any other article sold, offered for sale, stocked or dispensed in violation of any provisions of this Act may be seized by the Council.
- (2) Where medicines, drugs, poisons or other articles are seized under any of the provisions of this Act, the Council may —
- (a) place the medicines, drugs, poisons or other articles under seal; or
- (b) remove the medicines, drugs, poisons or other articles to a place designated by the Council.

Forfeiture of drugs, medicines, poisons.

58. Any drug, medicine, poison or other articles seized by the Council in accordance with the provisions of this Act shall be forfeited to the Federal Government free of any encumbrances and shall be dealt with in such manner as the Minister may determine.

PART XI - ETHICAL AND DANGEROUS DRUGS

59. (1) Ethical drugs shall not be stored, supplied, sold, offered to be sold or dispensed by any person unless under the direct supervision of a licensed pharmacist.

Storage and supply of ethical or dangerous drugs.

- (2) A person shall not store, supply, sell or dispense dangerous drugs unless -
- (a) he is a licensed pharmacist;
- (b) the drug is in a container of the prescribed description; and
- (c) the container bears a label indicating the prescribed particulars of its contents.
- (3) Where a drug is supplied on prescription, the supplier of the drug shall -

- (a) enter on the prescription in indelible writing, the -
- (i) date on which the drug is supplied, and
- (ii) name and address of the supplier; and
- (b) if the drug is fully dispensed, make entry in a manner as to be readily available for inspection.

Dangerous Drugs Record

- **60.** (1) A person who supplies dangerous drugs shall keep on the premises from where he supplied the drugs, a book of the prescribed description to be known as the "Dangerous Drugs Record".
- (2) Before a person supplies dangerous drugs, he shall record in the Dangerous Drugs Record the -
- (a) name and quantity of the drug to be supplied;
- (b) name, and address, signature or thumbprint of the person to whom it is supplied;
- (c) signature of the person who supplied the drug; and
- (d) date of supply.
- **61.** A pharmacist shall not dispense dangerous drugs, except under a prescription issued by a licensed medical practitioner, dentist or veterinary practitioner.

Control of dispensing of dangerous drugs.

- Preparation of restricted

 62. (1) A person shall not mix, compound, prepare or supply restricted drugs unless that person is
- a registered pharmacist or a licensed company under the supervision of a pharmacist.
- (2) The provisions of subsection (1) shall not apply to the mixing, compounding or preparing of a dangerous drug by a student under the supervision of a pharmacist.

PART XII - MISCELLANEOUS

Jurisdiction.

- **63.** The Federal High Court shall have the jurisdiction to hear and determine criminal and civil matters under this Act.
- **64.** (1) The Council may, with the approval of the Minister, make regulations, rules and guidelines as may be required to give effect to the provisions of this Act.

Regulations, rules and guidelines.

- (2) Without prejudice to the generality of the provisions of subsection (1), the Council may make rules, guidelines and regulations for –
- (a) ensuring the ethical sales, dispensing, distribution, importation, exportation, compounding, warehousing, manufacture of drugs, medicines, poisons, operations of pharmacy technicians, medicine vendors and such other persons as may be approved by the Council;
- (b) training of pharmacists, pharmacy technicians and patent medicines vendors;
- (c) supervision and regulation of the engagement, training and transfer of such persons;
- (d) prescribing the type of licence to be issued annually under this Act to a person to practice as an intern pharmacist or pharmacy technician and operating premises, or, where the Council considers

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- fit, for the annual renewal of the licence to be done by endorsement of the renewal on an existing licence;
- (e) restricting the right of practice as a pharmacist or operating a premises where there is a default of payment of the amount of the annual subscription and the default continues for longer than such period as may be prescribed by the rules;
- (f) restricting the right of practice as a pharmacist where the qualification granted outside Nigeria does not entitle the holder to practice as a pharmacist in Nigeria;
- (g) prescribing the form and manner of the inspection of premises where medicines, pharmaceutical raw materials are kept, stored, sold or manufactured;
- (h) reviewing all categories of pharmacy practice;
- (i) prescribing the procedure for maintaining and filing with the Council within two months of the publication of the result of the final examination conducted by a school of health technology or any other institution approved by the Council for persons seeking to qualify as pharmacy technician including the list of the candidates who are successful at the examination;
- (j) regulating all forms of manufacturing, compounding, storage, sale, dispensing, distribution, importation or exportation of drugs, poisons, medicines, herbal medicines, food supplements, nutriceuticals, veterinary drugs and pharmaceuticals or by whatever name described;
- (k) prescribing the requirement of re-certification as a condition for the retention of the name of registered pharmacists, pharmacy technicians and medicine vendors in the register or conditions for renewal of the practicing license of a registered pharmacist, pharmacy technicians and medicine vendors;
- (I) supervision and regulation of pharmacy technicians and restriction of the work of any pharmacy technician in default where such defaults continue longer than that prescribed by the rules;
- (m) regulating the grant, renewal, restoration, endorsement, revocation, suspension, cancellation, withdrawal of licence; or
- (n) prescribing the procedures for changes, variations and modification of licence.
- (3) The power to make regulations, rules and guidelines under subsections (1) and (2) shall not be exercised in the absence of the Council.
- (4) Any regulation, rule or guideline made under this Act shall be published in the Federal Government Gazette.
- **65.** The Dean of each faculty of pharmacy approved by the Council in any university in Nigeria shall furnish the Registrar –

Duty of Deans to furnish the Registrar details of pharmacy students in training.

(a) not later than 31 March in every year a list of the names and such other particulars as the Council may by order specifying all persons who are registered as pharmacy students in that faculty during the academic session; and

(b) with the list of candidates successful at the final pharmacy degree examination immediately after the release of the result.

Pre-action notice.

- 66. (1) A suit shall not commence against the Council before the expiration of a period of one month after a written notice of intention to commence the suit had been served on the Council by the intending plaintiff or his agent and the notice shall clearly state the —
- (a) the cause of action;
- (b) the particulars of the claim;
- (c) the name and place of abode of the intending plaintiff; and
- (d) relief which he claims.
- (2) The notice referred to in subsection (1) and any summons, notice or other document required or authorised to be served on the Council under this Act or any other law, may be served by –
- (a) delivering it to the abode of the intending plaintiff; or
- (b) sending it by registered post addressed to the Registrar at the head office of the Council.
- **67.** In any action or suit against the Council, no execution shall be levied or attachment process issued against the Council unless not less than 30 days' notice of the intention to execute or attach has been given to the Council.

68. A member of the Council, Registrar, officer or employee of the Council shall be indemnified out of the assets of the Council against any proceedings brought against him in his capacity as a member of the Council, Registrar, officer or employee of the Council where the act complained of is not *ultra vires* to his powers.

Repeal and savings.

- **69.** (1) The Pharmacists Council of Nigeria Act, Cap P17, Laws of the Federation of Nigeria, 2004, (in this Act referred to as "the repealed Act") is repealed.
- (2) Notwithstanding the provisions of subsection (1) -
- (a) any person who is registered and all regulations and amendments made under the repealed Act shall be deemed to have been made under this Act:
- (b) any register kept under the repealed Act shall be deemed to be part of the register kept under this Act;
- (c) any document referring to the provisions of the repealed Act shall be construed as referring to the corresponding provisions of this Act;
- (d) any direction, orders and appointments lawfully given, made or other acts done under the repealed Act and in force immediately before the commencement of this Act, shall be deemed to have been given, made or done under this Act and have effect accordingly;
- (e) any person who immediately before the commencement of this Act held appointment as an Senate Bill Page **29** of **36**

Restriction on execution against property of the Council.

Indemnity of officers of the Council. employee of the Council shall on the commencement of this Act be deemed to have been deployed to the Council as an employee without further assurance; and

(f) all property held by or on behalf of the Council immediately before the commencement of this Act, shall on the commencement of this Act be deemed to have been vested in the Council without further assurance.

70. (1) The Poisons and Pharmacy Act, shall be read with such modifications as are necessary to bring it into conformity with the provisions of this Act.

Adaptation of the Poisons and Pharmacy Act.

Cap. 535 LFN, 1990

(2) Where the provisions of the Poisons and Pharmacy Act are inconsistent with the provisions of this Act, the provisions of this Act shall prevail and the provisions of the Poisons and Pharmacy Act shall to the extent of the inconsistency be void in relation to matters provided for under this Act.

Interpretation.

71. In this Act -

"approved" means approved by the Council;

"article" includes-

- (a) any drug, poison, medicine or medical consumables;
- (b) anything used for the manufacture, preparation, preservation, packaging or storing of any drug poison or medical device;
- (c) any labeling or advertising material relating to or for use in connection with any drug, poison or medical device;
- (d) records and books required to be kept under this Act; or
- (e) electronic records, receipts, invoices and other relevant documents;

"Associate Member" means students in accredited faculties or schools of pharmacy;

"Collaborative Drug Therapy Monitoring" (CDTM) means a team approach to healthcare delivery, that seeks to maximise the expertise of the pharmacist and the physician in order to achieve optimal patient care outcomes through appropriate medication use and enhanced patient care services;

"chain retail pharmacy" means a number of registered pharmaceutical premises as specified by regulation bearing same name, engaged in retail pharmaceutical practice and owned by body corporate or pharmacist;

"community pharmacy" means a health care facility that provides pharmaceutical services to people in a local area or community;

"Council" means the Pharmacy Council of Nigeria established under section 1 of this Act;

"court" means the Federal High Court;

"dangerous drugs" means any drug to which the provisions of Dangerous Drugs Act apply;

"dispensing" means to prepare, to count out, measure or decant from a bulk supply, or mix, or dissolve, or disperse, and dispose the drug, for gain or otherwise for the treatment of a particular person or animal but does not include the actual administration of the drug; "drugs or medicines" include any substance of vegetable, animal or mineral origin or any

preparation or mixture, which is used for internal or external application in -

- (a) the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state, or the symptoms in man or in animals;
- (b) restoring, correcting or modifying organic functions in man or in animals;
- (c) disinfection, or the control of vermin, insects or pests; or
- (d) contraception.

"DUR" means Drug Utilisation Review which is a process of a comprehensive review of medication profile by a pharmacist;

"ethical drugs" means drugs or medicines dispensed under the direct supervision of a licenced pharmacist"

"fees" include annual subscription, practicing fee, registration fees, renewal fees or inspection fees;

"forensic pharmacy" means study of pharmacy and drug laws as well as the application of pharmaceutical sciences and practice to legal matters;

"GMP" with reference to the functions of the Council means the inspection of pharmaceutical facilities for the purposes of licensure and revalidation of such licences;

"GPP" means good pharmaceutical practice in accordance with best global practices;

"hospital pharmacy" is the department, section or unit of the hospital or clinic that manage the procurement, storage, preservation, packaging, sterilisation, compounding, preparation, dispensing or distribution of medicine in the hospital or clinics;

"label" in relation to any food, drug, cosmetic, medical device or package includes any legend, word or mark attached to, included in, belonging to or accompanying that food, drug, cosmetic, medical device or package;

"medical devices and accessories" used in this Act include needles, syringes, gauze, cotton wools;

"members" mean persons with full registration status with Pharmacy Council of Nigeria (PCN);

"Minister" means the Minister responsible for Health;

"package" includes anything in which any food, drug, cosmetic or device is wholly or partly contained, wrapped, placed or packed;

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"pharmacist" means any person who is registered and licensed to engage in pharmacy in Nigeria and whose name is in the register kept for such purpose by Pharmacy Council of Nigeria;

"pharmacy technician", means a person who has undergone a course of training for pharmacy technicians in a school of health technology or any other institution approved by the Council, duly registered and issued with an annual permit by the Council as a Pharmacy Technician;

"pharmaceutical activities" include dispensing, selling, distribution, storage, stocking, wholesaling or manufacturing of drugs and poisons;

"Pharmaceutical Inspection Officer or Inspector" means a registered pharmacist appointed or engaged by the Pharmacy Council of Nigeria to carry out inspection on premises where pharmaceutical activities, operations and businesses are carried out;

"pharmaceutical care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve and sustain a patient's quality of life;

"pharmaceutical marketing and representation" means any activity undertaken or organised or sponsored by a company, distributor, or an importer that is promoting the prescription, recommendation, supply, sale or distribution of a pharmaceutical product;

"pharmaceutical or sales representatives" means persons involved in pharmaceutical marketing and representation;

"pharmacy practice" include giving of patient-centred care, provision of drug information, monitoring of drug therapy, discovery and evaluation of drugs, clinical interventions and provision of technical aspects of pharmaceutical services or business such as importation, exportation, mixing, compounding, preparing, dispensing, selling and distribution of drugs and poisons;

"poison" includes substances whether natural or synthetic, mixed with other ingredients or not, and whatever restrictions under the provisions of this Act are placed on any particular poison shall apply to it whether it is unmixed or is contained as an ingredient in some preparation, unless it is contained in one of the preparations specifically exempted from such provisions;

"practicing fee" means payment made by registered members of the profession to the Council;

"premises" means a place approved and registered by the Council for any of the following purposes of dispensing, selling, distribution, storage, stocking, retailing, wholesale, manufacturing, importation, exportation of drugs and poisons, herbal and dietary supplements, scientific offices or any other form of pharmaceutical activities;

"prescribed" means prescribed by the regulations;

"President" means President of the Federal Republic of Nigeria;

"profession" means pharmacy profession;

"provisional members" means persons with provisional registration status with Pharmacy Council of Nigeria and this include non-Nigerians and Nigerian citizens undergoing internship programmes;

"register" means any register maintained or required to be maintained in accordance with the provisions of this Act;

"Registrar" means the Registrar appointed under the provisions of this Act;

"regulation" means rules and regulations made under this Act;

"restricted drugs" means controlled and psychotropic substances as well as any drug to which the provisions of Dangerous Drugs Act apply;

"retention fees" means annual fees paid for the retention of names of persons or premises in their respective registers;

"satellite medicine facility" means a retail medicine facility established through an arrangement with a registered community pharmacy of not less than five years of existence in Nigeria, for the sole purpose of improving access to quality, safe, efficacious and affordable pharmaceutical products and services in underserved communities and other areas the Council deems necessary; "selling" includes offering for sale, hawking for sale and displaying for purpose of sale and in possession for sales or distribution;

"Society" means the Pharmaceutical Society of Nigeria;

"Superintendent Pharmacist" means a registered and licenced pharmacist who applied for and through whom the registration of the pharmaceutical premises was procured and he exercises direct personal control and management of pharmaceutical activities carried on in the premises.

Citation.

72. This Act may be cited as the Pharmacy Council of Nigeria (Establishment) Act, 2022.

SCHEDULES

FIRST SCHEDULE

Section 3 (5)

SUPPLEMENTARY PROVISIONS RELATING TO THE COUNCIL

Proceedings of the Council

- 1. (1) Subject to the provisions of this Act, the Council may make standing orders regulating its proceedings or any of its committees.
- (2) Questions for determinations shall be decided by a majority of the members present and voting and, in the event of equality of votes, the Chairman, shall have a second or casting vote.
- (3) Standing orders made for a committee shall provide for the committee to report to the Council on any matter referred to it by the Council.
- (4) The quorum of the Council shall be one-third of the members of the Council and the quorum of a committee of the Council shall be fixed by the Council.
- (5) The Council may invite any person to attend and participate at any of its meetings provided that a person so coopted shall only be in attendance and shall not count towards the quorum or vote at the meeting.

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Meetings of the Council

- 2. (1) Subject to the provisions of any standing orders of the Council, the Council shall meet whenever it is summoned by the Chairman, and if the Chairman is requested to do so, by notice in writing given to him by not less than five other members and he shall summon a meeting of the Council to be held within 14 days from the date on which the notice is given.
- (2) At any meeting of the Council, the Chairman shall preside or in his absence, the members present at the meeting, shall appoint one of their members to preside.
- (3) Where the Council desires to obtain the advice of any person on a particular matter, the Council may co-opt him as a member for such period as the Council deems fit, but a person who is a member by virtue of this paragraph shall not be entitled to vote at the meeting and shall not count towards the quorum.
- (4) Notwithstanding anything in the provisions of this paragraph, the inaugural meeting of the Council shall be summoned by the Minister.

Committees

- 3. (1) The Council may appoint one or more committees to carry out on its behalf such functions as the Council may determine.
- (2) A committee appointed under this paragraph shall consist of the number of persons determined by the Council of whom not more than two thirds may be persons who are not members of the Council.
- (3) A person other than a member of the Council shall hold office in a committee in accordance with the terms of the letter by which he is appointed.
- (4) A decision of a committee of the Council shall be of no effect until it is confirmed by the Council.

Miscellaneous

- 4. (1) The fixing of the seal of the Council shall be authenticated by the signature of the Chairman, the Registrar or any other member of the Council authorised generally or specially by the Council to act for that purpose.
- (2) A contract or instrument which, if made or executed by a person not being a body corporate, would not be required to be sealed, may be made or executed on behalf of the Council, by any person generally or specially authorised to act, for that purpose by the Council.
- (3) A document purporting to be a document duly executed under the seal of the Council shall be received in evidence and shall, unless the contrary is proved, be deemed to be so executed.
- (4) The validity of any proceedings of the Council or of a committee of the Council shall not be adversely affected by any vacancy in membership of the Council or by any defect in the appointment of a member of the Council or of a person to serve on the committee, or by reason that a person not entitled to do so took part in the proceedings.
- (5) A member of the Council and any person holding office in a committee of the Council, who has a personal interest in any contract or arrangement entered into or proposed to be considered by the Council or a committee shall disclose his interest, and shall not vote on any question relating to the contract or arrangement.
- (6) A person shall not by reason only of his membership of the Council be treated as holding an office in the Public Senate Bill Page **34** of **36**

SECOND SCHEDULE

Section 46 (3)

SUPPLEMENTARY PROVISIONS RELATING TO THE PANEL AND THE TRIBUNAL

The Panel

- 1. The quorum of the Panel shall be three all of whom shall be pharmacists.
- 2. The Panel may, at any of its meeting attended by all the members of the Panel, make standing orders with respect to the Panel.
- 3. Subject to the provisions of any such standing orders, the Panel may regulate its own procedure.

The Tribunal

- 4. The quorum of the Tribunal shall be five members.
- 5. The Attorney-General of the Federation shall -
- (a) appoint an assessor to the Tribunal for the purpose of any proceeding before the Tribunal; and
- (b) make rules as to the selection of members of the Tribunal for the purpose of any proceeding, the procedure to be followed and the rules of evidence to be observed in proceedings before the Tribunal.
- 6. The rules made under paragraph 5 (b) of this Schedule shall in particular provide for -
- (a) securing that notice of the proceedings shall be given in such time and manner, as may be specified by the rules to the person who is the subject of the proceedings;
- (b) determining who, in addition to the person mentioned, shall be a party to the proceedings;
- (c) securing that any party to the proceedings shall, if he so requires, be entitled to be heard by the Tribunal;
- (d) securing that any party to the proceedings may be represented by a legal practitioner;
- (e) determining the costs of proceedings before the Tribunal;
- (f) requiring, in a case where it is alleged that the person who is the subject of the proceedings is guilty of infamous conduct in any professional respect, that where the Tribunal adjudges that the allegation has not been proved it shall record a finding that the person is not guilty of such conduct in respect of the matters to which the allegation relates; and
- (g) publishing in the Federal Government Gazette, notice of any direction of the Tribunal which has taken effect, providing that a person's name shall be struck off a register.
- 7. For the purpose of any proceedings before the Tribunal, any member of the Tribunal may administer oath and any party to the proceedings may issue out of the registry of the Federal High Court writs of *supoena ad testificandum* and *duces tecum* but no person appearing before the Tribunal shall be compelled to –

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- (a) make any statement before the Tribunal tending to incriminate himself; or
- (b) produce any document under such a writ which he could not be compelled to produce at the trial of an action.
- 8. For the purpose of advising the Tribunal on questions of law arising in proceedings before it, there shall in all such proceedings be an assessor to the Tribunal who shall be appointed by the Council on the nomination of the Attorney-General of the Federation and shall be a legal practitioner of not less than 10 years standing.
- 9. The Attorney-General of the Federation shall make rules as to the functions of assessors appointed under this paragraph and in particular such rules shall contain provisions for securing that —
- (a) where an assessor advices the Tribunal on any question of law as to evidence, procedure or any other matters specified by rules, he shall do so in the presence of every party or person representing a party to the proceedings who appear thereat or, if the advice is tendered while the Tribunal is deliberating in private, that every such party or person shall be informed what advise the assessor has tendered; and
- (b) every party or person as mentioned shall be informed if in any case the Tribunal does not accept the advice of the assessor on such a question.

Miscellaneous

- 10. A person ceasing to be a member of the Tribunal or the Panel shall be eligible for appointment as a member of that body.
- 11. A person may, if otherwise eligible, be a member of both the Tribunal and the Panel but no person who acted as a member of the Panel with respect to any case shall act as a member of the Tribunal with respect to that case.
- 12. The Tribunal or the Panel may act notwithstanding any vacancy in its membership, and the proceedings of either body shall not be invalidated by any irregularity in the appointment of member of that body by reason of the fact that any person who was not entitled to do so took part in the proceedings of that body.
- 13. Any document authorised or required by virtue of this Act to be served on the Tribunal or the Panel shall be served on the Registrar.
- 14. Any expenses of the Tribunal or Panel shall be defrayed by the Council.

15. A person shall not by reason of his appointment as an assessor to the Tribunal, be treated as holding an office in the Public Service of the Federation.

THIS BILL WAS PASSED BY THE SENATE ON TUESDAY, 21ST JUNE 2022

President,

Senate of the Federal Republic of Nigeria

Senate of the Federal Republic of Nigeria