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THE PHARMACY PRACTICE BILL, 2014
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THE PHARMACY PRACTICE BILL, 2014

A BILL for

AN ACT of Parliament to make provision for the training, registration and licensing of pharmacists and enrollment of pharmaceutical technicians, to regulate pharmacy practice and professional conduct for both, to provide for the establishment, powers and functions of the Pharmacy Practice Board and for connected purposes.

ENACTED by the Parliament of Kenya as follows-

PART I-PRELIMINARY

1. This Act may be cited as the Pharmacy Practice Act, 2014 and shall come into operation after the expiry of ninety days from its date of publication.

Short title and commencement

2. (1) In this Act, unless the context otherwise requires-

Interpretation

“approved institution” means a university and such other training institution as the Board may approve;

“Board” means the Pharmacy Practice Board established by section 3;

“Cabinet Secretary” means the Cabinet Secretary for the time being responsible for matters relating to health;

“community pharmacy” means the practice of pharmacy which involves patient care and dispensing of medicines to the end user;

“medicine” means any medicament or curative or preventive substance, whether proprietary or in the form of preparation for use in both humans and animals;

“pharmacist” means a person registered as a pharmacist under section 23;

“Pharmaceutical product” means all health products and technologies for both humans and animals

“pharmaceutical technician” means a person enrolled as a pharmaceutical technician under section 24;

“pharmacist-in-charge” means the pharmacist responsible for a particular practice at any given time

“Register” means the Register of Pharmacists maintained under section 25;

“Roll” means the Roll of Pharmaceutical Technicians maintained under section 25; and
“Registrar” means the Registrar of Pharmacy Practice Board appointed under section 10.

PART II – THE PHARMACY PRACTICE BOARD

3. (1) There is established a Board to be known as the Pharmacy Practice Board. Establishment
of the Board
- (2) The Board shall be a body corporate with perpetual succession and a common seal, and shall, in its corporate name, be capable of –
- (a) suing and being sued;
 - (b) taking, purchasing or otherwise acquiring, holding, charging or disposing of both movable and immovable property;
 - (c) borrowing money;
 - (d) entering into contracts;
 - (e) doing or performing all such other acts necessary for the proper performance of its functions under this Act, which may be lawfully done or performed by a body corporate.
4. (1) The object and purpose for which the Board is established is to exercise general supervision and control over the training and practice of pharmacists and working as a pharmaceutical technician in the national and county health facilities and to advise the Government in relation to all aspects thereof. Functions of
the Board
- (2) Without prejudice to the generality of sub-section (1), the Board shall-
- (a) promote the practice of pharmacy that complies with universally accepted norms and values;
 - (b) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be registered as pharmacists under this Act;

- (c) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be enrolled as pharmaceutical technicians under this Act;
 - (c) maintain a register of all persons registered or enrolled under this Act;
 - (d) prescribe and conduct examinations for purposes of registration or enrolment under this Act;
 - (e) Approve institutions for the training of pharmacists and pharmaceutical technicians;
 - (f) license the private practice of pharmacists under this Act;
 - (g) approve and license the premises for the practice by pharmacists under this Act;
 - (h) regulate the professional conduct of pharmacists and pharmaceutical technicians and take such disciplinary measures as may be appropriate to maintain proper professional standards and ethics;
 - (h) establish, approve and accredit continuing professional educational programs for pharmacists and pharmaceutical technicians; and
 - (i) establish and maintain a professional code of conduct for pharmacists and pharmaceutical technicians.
5. (1) The Board shall have all powers necessary for the proper performance of its functions under this Act.
- (2) Without prejudice to the generality of sub-section (1), the Board shall have power to –
- (a) control, supervise and administer its assets in such manner and for such purpose as best promotes the purpose for which it is established;
 - (b) determine the provisions to be made for its capital and recurrent expenditure and for its reserves;
 - (c) receive any grants, gifts, donations or endowments and make legitimate disbursements therefrom;

- (d) levy such fees as it may determine for its services rendered;
- (e) enter into association with other bodies or organizations within or outside Kenya as may be desirable or appropriate in furtherance of the purpose for which it is established;
- (f) open a banking account or banking accounts for its funds;
- (g) invest any of its funds not immediately required for its purposes in the manner provided in section 18; and
- (h) undertake any other activities that may be necessary for the

6. (1) The board shall consist of-

- a) A chairperson appointed by the cabinet secretary from amongst the persons nominated under paragraph(c);
- b) The director of pharmaceutical services or its equivalent;
- c) Five registered pharmacists appointed in accordance with sub-section (3) of whom one shall be from the following sectors:
 - i. Community pharmacy;
 - ii. Hospital pharmacy;
 - iii. Pharmaceutical Manufacturers;
 - iv. Pharmaceutical Distributors; and
 - v. Pharmaceutical Training Institutions
- (d) One enrolled pharmaceutical technicians appointed in accordance with sub-section (4) from the Community Pharmacy sector

Composition
of the Board

(e) the Registrar as an ex-officio member with no right to vote

(2) No person shall be appointed as Chairperson of the Board unless such person –

(a) is a registered pharmacist of not less than ten years standing;

(b) is a holder of at least a master's degree in a pharmacy related discipline; and

(c) satisfies the requirements of Article 10 and chapters six and thirteen of Constitution.

(3) The members representing the sectors referred in paragraph (c) of subsection (1) shall be appointed by the cabinet secretary having regard to gender and ethnic balance from a list of 2 names for each of the sectors submitted by the Pharmaceutical Society of Kenya.”

(4) The members representing the sectors referred to in paragraph (d) of sub-section (1) shall be appointed by the Cabinet Secretary having regard to gender and ethnic balance from a list of two names of either gender for each sector submitted by the Kenya Pharmaceutical Association after a competitive and transparent nomination process conducted by the Association.

(5) No person shall be appointed as a member of the Board under sub-section (1)(c) and (d) unless such person –

(a) is a registered pharmacist or enrolled pharmaceutical technician

(b) is in good standing with the nominating professional body; and

(c) satisfies the requirements of Chapter 2, Article 10, Chapter 13 Article 232 and chapters six of the constitution

7. (1) The conduct and regulation of the business and affairs of the Board shall be as provided in the First Schedule.

(2) Except as provided in the First Schedule, the Board may regulate its own procedure.

8. The Board may, by resolution generally or in any particular case, delegate to any committee of the Board the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act.

Delegation
by the
Board

9. The Board shall pay its members such remuneration, fees or allowances as may be determined by the Cabinet Secretary upon the advice of the Salaries and Remuneration Commission.

Remuneration
of Board
members

10. (1) There shall be a Registrar of Pharmacy Practice who shall be competitively recruited and appointed by the Board and whose terms and conditions of service shall be determined by the Board upon the advice of the Salaries and Remuneration Commission.

The
Registrar

(2) No person shall be appointed under this section unless such person-

(a) is a registered pharmacist with a valid practicing licence;

(b) has at least ten years' post qualification working experience five of which should be in senior management; and

(c) satisfies the requirements of Article 10,232 and chapters six of the Constitution.

(3) The Registrar shall-

(a) be the chief executive officer of the Board;

(b) implement the decision of the Board under this Act;

(c) subject to the directions of the Board, be responsible for the day to day management of the affairs and staff of the Board; and

(d) perform such other functions as may be provided for in this Act or as the Board may from time to time determine.

(4) The Registrar shall serve for a term of four years and shall be eligible for re-appointment for one further term.

11. The Registrar shall be the secretary to the board

Secretary to
the Board

12. The Board may appoint such officers and other staff or hire such experts as may be necessary for the proper discharge of its functions and under this Act and upon such terms and conditions of service as the Board may determine upon the advice of the Salaries and Remuneration Commission.

Staff of the
Board

13. (1) No matter or thing done by a member of the Board or agent of the Board shall, if the matter or thing is done bona fide while executing the functions, powers and duties of the Board under this Act, render the member or agent or any person acting on their directions personally liable to any action, claim or demand whatsoever.

Protection
from
personal
liability

(2) The provisions of sub-section (1) shall not relieve the Board of the liability to pay compensation or damages to any person for any injury done to him, his property or any of his interests caused by the exercise of any power conferred by this Act, or by the failure, whether wholly or partially, of any works.

PART III – FINANCIAL PROVISIONS

14.(1) The funds of the Board shall comprise of –

(a) such membership, practicing or other fees, monies or assets as may accrue to or vest in the Board in the course of the exercise of its powers or the performance of its functions under this Act or under any written law;

Funds of
the Board

(b) grants, gifts or donations that the Board may receive as a result of public and private appeal from local and international donors or agencies for the purposes of carrying out its functions; and

(c) the proper maintenance of the buildings and grounds of the Board;

(2) The Board shall open a bank account for its funds.

15. The financial year of the Board shall be the period of twelve months ending on the thirtieth of June in each year.

Financial
year

16. (1) At least three months before the commencement of each financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Board for that year.

Annual
estimates

(2) The annual estimates shall make provision for all estimated expenditure of the Board for the financial year and in particular, the estimates shall provide for –

(a) the payment of the allowances and other charges in respect of members of the Board;

(b) the payment of salaries, allowances, pensions, gratuities and other charges in respect of the staff of the Board;

(c) the proper maintenance of the buildings and grounds of the Board;

(d) the maintenance, repair and replacement of the equipment and other property of the Board; and

(e) the creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance or replacement of buildings, equipment and other property of the Board, or in respect of such other matter as the Board may deem appropriate

(f) the establishment and accreditation of continuous educational programmes for pharmacists and pharmaceutical technicians.

(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate and shall then be submitted to the Cabinet Secretary for approval and after the Cabinet Secretary's approval, the Board shall not increase the annual estimates without the consent of the Cabinet Secretary.

17. (1) The Board shall cause to be kept all proper books and records of accounts of the income, expenditure and assets of the Board.

Accounts
and audit

(2) Within a period of four months from the end of each financial year, the Board shall submit to the Auditor-General or to an auditor appointed under this section, the accounts of the Board together with-

- (a) A statement of the income and expenditure of the Board during that year; and
- (b) A balance sheet of the Board on the last day of that financial year.

(3) The accounts of the Board shall be audited and reported upon in accordance with the Public Audit Act, 2003.

Cap.412B

18. The Board may invest any of its funds in securities, in which for the time being trustees may by law invest trust funds, or in any other securities or banks which the Treasury may, from time to time, approve for that purpose.

Investment
of funds

19. (1) The Board shall, within three months after the end of each financial year, prepare and submit to the Cabinet Secretary a report of the operations of the Board for the immediate proceedings year.

Annual
report

(2) The Cabinet Secretary shall lay the annual report before the National Assembly within three months of the day the National Assembly next sits after receipt of the report.

PARTY IV- TRAINING, REGISTRATION AND ENROLMENT

20. (1) No person being in charge of training institution in Kenya shall-

Approved training
institutions

- a) Admit persons for training with a view to qualifying for registration under this Act;

- b) Conduct a course of training or administer the examination prescribed for the purposes of registration under this Act; or
- c) Issue any document or statement milting that the holder thereof has undergo a course of training or passed the examination prescribed by the Board for purposes of registration;

unless such institution is approved and accredited by the Board for that purpose in accordance with this Act.

(2) a person who contravenes any of the provisions of sub-section (1) commits an offence and shall, on conviction, or to imprisonment for a term not less that two years, or to both.

(3) The Board shall prescribe the procedure for approving training institutions.

(4) The Board shall publish in the Gazette a list of the training institutions approved under this Act.

21. (1) The Board shall satisfy itself that the courses of study leading to the award of a qualification in pharmacy practice, including the standard of proficiency required for admission and the standard of proficiency required for admission and the standards of examination leading to the award of the qualification, are sufficient to guarantee that the holder of the qualification has acquired the knowledge and skills necessary for registration under this Act.

Supervisory
role of the
Board

(2) For the purposes of this section, the Board may-

- (a) Appoint persons to visit any university or other institution in Kenya offering a course in pharmacy practice and to report to it on the course of study, staffing and facilities available for training in pharmacy practice and other arrangements available for such trainings;
- (b) Appoint person to attend examinations in any aspect of pharmacy practice at any university or institution and to report to it on the sufficiency of the examinations and on such matters relating thereto as the Board may require; or

(c) Require the dean or head of the pharmacy practice department at any university or institution to provide written information to it concerning any of the matters referred to in paragraphs (a) or (b).

(3) The Board shall forward a copy of any report made under sub-section (2) to the university or institution concerned and may, if it is satisfied that the standard of any course, examination or facilities is insufficient, and after it has given the university or institution an opportunity to make observations on the report, in writing, require the university or institution to take such measure as the Board may specify to improve the standard of the course, examination or facilities.

(4) If the Board is satisfied that the university or institution referred to in sub-section (3) has failed to take measures which are in the opinion of the Board necessary to improve the standard of any course, examination or facilities, the Board may cancel or suspend any recognition of the qualification awarded by that university or institution.

(5) A qualification awarded prior to a cancellation or suspension under sub-section (4) shall be subject to direction by the Board.

22. (1) A person wishing to be registered as a pharmacist or enrolled as a pharmaceutical technician under this Act shall apply for registration or enrollment to the Board..

Application for
registration

(2) The application under sub-section (1) shall be in the prescribed manner and shall be accompanied by the prescribed fee.

23. (1) Subject to the provisions of this section, a person shall be eligible for registration under this Act as a pharmacist if the person-

Registration as a
pharmacist

(a) Is a citizen of Kenya

(b) Is the holder of a bachelor of pharmacy degree or its equivalent as recognized by the Board;

(c) after obtaining the qualification under paragraph 23(1)(b), has engaged in internship under the supervision of a registered pharmacist for not less than one year or such period and in such manner as the Board may prescribe;

(d) Satisfies the Board that, while engaged in internship as specified in paragraph (c), has acquired sufficient knowledge of, and experience in the practice of pharmacy; and

(e) is a member of the Pharmaceutical Society of Kenya

(2) A person who is the holder of a degree qualification from an institution outside Kenya shall be eligible for registration under this Act as a pharmacist if the person-

- (a) Is the holder of a degree qualification obtained from an institution that is accredited and recognized by the regulating authority responsible for the registration of pharmacist in the country where the person studied.
- (b) Satisfies the Board that the qualifications obtained by the person meet such requirements for a course leading to a qualification in pharmacy practice as the Board shall from time to time prescribe pursuant to section 4(2) (a); and
- (c) Fulfils the requirements of sub-section (1) (b), (c) and (d).

(3) Where the Board is not satisfied that a person has fulfilled any of the requirements for registration specified under this section, the Board may require that person to-

- (a) Attend such interview as may be appropriate;
- (b) Undergo and pass such written or oral examination as it may specify; or
- (c) Undergo such further period of training or undertake such courses in such institutions as the Board may specify prior to registration.

(4) The Board may, where it considers it expedient delegate the assessment of suitability for registrations under this section to a committee of the board which shall, after making the assessment, make recommendations to the Board.

(5) The board shall cause the Registrar to enter the prescribed particulars of every qualified pharmacist approved for registration under this section into the Register.

(6) Upon entry of the particulars into the register the pharmacists shall henceforth use the title “Dr” under the provision of this act

24. (1) Subject to the Provisions of this section, a person shall be eligible for enrollment under this section Act as a pharmaceutical technician if the person-

Enrolment of
Pharmaceuti
cal
Technician

- (a) is the holder of a diploma in a pharmacy course to its equivalent as recognized by the board;
- (b) After obtaining the qualification under paragraph (a), has engaged in internship for such period and in such manner as the Board may prescribe;
- (c) satisfies the Board that, while engaged in internship as specified in paragraph (b), has acquired sufficient knowledge of, and experience to work as a pharmaceutical technician; and
- (d) is a member of a relevant professional body recognized by the Board.

(2) The provisions of sub-section (2), (3), (4) and (5) of section 23 shall apply with the necessary modifications to enrollment of pharmaceutical technician.

(3) The board shall cause the Registrar to enter the prescribed particulars of every qualified pharmaceutical technician approved for enrollment under the section into the Roll.

25. (1) The Registrar shall maintain

- (a) a register for persons registered as pharmacists under this Act to be known as the Register of Pharmacists; and
- (b) a roll of persons enrolled as pharmaceutical technician under this Act to be known as the Roll of Pharmaceutical Technician.

Register of
Pharmacists
and Roll of
Pharmaceuti
cal
Technician

(2) The Register and Roll maintained under section (1) may be in such form as may be prescribed and different registers and rolls may be kept for different categories of pharmacists or pharmaceutical technician as the case may be.

(3) The Registrar shall -

- (a) not later than the 31st March in every year, publish in the Gazette, the names, addresses, qualifications and practicing licence status of all registered pharmacists and enrolled pharmaceutical technician; and
- (b) subject to the directions of the board, cause to be published any amendments or deletion from the Register or Roll as the case may be

(4) Every pharmacist or pharmaceutical technician shall notify the Registrar of any change in the registered address.

(5) Any person may inspect the Register or Roll and any documents relating to any entry therein, and may obtain from Registrar, a copy of, or an extract from the registers on payment of the prescribed fee.

(6) If the Registrar is satisfied –

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

(b) by virtue of an affidavit submitted by the registered or enrolled person concerned, that a registration or enrollment certificate has been lost; the register may issue a duplicate registration or enrollment certificate to that person upon payment of the prescribed fee.

26. (1) A copy of the last published issue of a Register or Roll or any supplementary list purporting to be printed and published under the authority of the Board shall be *prima facie*, and the absence of the name of person from such copy shall be proof, until the contrary is proved, that such a person is not registered or enrolled according to the provision of this act.

(2) Where a person's name –

(a) does not appear in the copy under sub-section (1) or the name has been added to the Register or roll after the date of the last published issue, a certified copy under the hand of the Registrar of the entry of the name of such person in registered or enrolled under the provisions of this Act;

Register
or Roll
As proof

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

27. (1) The Registrar shall remove from the Register or Roll -

- (a) the names of all deceased persons;
- (b) the names of all persons removed from the Register or Roll under this Act; and
- (c) any entries fraudulently or erroneously made.

(2) The Registrar shall, as soon as reasonably practicable, cause the names and address of every person whose name is removed from the Register or Roll under this section, to be published in the Gazette.

Removal names
from the
Register or Roll

PART V - LICENSING

28. (1) Subject to this Act or any other written law, no person shall engage in practice as a pharmacist unless that person holds a valid practicing licence issued under this Act.

(2) For the purposes of this Act, a person shall be deemed to be engaged in pharmacy practice if the person is engaging in - :

- (a) Manufacturing, importing, distributing, wholesaling, and retailing of pharmaceutical raw materials and finished pharmaceutical products.
- (b) Training of pharmacists or pharmaceutical technicians.
- (c) Research, Review, Consultancy and Dissemination of pharmaceutical information in the field of pharmacy.

Practicing
licence

(d) Detailing of pharmaceutical technical information to healthcare professionals and Marketing of pharmaceutical products.

(e) Clinical management and provision of pharmaceutical care to patients.

(f) Practicing as a public sector pharmacist.

(g) Advertising or representing themselves by the title, sign, display as a pharmacist, Dr, Druggist, Chemist

as pertains to this Act.”

3) A person who contravenes the provision of this section commits an offence and shall on conviction be liable to a fine of not more than 5 million or to imprisonment for a term not less than two years or both.

29 (1) An application for a practicing licence shall be made to be Board in such manner and form as may be prescribed fee.

Application
fr practicing
licence

(2) Every application under this section shall be accompanied by the prescribed fee.

(3) The Board shall, within sixty days of receipt by the Board of the application, issue to the applicant a practicing licence in the prescribed form upon being satisfied that the applicant-

(a) is duly registered under this Act;

(b) is not for the time being suspended from practice; and

(c) has complied with such other conditions as the Board may prescribed requirements for continuous professional education for that year.

Licensing
of non
citizens

30. A non-citizen pharmacist who wishes to obtain a practicing licence in Kenya shall

–

- (a) Submit a written application in the form prescribed by the Board.
- (b) Posses at the time of initial licensing as a pharmacist in a foreign country all qualifications necessary to have been eligible for licensing at that time in Kenya as provided in Section 23(2) a, b, and c;
- (c) present to the Board proof of initial licensing in a foreign country and evidence that such practicing license is in good standing in that country in that it has not been suspended, revoked, or otherwise restricted for any reason except non-renewal of for the failure to obtain the required continuing education credits in that country.
- (d) Present proof of membership of the foreign country's respective professional association;
- (e) pay the fees prescribed by the board ; and
- (f) fulfill such other conditions as may be prescribed by the Board.

31 (1) No person shall operate a premise for the manufacture, production, sale, distribution, possession, or dispensing of medicines unless such premise is licensed by the Board.

Licensing of
Premises

(2) The following conditions shall apply to a premise licence issued under this Act-

- (a) where operations are conducted at more than one location, each location must be licensed by the Board;
- (b)each premises as captured in 31(1) shall have a pharmacist-in-charge ;
- (c) the licence must be displayed in a conspicuous place in the premise for which it was issued in such a manner that will enable a customer to see its contents with clarity.

- (d) The licence shall be issued subject to a satisfactory inspection of the premise by the Board;
- (e) All pharmacy premise licenses shall only be issued in the name of a pharmacist;
- (f) no person shall be licenced for more than one category of premises licence;
- (g) no premise shall be licenced for more than one category of premise licence; and
- (h) All medical facilities with in and out-patient pharmacy services shall be superintended by a pharmacist.

32. (1) An application for a premise licence shall be made to the Board in such manner and form as may be prescribed.

Application
for premises
licence

(2) Every application under this section shall

- (a) be accompanied by the prescribed fee;
- (b) be submitted at least thirty days before the proposed date of opening of the premises;
- (c) be accompanied by an inspection report of the premise conducted by the Board; and
- (d) contain such other matters as required by this Act as may be prescribed by the Board.

(3) The Board shall, within sixty days of receipt by the Board of the application, issue to the applicant a premise licence in the prescribed form upon being satisfied that the applicant has fulfilled the requirements of this Act.

(4) Nothing in this Act shall be construed as excluding public health facilities from the requirements of this Act that require-

- 1. distributing or dispensing prescription medicines to be licenced by the Board; and
- 2. each pharmacy to have a pharmacist-in-charge.

33. (1) The board may issue to a pharmacist -

(a) any of the practising licences of the type specified in part A of the second schedule; and

(b) Any of the premise licence of the type specified in Part B of the Second Schedule

(2) The board may, with the approval of the cabinet Secretary, amend the Second Schedule.

34. (1) Every licence shall bear the date in which validity of licence issued and shall have effect from that day.

(2) A licence issued under this Act shall-(a) not be transferable and any change of ownership in the case of a sole proprietorship or a gain or loss of a partner in the case of a partnership or a change of name or location invalidates the licence.

(b) Be valid for the year from the date it is issued; and

(c) expire on the 31st of December of the year it is issued.

(3) A holder of licence that expires on the 31st of December of the year it is issued shall not be in breach of this section for continuing to practice without a renewed licence for no later than the last day of February of the succeeding year.

(4) The Registrar shall enter in the Register the date of issue of every licence issued under this Act.

(5) Where the name of the pharmacist or pharmaceutical technician is removed or struck off the Register or Roll, any licence issued shall expire forthwith.

(6) A person whose name is removed from the Register or Roll or in the case of a deceased person, his legal representative shall, within thirty days of the publication of such removal, surrender the certificate of registration or enrollment of that person to the Board.

35. (1) The board may deny or refuse to issue or renew a licence under this Act if it determines after due process that-

(a) the applicant has failed to comply with the requirements of this Act or its rules;

or

(b) the granting or renewing of such licence would not be in public interest.

(2) The Board shall, where it decline an application under sub-section (1), notify the applicant in writing of its decision and the reasons for its decision.

(3) An applicant who is aggrieved by the decision of the Board under this section shall have the right of appeal to the Cabinet Secretary in such manner as may be prescribed within thirty days of being notified of the decision under this section.

(4) An applicant who is aggrieved by the decision of the Cabinet Secretary under sub-section may appeal to the High Court of Kenya within sixty days of being notified of that decision.

36. (1) A pharmacists issued with a license in the prescribed form at least thirty days before the date of expiry thereof.

Renewal,
cancellation
and
suspension
of licence

(2) A pharmacist who fails to renew a licence within the prescribed period shall, when applying for a renewal, be required to pay late application fee, as shall be prescribed.

(3) The Board shall have the power to renew any practicing certificate and may, refuse to renew, cancel, withdraw or suspend a licence for a period not exceeding twelve months, if satisfied that the pharmacist has committed a professional misconduct or is in breach of any provisions of this Act or its rules.

-PART VI-ETHICS AND DISCIPLINARY

COMMITTEE

37.(1) The Board shall establish An Ethics and Disciplinary Committee which shall inquire into any matter referred to it by the Board under sub-section (2) and make its recommendations thereon to the Board.

Ethics and
Disciplinary
committee

(2) The Board may refer a matter to Ethics and Disciplinary Committee if it has reason to believe that a person registered or enrolled under this Act has been, either before or after registration or enrolment-

- a) Convicted of an offence punishable by imprisonment for more than six months, the commission of which in the opinion of the Board, has dishonored him in the public estimation; or
- b) Commits an act of negligence, impropriety or professional misconduct in respect of the profession.

38. (1) Upon an inquiry under section 37, the pharmacist or pharmaceutical technician subject to the inquiry shall be afforded an opportunity to be heard either in person or through an advocate..

Procedure
Of the
Committee

(2) For the purpose of proceedings at any inquiry by the Committee, the Committee may administer oaths or affirmations any may, subject to any rules made under this Act, enforce the attendance of persons as witnesses and the production of any books or other documents relevant to the inquiry.

(3) The Committed shall, subject to any rules made under this Act, have power to regulate its own procedure in any disciplinary proceedings.

39. (1) where on the recommendations of the Committee the Board is satisfied that a pharmacist is in breach of any of the terms of or conditions of practice prescribed by the Board, the Board may-

Disciplinary
measures

- (a) issues the pharmacist with a letter of admonishment;
- (b) Impose a fine which the Board deems appropriate in the circumstances;
- (c) Suspend the registration of the pharmacist
- (d) remove the name of the pharmacist from the Register

(2) The Board may order a pharmacist to reimburse costs and expenses incurred in connection with a disciplinary hearing and such costs shall be a civil debt recoverable summarily by the Board.

(3) Where, after the hearing in disciplinary proceedings under this Act the Committee recommends to the Board that a pharmacist is unfit to practice as a result of ill health, the Board may, if satisfied with the Committee's recommendations, withdraw the certificate of registration or practicing certificate of the until such time as the Board is satisfied that the s fully recovered to resume his duties.

(4) A pharmacist who is aggrieved by the decision of the Board in the exercise of its power under this section may, within sixty days from the date of the decision of the Board, appeals to the High Court.

40. (1) A pharmacists who has been suspended from practicing may appeal to the Board for the lifting of the suspension at any time before the expiry therefor.

Lifting of
suspension

(2) Where the Board is satisfied that the suspension of a pharmacist should be lifted, the Board shall, upon the receipt of the prescribed fee, lift the suspension and restore to the pharmacis the registration and practicing certificate and licence issued under the Act .

41. (1) A pharmacist of pharmaceutical technician whose name has been removed from the Register of Roll may after the expiry of such period as may be prescribed, appeal to the Board for restoration of his name in the Register or Roll.

Restoration of
name in
Register or Roll

(2) The Board may, after considering the appeal made under-section (1), cause the name of the applicant to be restored in the appropriate Register or Roll, upon payment of the prescribed fee.

PART VII- ENFORCEMENT

42. (1) The Board shall appoint any pharmacist to be an authorized officer for Purposes of this Act.

Authorized
officers

(2) The Board shall issue a certificate of appointment to every person appointed under this section.

43. (1) For the purposes of ensuring compliance with this Act, an authorized officer may, at any reasonable time, enter any premise in which the officer believes on reasonable grounds that any person or persons is in any way contravening the provisions of this Act.

Premises
authorized
officers
may enter

(2) An authorized officer entering any premises under this section shall, if so required, produce for inspection by the person who is or appears to be in charge of the premises the certificate issued to him under section 42(2) unless he falls under the officers described in section 42(3).

(3) The right to privacy enshrined in Article 31 of the Constitution and the right to property enshrined in Article 40 of the Constitution are limited as specified in this section for the purpose of ensuring the health and safety of the public.

44. In carrying out an inspection in any place pursuant to section 43, an authorized officer may –

Powers of
officers

(a) examine any medicine or any related thing;

(b) require any person in such place to produce for inspection, in the manner and form requested by the officer, the medicine or thing;

(c) open or require any person in the place to open any container or package found in the place that the officer believes on reasonable grounds contains the medicine or thing;

(d) conduct any test or analysis or take any measurements; or

(e) require any person found in the place to produce for inspection or copying, any written or electronic information that is relevant to the administration or enforcement of this Act.

Use of
records

45. In carrying out an inspection in a place, an authorized officer may –

- (a) use or cause to be used any computer system in the place to examine data contained in or available to the computer system that is relevant to the administration or enforcement of the Act;
- (b) reproduce the data in the form of a print-out or other intelligible output and take it for examination or copying;
- (c) use or cause to be used any copying equipment in the place to make copies of any data, record or document; or
- (d) scrutinize any other record system in use in that place.

46. (1) An authorized officer may enter a premise except with the consent of the occupant or under the authority of a warrant issued under sub-section (2)

Entry of
premise.

(2) Upon an ex-parte application, a magistrate or judge of the High Court, may issue a warrant authorizing the authorized officer named in the warrant to enter and inspect a premise, subject to any conditions specified in the warrant, if the magistrate or judge is satisfied by information on oath that-

- (a) the premise is a place referred to in section 43
- (b) entry to the premise is necessary for the administration or enforcement of this Act; and
- (c) the occupant does not consent to the entry, or that entry has been refused or there are reasonable grounds for believing that it will be refused.

(3) The time of such entry shall be between six o'clock in the forenoon and six o'clock in the afternoon of any day of the week.

(4) An authorized officer executing the warrant issued under this section shall not use force unless such officer is accompanied by a police officer and the use of force is specifically authorized in the warrant.

(5) Nothing in this sub-section 46 may prevent an authorized officer to enter a premises deemed to be no registered but carrying out the activities as outlined in section 28 Sub Section (2) without a warrant.

47. (1) An authorized officer who carried out an inspection under this Act shall-

Inspection
report

- (a) make a preliminary report immediately upon completion of the inspection in a prescribed format, a copy of which shall be retained in the premises; and

(b) file a full written report with the Board within fourteen days of the last day of inspection.

(2) The report referred to in sub-section (1) shall consist of such matters and shall be dealt with by Board in such manner as may be prescribed.

48. (1) The owner of a premises inspected by an authorized officer this Act or the person in charge of the premises and every person found in the premise shall-

Assistance of
officers

(a) Provide all reasonable assistance to enable the authorized officer to carry out his duties under this Act; and

(b) Furnish the authorized officer with such information as the officer reasonably requires for the purpose for which entry into the place has been made.

(2) The inspecting agent in sub-section (10) shall issue the respective inspection completion certificate once satisfied with inspection.

49. (1) No person who contravened sub-section 91) commits an offence.

Obstruction

50. (1) during an inspection under this Act, an authorized officer may seize any medicine under this Act, an authorized officer may seize any medicine or related thing by means of which or in relation to which the officer believes, on reasonable grounds, that this Act has been contravened and a full inventory thereof shall be made at the time of such seizure by the officer.

Seizure

(2) The authorized officer may direct that any medicine or thing seized be kept or stored in the premise where it was seized or that it be removed to another place.

(3) unless authorized by an officer, no person shall remove, alter or interfere in any manner with any medicine or other thing seized.

(4) Any person from whom a medicine or thing was seized may, within thirty days after the date seizure, apply to court for an order of restoration, and shall send notice containing the prescribed information to the Board within the prescribed time and in the prescribed manner.

51. (1) The court may order that the medicine or thing by restored immediately to the applicant if, on hearing the application, the court is satisfied that-

Order for restoration

- (a) The applicant is entitled to possession of the medicine or thing seized; and
- (b) The medicine, or thing seized is not and will not be required as evidence in any proceedings in respect of an offence under this Act.

(2) Where upon hearing an application made under subsection (a) the court is satisfied that the applicant is entitled to possession of the medicine, or thing seized but is not satisfied with respect to the matters mentioned in paragraph (b) of subsection (1), the court may order that the medicine, or thing seized be restored to the applicant on the expiration of thirty days from the date of seizure if no proceedings in respect of an offence under this Act have been commenced before that time.

52. (1) Any act or omission which is an offence under this Act or any rules made hereunder shall, if done by a body corporate, be deemed to be an offence committed by every director of the body corporate unless proved that the offence was committed without consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to nature of his functions and the circumstances of the case.

Offences
By partnership
or
Bodies
cooperate

(2) If an offence under this Act or any rules made hereunder is committed by a partner in a firm, every person who, at the time of the commission of the offence, was a partner in that firm, or was purporting to act in that office shall be deemed to have committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions and the circumstances of the case.

(3) In any prosecution for an offence under this Act, it shall be sufficient proof of the offence to establish that the offence was committed by an employee or agent of the accused.

(4) Any act or omitted to be done by an employee in contravention of any of the provisions of this Act shall be deemed also to be the act or omission of the employer and the employee.

53. (1) In any prosecution for an offence under this Act, a copy of any written or electronic information obtained during an inspection under this Act and certified to be a true copy thereof shall be admissible in evidence and shall, in the absence of evidence to the contrary, be proof of its contents.

(2) Subject to this Part, a certificate or report purporting to be signed by an officer stating that the officer analyzed anything to which this Act applies and stating the results of the analysis, shall be admissible in evidence in any prosecution for an offence under this Act with proof of the signature or official character of the person appear to have signed the certificate or report.

(3) The certificate or report may not be received in evidence unless the party intending to produce it has, before the trial, given the party against which it is intended to be produced notice of not less than seven days of that intention together with a copy of the certificate or report.

(4) The party against whom the certificate or report provided for under sub-section (3) is produced may, with leave of the court, require the attendance of the officer for purposes of cross examination.

(5) In a prosecution for a contravention of this Act-

- (a) Information on a package indicating that it contains a medicine on a package indicating that it contains a medicine is, in the absence of evidence to the contrary, proof that the package contains that medicine; and
- (b) A name or address on a package purporting to be the name or address of the person by whom the medicine was manufactured is, in the absence of evidence to the contrary, proof that it was manufactured by that person.

54. (1) A person who-

- (a) Destroys or defaces a certificate of registration or enrolment or any licence issued under this Act;
- (b) Without reasonable excuse, it is in possession of a certificate of registration or enrolment or licence not issued to him or her; or
- (c) Fails to surrender a certificate of registration or enrolment or licence in accordance with section 34 (5)

Commits an offence and shall, on conviction, be liable to a fine not less than one hundred thousand shillings, or to imprisonment for a term not exceeding three months, or to both.

55. (1) No person while in charge of an institution or any other organization in Kenya shall engage the services of a person who is not registered as a pharmacist or enrolled as a pharmaceutical technician under this Act

Offence
relating
To registration
or enrolment

(2) A person who contravenes the provisions of sub-section (1) commits an offence and shall, on conviction, be liable to a fine not more than five hundred thousand shillings, or to imprisonment for a term not less than twelve months, or both.

(3) Any person who, in an application for registration, enrolment or licence, willfully makes a false or misleading statement or submits a false certificate, commits an offence and shall, on conviction be liable to a fine not more than two hundred thousand shillings, or to a fine not more than two hundred thousand shillings, or to imprisonment for a term not less than one year, or both.

(4) The sub-section (1) shall not be construed as restricting or limiting the practice of any profession authorized by any written law.

56. Any person convicted of an offence under this Act for which no other penalty is provided shall be liable to a fine not exceeding five hundred thousand shillings, or to imprisonment for a term not exceeding three years, or to both.

General
penalty

PART VIII-PROVISION ON DELEGATED POWERS

57. (1) The Cabinet Secretary shall, on the recommendation of the Board, make rules generally for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of the foregoing, such rules may provide for-

- (a) Prescribing anything required to be prescribed under this Act;
 - (b) The form and method of keeping the registers and other records under this Act;
 - (c) The conditions under which training institutions other than those.
 - (d) The course content, examination and internship for persons wishing to be registered or enrolled as pharmacist of pharmaceutical technologies under this Act
 - (e) The code of conduct and conditions for
 - (i) Professional practice of registered pharmacists as prescribed by the Pharmaceutical Society of Kenya; and
 - (ii) Enrolled pharmaceutical technicians as prescribed by the relevant Body
 - (f) The scale of fees to be levied by registered or enroll persons under this Act;
 - (g) The forms and fees for the purposes of this Act;
 - (h) The form and method of conducting any disciplinary proceeding, inspection, assessment, evaluation, examination or regulation required under this Act;
 - (i) The minimum requirement for establishing a place to be licensed as a premise to carry our pharmacy service;
 - (j) prescribe in accordance with Standard International Best Practices including but not limited to - :
 - (i) good manufacturing practice
 - (ii) good distribution practice
 - (iii) good warehousing practice
 - (iv) good dispensing practice
 - (v) good clinical practice
- and
- (j) Any other matter that may related to the practices of pharmacy in Kenya.

58. The principles and standards applicable to the delegated power referred under section 57 are those found in-

Principles and standards of Delegated power

(a) The statutory instruments Act, 213;

No. 23 of 2013

(b) The interpretation and general provisions Act,

Cap 2

(c) The general rules of international law as specified under Article 2 (5) of the constitution; and

(d) Any treaty and convention ratified by Kenya under Article 2 (6) of the Constitution.

PART IX –FINAL PROVISIONS

59. The provisions of the Pharmacy and Poisons Act specified in the first column of the Third Schedule are amended in the manner respectively set out in the second column of that schedule.

Amendment of Cap.244

60. (1) In this section-

Transitional

“effective date” means the day upon which this Act comes into operation; and

“former Board” means the pharmacy and poisons Board established under the pharmacy and poisons Act.

Cap.244

(2) On the effective date, all the funds, assets and other property, both movable and immovable, which immediately before such date were vested in the section of pharmacy practice in the former board shall, by virtue of this sub-section, vest in the Board. All other funds, assets, property both moveable and immovable shall be vested on an authority to regulate all health products and technology to be created.

(3) On the effective date, all right, powers and liabilities, whether arising under any written law or otherwise which immediately before such day were vested in, imposed on or enforceable against the former board, shall by virtue of this sub-section, be deemed to be vested in, imposed on or enforceable against the Board, in the areas of practice shall, by virtue of this sub-section, be deemed to be vested, in, imposed on or enforceable against the Board.

(4) On the effective date, any person who immediately before the commencement of this act-

(a) was a member of the former Board and is a pharmacist or a pharmaceutical technician shall be deemed to be a member of the board for the unexpired term;

(b) was a member of staff of the former board as pertains to pharmacy practice shall be deemed to be a member of staff of the board for the unexpired period of his/her service.

(c) was registered as a pharmacist or enrolled as a pharmaceutical technician by former Board shall be deemed to be registered or enrolled by the Board under this Act; and

(d) was the holder of licence issued by the Board under this Act for its unexpired term.

(e) was an enrolled pharmaceutical technologist shall be henceforth recognized as a pharmaceutical technician.

(5) Any reference in any written law or in any document or instrument to the former Board shall on and after the appointed day, be construed to be a reference to the Board.

(6) The annual estimates of the former Board for the financial year in which the appointed day occurs shall be deemed to be annual estimated of the Board for the remainder of that financial year but such estimated maybe varied by the Board in such manner as the Cabinet Secretary may approve.

(7) The administrative directors made by the former Board or by the Cabinet Secretary which are in force immediately before the appointed day shall, on and after such day, have force as if they were directors made by the Board or the Cabinet Secretary under this Act.

PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

1. The Chairperson or a member of the Board other than ex-officio members shall, subject to the provisions of this schedule, hold office for a period of three years, on such terms and conditions as may be specified in the instrument of appointment, but shall be eligible for re-appointment for one further term. Tenure of office

2. (1) A member other than an ex-officio member may Vacation of office
 - (a) At any time resign from office by notice in writing to the Cabinet Secretary;
 - (b) Be removed from office by the Cabinet Secretary on recommendation of the Board if the member-
 - (i) Has been absent from three consecutive meetings of the Board without its permission;
 - (ii) Is found to have contravened the provision of chapter six of thirteen of the Constitution;
 - (iii) Is convicted of a criminal offence that amounts to a felony in Kenya;
 - (iv) Is incapacitated by prolonged physical or mental illness for a period exceeding six months; orIs otherwise unable or unfit to discharge his functions.

- 3 (1) The quorum for the conduct of the business of the board shall be 5 members. Meetings
 - (2) In the absence of the chairman, the members present shall appoint one of their own to chair the meeting.
 - (3) The board shall in its first sitting come up with its rules of conducting its meetings”

- 4 (1) The Board may establish such committees as it may deem appropriate to perform such functions and responsibilities as it may determine. Committees of the Board
 - (2) The Board shall appoint the chairperson of a committee established under sub0paragraph (1) from amongst its members.
 - (3) The Board may where it deems appropriate, co-opt any person to attend the deliberations of any its committees.

(4) All decisions by the committees appointed under sub-paragraph (I) shall be ratified by the Board.

(5) Without prejudice to the generality of sub-paragraph (1), the Board shall ensure the establishment of separate committees responsible for-

- a) Management issues;
- b) Practice issues; and
- c) Training and assessment.

5 (1) A members who has an interest in any contract, or other matter present at a meeting shall at the meeting and as soon as reasonable practice after the commencement, disclose the fact thereof and shall not take part in the consideration or discussion of, or vote on, any questions with respect to the contract or other matter, or counted in the quorum of the meeting during consideration of the matter.

Disclosure of
the Board

(2) A disclosure of interest made under sub-paragraph (1) shall be recorded in the minutes of the meeting at which it is made.

(3) A member of the Board who contravenes sub-paragraph (1) commits an offence and is liable to a fine not exceeding two hundred thousand shillings.

6. Any contract or instrument which, if entered into or executed by a person not being a body corporate would not require to be under seal, may be entered into or executed on behalf of the Board by any person generally or specially authorized by the Board for that purpose.

Contract and
instruments

7. (1) The affixing of the common seal of the Board shall be authenticated by the signature of the Chairperson and the Registrar and any document not required by law to be made under seal and all decisions of the Board may be authenticated by the signatures of the Chairperson and the Registrar.

Common
Seal

(2)The Board shall, in the absence of either the Chairperson or the Registrar in any particular matter, nominate one member to authenticate the seal of the Board on behalf of either the Chairperson or the Registrar.

SECOND SCHEDULE (s. 33)

TYPES OF LICENCES

PART A- PRACTISING LICENSE

1. Pharmacist Practicing License

This license shall authorize the scope of activities to be involved in by a registered pharmacist in the following areas of pharmacy practice:

- (a) Manufacturing, importing, distributing, wholesaling, and retailing of pharmaceutical raw materials and finished pharmaceutical products.
- (b) Training of pharmacists or pharmaceutical technicians.
- (c) Research, Review, Consultancy and Dissemination of pharmaceutical information in the field of pharmacy.
- (d) Detailing of pharmaceutical technical information to healthcare professionals and Marketing of pharmaceutical products.
- (e) Clinical management and provision of pharmaceutical care to patients.
- (f) Practicing as a public sector pharmacist.
- (g) Advertising or representing themselves by the title, sign, display as a pharmacist, Dr. Druggist, chemist
- (h) such other activities as may be prescribed by the Board”

2. Specialist Pharmacy Practicing License

- (a) The board shall recognize and issue registration certificate and licenses for the various levels of specialist pharmacy practice
- (b) Holders of specialist pharmacy licenses and certificates shall be recognized as consultants
- (c) The board shall maintain a list of the specializations, the curriculum for training and approving purposes and maintain this from time to time

3. Professional Review Pharmacy Practicing Licence

- (a) The initiation and conducting of pharmaceutical research and development;
- (b) The application for the registration of a medicine;
- (c) The supervision of a pharmacy;
- (d) The promotion of public health and the advancement of pharmacy knowledge, skills and competencies in specific areas of practice; and
- (e) Any other health service as may approved by the Board from time to time.

PART B- PREMISE LICENCES

4. Pharmaceutical Manufacturing Licence

1. (1) Except as provided for in the Pharmacy and Poisons Act, only the following services pertaining to the scope of practice of pharmacy, may be provided in a manufacturing pharmacy.-
 - a) The manufacturing of active pharmaceutical ingredient , non active pharmaceutical ingredient, any medicine or scheduled substance;
 - b) The purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;
 - c) Importation and exportation of active and non active pharmaceutical ingredients;
 - d) The furnishing of information and advice to any person with regard to medicine manufactured by him, her or it;
 - e) The application for the registration of a medicine;
 - f) The formulation of medicine for the purposes of registration as a medicine
 - g) The distribution of medicine or scheduled substances;
 - h) The repackaging of medicine;
 - i) The initiation and conducting of pharmaceutical research and development and formulations;
 - j) Medical and pharmaceutical marketing subject to regulations established by the Board; and

Any other health service as may be approved by the Board from time to time.

1. (2) A manufacturing pharmaceutical plant shall only sell medicines manufactured by it on its behalf to a licensed distributor.

1. (3) The manufacturing pharmaceutical plant must have a registered pharmacist as per this act in-charge the following departments: regulatory, production, quality control, quality assurance, warehousing, release, sales, marketing, distribution, post market surveillance and pharmacovigilance.”

5. Distribution Practicing Licence

2. (1) The following services pertaining to the scope of practice of pharmacy, may be provide in a distribution or import pharmacy practice-

(a) The distribution to a wholesale dealer of nay medicine or authorized schedule substance through the purchasing, acquiring, keeping, possessing, using, supplying or selling of nay medicine or scheduled substance;

(b) The furnishing of information and an advice to any person with regard to medicine distributed by him, her or it.

(c) Importation or exportation of the medicines or medicinal substances;

(d) Importation or exportation of active pharmaceutical ingredients and non active pharmaceutical ingredient and non-active pharmaceutical ingredient from bona fide manufacturers and warehousing in accordance with good storage practices prescribed by the board;

(e) The application for the registration of a medicine as domicile agents of foreign manufactures;

(f) Medical and pharmaceutical marketing, subject to regulations established by the Board; and

(g) Any other health services as may be approved by Board from time to time.

2. (2) This licence does not allow a distributor to sell directly to the community outlet or send-use.

2. (3) The Distribution practicing premises must have a registered pharmacist as per this act in-charge the following departments: regulatory, operations, quality assurance, warehousing & release, distribution, sales & marketing, post market surveillance and pharmacovigilance.

7. Wholesale Pharmacy Practicing Licence.

3. (1) The following services pertaining to the scope of practice of pharmacy, may be provided in a wholesale pharmacy-
 - (a) The wholesale distribution of any medicine or scheduled substance through the purchasing, acquiring, keeping, warehousing and storage, possessing, using supplying or selling of any medicine or scheduled substance;
 - (b) The furnishing of information and advice to any person with regard to medicine distributed by him, her or it;
 - (c) Breaking bulk to quantities of the community outlets but limited to the multiples of consumer packs as a minimum quantity; and
 - (d) Any other health services as may be approved by Board from time to time.

- 3 (2) The wholesale practicing premises must have a registered pharmacist as per this act in-charge of operations, warehousing and release, distribution, sales & marketing.

- 3 (3) This licence shall not allow a wholesale pharmacy to sell directly to the end-user

7. Community or Institutional Pharmacy Practicing License.

4. (1) The following services pertaining to the scope of practice of pharmacy, may be provided in a community or institutional pharmacy-

- (a) The provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs; which shall include but not be limited to the following functions-
 - (i) Evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;
 - (ii) Furnishing of any medicine or scheduled substance on the prescription of an authorized prescriber;
 - (iii)Furnishing of information and advice to any person with regard to medicine;
 - (iv)Determining patient compliance with the therapy and follow up to ensure that the patient's needs are being met;
 - (v) Provision of pharmacist initiated therapy;
 - (vi)The compounding, manipulation or preparation of any medicine or scheduled substance;
 - (vii) The purchasing, acquiring, keeping, possessing, storing, supplying or selling of any medicine or scheduled substance; and
 - (viii) The re-packaging of medicine;
- (b) The promotion of public health in accordance with guidelines and standards as determined by a competent authority which includes but shall not be limited to-
 - (i) The provision of information and education regarding the promotion of human health;
 - (ii) The provision of immunization, mother and childcare, blood pressure monitoring; health education; blood-glucose monitoring; and
 - (iii)Screening tests for pregnancy; family planning; cholesterol screening tests; diagnostic screening tests; urine analysis; and visometric and audiometric screening test;

(c) The provision of human health care services which includes-

- (i) The compounding and dispensing of prescriptions written by licensed medical practitioners;
- (ii) The provision of information and education regarding the promotion of rational use of human medicines;

(d) The provision of animal health care services which includes-

(e) The provision of animal health care services which includes-

(i) the compounding and dispensing of prescriptions written by licensed veterinary surgeons;

The provision of information and education regarding the promotion of animal health;

(f) the provision of primary animal care medicine therapy; and

(g) any other human or animal health services as may be approved by Board from time to time.

4. (2) The community or institutional practicing premises must have a registered pharmacist as per this act in-charge of operations, as described under 4 (1)

THIRD SCHEDULE (s.580)

CONSEQUENTIAL AMENDMENTS TO THE PHARMACY AND POISONS ACT

(CAP.244)

Amendment

Delete the definition of-

provision of cap

244

Section 2

- a) “ authorized officer”;
- b) “authorized seller of poisons”
- c) “Board”;
- d) “enrolled pharmaceutical technician”;
- e) “register”;
- f) “registrar pharmacist”;
- g) “registrar’; and
- h) :Roll”;

Insert the following new definition in their proper alphabetical sequence-

“Authorized seller of poisons” means a person authorized as such under the pharmacy practice Act;

“Board” mean the pharmacy practice Board established under the pharmacy practice Act;

“Pharmaceutical technician” means a person enrolled as such under the pharmacy practice Act; and

“Wholesale dealer” means a person licensed as such under the pharmacy practice Act.

| | |
|--------|------------|
| Delete | section 3 |
| Delete | section 4 |
| Delete | section 5 |
| Delete | section 6 |
| Delete | section 7 |
| Delete | section 8 |
| Delete | section 9 |
| Delete | section 10 |
| Delete | section 11 |
| Delete | section 12 |
| Delete | section 13 |
| Delete | section 14 |
| Delete | section 15 |
| Delete | section 16 |
| Delete | section 17 |
| Delete | section 18 |
| Delete | section 19 |
| Delete | section 20 |
| Delete | section 21 |
| Delete | section 22 |
| Delete | section 23 |
| Delete | section 24 |

Delete the words “licensed under section 27 of this Act”;
26(1)(a) section

Delete the words “section 23 of this Act” and substitute the words “the pharmacy practice Act”; section26
(1)(b)

Delete section 27

Delete the words “a person licensed under section 27 to deal as” section 29(1)

Delete the words “a person licensed under section 27”to deal as section 33(2)(a)

Delete the words “licensed under 27” section 33(2)

Delete the words “the pharmacy and poisons Board” and substitute therefore the words “the cabinet secretary upon recommendation by the pharmacy practice Board through a competitive and transparent process conducted by the Board with due regard to gender and regional balance principles”.

Section 35f (1)

Delete the word “twenty” and substitute therefore the words “three hundred”. Section 40(1)(a)

Delete the word “thirty” and substitute therefore the section 40(1)(b)

MEMORANDUM OF OBJECTS AND REASONS

Statement of Objects and Reasons

The principal object of this bill is to provide for the training, registration and licensing of pharmacists and enrollment of pharmaceutical technicians, so as to regulate pharmacy practice and professional conduct for both.

Part I (Clauses 1-2) contains preliminary matters

This part contains the title of the bill and the interpretation of terms used in the proposed Act.

Part II (Clauses 3-130) provides for the establishment of the pharmacy practice board

This part provides for the establishment, composition, functions and power of the pharmacy practice board of Kenya. It is proposed that the board shall be the regulatory body in respect of the training, licensing and controlling of the practice of pharmacy in Kenya. The part also contains matters to do with the conduct of business and affairs of the remuneration of board members. The part also establishes the office of the registrar and the board as well as the protection from personal liability of the members and against the board.

Part III (Clauses 14-19) contains the financial provision of the proposed Act.

This part contains provisions relating to the financial aspects of the board including sources of fund for the board, the financial year, annual estimate and accounting and auditing provisions. It also provides for guidelines on investment of funds as well as the preparation and submission of the board's annual report to the cabinet secretary.

Part IV (20 – 27) provides for the training, registration of pharmacists and enrolment of pharmacy technicians.

This part contains provisions relating to the training, registration of pharmacists and enrolment of pharmacy technicians under the proposed act. This part will affect all training institutions and courses that are foreign based. The part further provides for a register of pharmacist and roll to be maintained and cases that might lead to removal from that register or roll. “

Part V (Clauses 28 – 37) contains matters to do with licensing

This part contains provisions relating to pharmacy practice. It is proposed that pharmacists wishing to offer their services directly to the public be issued with an annual practicing certificate by the Board so as to safeguard the public from unfit persons claiming to offer these services. The part also contains provisions of the validity of those license and instances of refusal to issue the licenses. It further provides guidelines on the renewal, cancellation and suspension of the license.

Part VI (clauses 37 – 41) provides for the establishment of the ethics and disciplinary committee.

This part contains provisions relating to discipline of registered pharmacist. It is proposed to establish an Ethics and Disciplinary committee that will undertake the task of ensuring that registered pharmacists undertake the practice of their profession within their professional norms and standards. The part also contains the procedure to be followed by the committee as well as the disciplinary measures it may choose to employ on the pharmacist. It further provides for the conditions of lifting the suspension of a pharmacist as well as his or her restoration in the name in the register and the pharmaceutical technician as well as his or her restoration of name in the Register or Roll.”

Part VII (Clauses 42-56) contains enforcement provisions of the proposed Act

This part provides for the appointment of authorized officers who have power to enter premises in the enforcement of the Act and inspect their record to confirm compliance with the Act. It further mandates for assistance to be given to these officers and the offence of obstruction. The part also provides for the power of the high court in restoring seized medicine, or related thing as well as the nature of taking evidence during proceedings. It finally provides for offences concerning interference with certificates against the Act; offences relating to registration or enrolment; offences by partnership or body corporate; as well as a general penalty for all offences under the Act.

Part VIII (Clauses 57-58) contains provisions on delegated powers.

This part contains the power of the cabinet secretary to make rules under the Act as well as the principles and standards applicable to the exercise of that delegated power.

Part VIII (Clauses 59-60) contains miscellaneous provisions

This part contains the consequential amendments to the pharmacy and poisons Act as well as transitional provisions.

The First Schedule contains provisions relating to meeting of the boards and their conduct.

The Second Schedule contains the type of licences to be issued under the proposed Act.

The Third Schedule contains the consequential amendments to the pharmacy and poisons Act.

Statement on the Delegation of Legislative Powers and Limitation of Fundamental Rights and Freedoms

This bill delegates legislative powers in accordance with provisions of Article 94(6) of the constitution as well as standing Order 188 of the Nation Assembly Standing Orders.

The bill proposes to limit fundamental rights and freedoms specifically the right to privacy and the right to property enshrined in Article 31 and 40 of the constitution allows limitation of fundamental rights and freedoms all relevant factors which interlaid includes the importance of the purpose of the limitation and the nature and extent of limitation. In any case, standing Order 158 of the national assembly standing order provides that no private bill which directly affects the private right or property of any persons, shall originate in the house unless a notice has been published in not less than three separate issues of the Gazette, specifying the general nature and objects of the Bill; the last of such publications being not less than fourteen days before the presentation of the petition referred in standing order 159(petition for leave).

Statement of the Financial Implication of the Bill

The enactment of this Bill shall occasion additional expenditure of public funds.

RACHAEL NYAMAI,

Chairperson,

National Assembly Committee on
Health.