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CONTENT

Bill for Introduction into the National Assembly—

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THE PHARMACY AND POISONS (AMENDMENT) BILL, 2014

A Bill for

AN Act of Parliament to amend the Pharmacy and Poisons Act

ENACTED by the Parliament of Kenya, as follows—

Short title

1. This Act may be cited as the Pharmacy and Poisons (Amendment) Act, 2014.

Amendment of section 2 of Cap 244

2. Section 2 of the Pharmacy and Poisons Act (hereinafter referred to as the "the principal Act") is amended by inserting the following new definition in proper alphabetical sequence—

"Authority" means the Pharmacy and Poisons Authority established under section 3 of the Act;

Repeal and replacement of section 3 of Cap 244

3. The principal Act is amended by repealing section 3 and substituting therefor the following new section-

3. (1) There is established an Authority to be known as the Pharmacy and Poisons Authority.

(2) The Authority shall be a body corporate with perpetual succession and a common seal, and shall be capable in its corporate name of—

(a) suing and being sued;

(b) acquiring, holding and disposing of property;

(c) borrowing and lending money.

Insertion of new sections 3A, 3B, 3C and 3D in Cap 244.

4. The principal Act is amended by inserting the following new sections immediately after section 3.

Functions of the Authority.

3A. The functions of the Authority shall perform the following functions—

(a) advise the government and government agencies in all matters relating to the safety, packaging

and distribution of medicines;

(b) regulate the pharmaceutical profession and the practice of pharmacy in Kenya;

(c) ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy;

(d) ensure that the personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances comply with the defined codes of practice and other prescribed requirements;

(e) enforce the prescribed standards of quality, safety, and efficacy of all medicinal substances manufactured, imported into or exported out of the country;

(f) grant or revocation of licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;

(g) maintain an inventory of all authorized medicinal substances;

(h) publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing authorizations;

(i) consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances;

(j) inspect and licence all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies (including

those in hospitals and clinics) and other retail outlets;

(k) prescribe a system for sampling, analysis and other testing procedures of finished medicinal products released into the market to ensure compliance with the labelled specifications;

(l) monitor the market for the presence of illegal or counterfeit medicinal substances;

(m) ensure that the promotion and marketing of medicinal substances is in accordance with approved product information;

(n) approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use;

(o) approve clinical trials on medicinal substances;

(p) disseminate information on medicinal products to health professionals in order to promote their rational use;

(q) levy appropriate charges and fees as may be required for the purposes of performing its functions under the Act;

(r) advise the Cabinet Secretary on matters relating to control, authorization and registration of medicinal substances

Board of the Authority

3B. (1) The Authority shall be managed by a Board which shall consist of the following persons—

(a) a non-executive Chairperson, appointed by the President;

(b) the Principal Secretary responsible

for finance;

(c) the Principal Secretary responsible for health;

(d) the Director of Veterinary Services;

(e) the Director of Medical Services;

(f) the following members, appointed by the Cabinet Secretary-

(i) one pharmacist nominated by the Pharmaceutical Society of Kenya;

(ii) one person nominated by the Medical Practitioners and Dentists Board;

(iii) one pharmaceutical technologist nominated by the Kenya Pharmacy Association;

(iv) one person nominated by the public universities teaching pharmacy;

(v) one person nominated by a recognized association of pharmaceutical consumers;

(vi) one person with accounting and financial knowledge;

(vii) one person with legal background nominated by the Law Society of Kenya;

(g) the Director-General, who shall be the secretary to the Board.

(2) The members of the Board appointed under paragraph (f) of subsection (1)—

(a) shall hold office for a period of three years but shall be eligible for re-appointment;

(b) may at any time resign by instrument in writing addressed to the Chairman.

(3) Notwithstanding the provisions of subsection (2) the Cabinet Secretary may, if at any time it appears to him or her that a member of the Board has failed to carry out

his or her functions under this Act, revoke the appointment of that person and shall appoint another person under subsection (1) in place of that member for the remainder of the period of office of that member and if that member is nominated or elected by any other authority or body, his or her nomination or election shall be deemed to have been annulled on account of the revocation of his appointment to the Board.

(4) The Cabinet Secretary may appoint an appropriately qualified person to act temporarily in the place of any member of the Board other than the Chairperson in the case of death, illness, resignation or absence from Kenya.

(5) The appointment, removal, death, resignation of any member shall be notified in the Gazette.

Director-General of the Authority.

3C. (1) There shall be a Director-General of the Authority who shall be responsible to the Board of Directors for the day to day management of the affairs of the Authority.

(2) The Cabinet Secretary shall appoint the Director General of the Authority from amongst the three persons competitively recruited and recommended by the Board.

(3) The Director General shall perform such duties and exercise such powers, in addition to those required under the provisions of this Act to be performed and exercised, as the Board may from time to time direct.

(4) The Director-General shall hold office for term of five years, but is eligible

for reappointment for one more term.

(5) A person shall not be appointed as the Director-General unless that person possesses a basic university degree in a relevant field and a postgraduate degree in pharmacy or pharmaceutical quality control and has at least five years management experience.

Functions of the Director-General.

3D. The Director-General shall be the chief executive officer of the Authority and shall, subject to the general directions of the Board, be responsible for the staff and day to day management of the affairs of the Authority.

Staff of the Authority.

3F. The Board may appoint such staff as may be necessary for the proper discharge of its functions under this Act, upon such terms and conditions of service as it may determine, upon the advice of the Salaries and Remuneration Commission.

Amendment of section 4 of Cap. 244

5. Section 4 of the principal Act is amended in subsection (4) by deleting all the words after the word 'five'.

Amendment of section 5 of Cap. 244

6. Section 5 of the principal Act is amended in subsection (1) by deleting the words 'Chief Pharmacist' and substituting therefor the words 'Director-General'.

Amendment of section 19 of Cap. 244

7. Section 19 of the principal Act is amended in subsection (2) by deleting the words 'thirty thousand shillings' and substituting therefor the words 'one million shillings'.

Amendment of section 20 of Cap. 244

8. Section 20 of the principal Act is amended—

(a) by inserting the following new subsection immediately after subsection (1A)—

(1B) No person shall operate the business of a pharmacist or pharmaceutical technologist without the presence of a registered pharmacist

or pharmaceutical technologist in the premises where such business is being carried out.

(b) in subsection (2), by deleting the words 'twenty thousand shillings' and substituting therefor the words 'two hundred thousand shillings.

Amendment of section 23 of Cap. 244.

9. Section 23 of the principal Act is amended—

(a) in subsection (1), by inserting the words "or pharmaceutical technologist" immediately after the word 'pharmacist';

(b) in subsection (6), by deleting the words "thirty thousand shillings' and substituting therefor the words "five hundred thousand shillings';

Insertion of section 23A in cap. 244

10. The principal Act is amended by inserting the following new section immediately after section 23—

Power to close premises.

23A.(1) Any premises having been deleted from the register by the Authority or any premises which in the Authority's opinion have become unsuitable for the carrying on of the business of a pharmacist shall be closed.

(2) The Authority shall give the pharmacist in charge of the premises at least fourteen days notice of the intended closure under paragraph (1) and the reasons thereof in writing.

(3) If at the expiry of the period of notice under paragraph (2), the Authority is not satisfied that the improvements required have been made, an authorized officer shall seize all the stock held and order closure of the premises.

(4) The protection of right to property under Article 40 of the Constitution shall be limited as specified under this Part for the purposes of protecting the standards of medicinal substances and safety of the

public.

Amendment of section 26 of Cap. 244

11. Section 26 of the principal Act is amended in subsection (2) by deleting the words "one hundred thousand shillings" and substituting therefor the words "three hundred thousand shillings".

Amendment of section 27 of Cap. 244

12. Section 27 of the principal Act is amended by inserting the following new subsection immediately subsection (6)-

(7) A person who sells poison for the purposes specified under paragraph (1) contrary to this section shall be liable to a fine not exceeding five hundred thousand shillings or to imprisonment of a term not exceeding two years, or both.

Amendment of section 29 of Cap. 244

13. Section 29 of the principal Act is amended in subsection (5)—

(a) by deleting the words "one hundred thousand shillings" and substituting therefor the words "five hundred thousand shillings" and

(b) deleting the words "ten years" and substituting therefor the words "three years"

Amendment of section 29 of Cap. 244.

14. The principal Act is amended in section 29 by inserting the following new subsection immediately after subsection (5)—

(6) A person who offers for sale any counterfeit, expired, illegally imported or unregistered pharmaceutical substance and medicinal devices commits an offence and is liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding ten years or to both.

Amendment of section 35A of Cap. 244

15. Section 35A of the principal Act is amended in by inserting the following new subsections immediately after subsection (5)—

(6) A person who manufactures for sale any counterfeit or unregistered pharmaceutical substance or medicinal device commits an offence and is liable to a fine not exceeding three million shillings or to imprisonment

for a term not exceeding three years or both.

(7) A person who manufactures for sale any pharmaceutical substances or medicinal devices without a license to manufacture medicinal substances commits an offence and is liable to a fine not exceeding ten million shillings or to imprisonment for a term not exceeding five years or to both.

Amendment of section 35D of Cap. 244

16. Section 35D of the principal Act is amended in paragraph (c) by inserting the words 'medical devices' immediately after the word "drugs" wherever it appears.

Repeal and replacement of section 35F of Cap. 244

17. The principal Act is amended by repealing section 35F and substituting therefor the following new section—

Board of Management.

35F. (1) There shall be a Board of Management of the Laboratory which shall comprise of—

(a) a chairperson appointed by the Cabinet Secretary:

(b) the Principal Secretary responsible for health:

(c) the Principal Secretary responsible for finance:

(d) three persons appointed by the Cabinet Secretary as follows—

(i) one person nominated by public universities teaching pharmacy:

(ii) one person nominated by the Authority:

(iii) one person nominated by the Kenya Bureau of Standards from amongst members of its Board.

(e) the Director, appointed from in accordance with section 35H.

(2) A member of the Board of

Management appointed under subsection (1) (d) shall hold office for three years but shall be eligible for reappointment for one further term.

(3) A quorum of the Board of management shall be three members.

(4) The Board of Management shall meet not less than four times in each calendar year.

(5) Subject to this subsection, Board of Management may regulate its own procedure.

Repeal and replacement of section 35H of Cap. 244.

18. The principal Act is amended by repealing section 35H and substituting therefor the following new section—

Director of the Laboratory.

35H. (1) The Cabinet Secretary shall appoint a Director of the Laboratory from amongst three persons competitively recruited and recommended by the Authority.

(2) The Director shall hold office for term of four years, but is eligible for reappointment for one more term.

(3) A person shall not be appointed as the Director unless that person possesses a first University degree in pharmacy, a relevant postgraduate degree and at least four years management experience.

(4) The Director shall hold office on such terms and conditions of service as may be specified in the instrument of his or her appointment.

(5) The Director shall be the secretary of the Board of Management.

Amendment of section 41 of Cap. 244

19. Section 41 the principal Act is amended by inserting the following new subsections immediately after subsection (3)—

(4) All articles for clinical trials shall be appropriately

labeled and coded.

(5) Any person found deliberately or fraudulently mislabeling a pharmaceutical substance or in possession of a counterfeit pharmaceutical substance or medicinal device commits an offence and is liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding five years or to both.

Amendment of section 46 of Cap. 244

20. Section 46 the Principal Act is amended by inserting the following new subsection immediately after subsection (4)—

(5) The Authority may retain or confiscate a pharmaceutical substance that it has reasons to believe is a counterfeit or is illegally imported and the substance, if found to be counterfeit or illegally imported shall be disposed at the expense of the owner or importer of such substance.

(4) The protection of right to property under Article 40 of the Constitution shall be limited as specified under this section for the purposes of protecting the standards pharmaceutical substances and the safety of the public.

Amendment of section 47 of Cap. 244

21. Section 47 of the principal Act is amended by inserting the following new subsections immediately after subsection (2)—

(3) The officers of the Authority may enter any premises and inspect all records pertaining to clinical trials and protocols for the same conducted in Kenya.

(4) Any person who obstructs an authorized officer from performing his or her duties under subsection (3) commits an offence.

(5) The right to privacy of under Article 31 of the Constitution shall be limited as specified under this section for the purposes of—

(a) ensuring that the personnel, premises and practices engaged in medicinal substances comply with the codes of practice and other requirements; and

(b) public interest and public safety.

Insertion of section 48A in Cap. 244

22. The principal Act is amended by inserting the following new section immediately after section 48-

Approval for clinical trials

48A. (1) No person shall conduct a clinical trial in Kenya whether for investigation of new drugs or for new indications unless he has been granted approval by the Authority.

(2) The Cabinet Secretary may, in consultation with the Authority, make rules to regulate the conduct of clinical trials under subsection (1).

(3) The Board shall carry out routine inspections, with or without prior notification, at sites where clinical trials are being conducted ;

(4) For purposes of inspections, the Authority shall have the power to enter, search and investigate any premises and interview any persons therein and may require the investigator to take any measures necessary to ensure compliance with the regulations ;

(5) where the investigator fails to undertake the measures stipulated by the authority under subsection (4), the Authority may order that the termination of the trial and revoke the license for the clinical trial;

(6) Any person who conducts a clinical trial in Kenya without prior approval of the Authority commits an offence and is liable to a fine not exceeding two hundred thousand shillings or to imprisonment for a term not exceeding three years or to both.

(7) Any clinical trial investigator who fails or declines to adhere to the prescribed rules or misrepresents results commits an offence and is liable to a fine not exceeding two hundred thousand shillings or to imprisonment for a term not exceeding two years or to both.

23. The principal Act is amended by inserting the following new section immediately before section 50—

Offences under the Act.

50A.(1) A person who engages in the manufacture, importation, exportation, compounding, storage, sale, promotion or distribution of medicinal substances—

(a) that is unfit for use in humans or in animals;

(b) that is adulterated;

(c) that has upon it any natural or added deleterious substance which renders it injurious to human or animal health;

(d) that has been manufactured, prepared, preserved, packaged or stored for sale under insanitary and or unfavorable conditions; or

(e) that has been labeled, packaged or promoted in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its source, character, value, quality, composition, potency, merit or safety;

(f) or any counterfeit starting materials;

commits an offence under this Act.

MEMORANDUM OF OBJECTS AND REASONS

The principal purpose of this Bill is to make some necessary amendments to the Pharmacy and Poisons Act, Cap. 244, Laws of Kenya. The amendments proposed in this Bill seek to transform the Pharmacy and Poisons Board into a more effective semi-autonomous authority to be known as the Pharmacy and Poisons Authority.

The Bill also seeks to create new offences relating to the regulation of the pharmaceutical sector in the country. The Bill further proposes to enhance the current penalties meted out for offences under the Act to bring them in reality to modern economic realities taking into consideration inflationary trends.

Clause 3 of the Bill seeks to repeal and replace section 3 of the Act which establishes the Pharmacy and Poisons Board. The Bill proposes to replace the Board with the Pharmacy and Poisons Authority.

Clause 4 of the Bill proposes to insert new sections into the Act in order to enable the Authority to function as envisaged under Clause 3.

Clause 3A sets out the functions of the Authority. These functions include advising the government and government agencies in all matters relating to the safety, packaging and distribution of medicines and the regulation of the pharmaceutical profession and the practice of pharmacy in Kenya.

Clause 3B provides that the Authority shall be managed by a Board consisting of the following persons: a non-executive Chairman, appointed by the President; the Principal Secretary responsible for Finance; the Principal Secretary responsible for Health; the Director of Veterinary Services; the Director of Medical Services; seven members appointed by the Cabinet Secretary and the Director-General of the Authority.

Clause 3C provides for the office of the Director-General of the Authority, who shall be responsible to the Board for the day to day management of the affairs of the Authority.

Clause 3D provides for the functions of the Director-General which include being the registrar under the Act.

Clause 3F provides for the staff of the Authority who shall be appointed by the Board of the Authority.

Clause 7 seeks to enhance the fine payable for contravention of section 19 of the Act to an amount not exceeding one million shillings.

Clause 9 seeks to enhance the fine payable for contravention of section 23 of the Act to an amount not exceeding five hundred shillings.

Clause 10 of the Bill proposes to insert a new section 23A in the Act that shall give the Authority power to order the closure of premises that are unsuitable for the carrying on of the business of a pharmacist.

Clause 14 seeks to create a new offence of selling counterfeit, expired or unregistered pharmaceutical substances and medicinal devices and the offence is punishable by a fine not exceeding one million shillings or imprisonment for a term not exceeding ten years, or both.

Clause 15 seeks to create a new offence of manufacturing for sale counterfeit or unregistered pharmaceutical substances and medicinal devices and the offence is punishable by a fine not exceeding ten million shillings or imprisonment for a term not exceeding five years, or both.

Clause 17 seeks to repeal and replace section 35F of the Act in order to provide for a different composition of the Board of Management of the National Quality Control Laboratory.

Clause 18 proposes to repeal and replace section 35H of the Act in order to change the manner of appointment of the Director of the Laboratory. It is now proposed that the Director be appointed by the Cabinet Secretary instead of the Pharmacy and Poisons Board, proposed to be repealed.

Clause 22 proposes to insert a new section 48A in the Act to empower the Authority to approve and regulate the conduct of clinical trials in the country.

The enactment of this Bill shall not occasion additional expenditure of public funds.

ROBERT PUKOSE,
Member of Parliament.

Section 3 of the Pharmacy and Poisons Act which it is proposed to repeal and replace—

Establishment of Pharmacy and Poisons Board. 11 of 1993, Sch., 2 of 2002, Sch.

". (1) The Minister shall appoint a Board to be known as the Pharmacy and Poisons Board which shall consist of the following persons—

(a) the Director of Medical Services who shall be the Chairman;

(b) the Chief Pharmacist;

(c) the Director of Veterinary Services or a veterinary surgeon nominated by him;

(d) four Pharmacists appointed by the Minister from a panel of names submitted by the Pharmaceutical Society of Kenya of whom—

(i) one shall be from the Civil Service;

(ii) one shall be from the community pharmacy; and

(iii) one from the pharmaceutical industry;

(e) one representative of the Department of Pharmacy of the University of Nairobi nominated by the Faculty Board; and

(f) one pharmaceutical technologist appointed by the Minister from a panel of names submitted by the Kenya Pharmaceutical Society.

(2) Those members of the Board appointed under paragraphs (d),

(e) and (f) of subsection (1)—

(a) shall hold office for a period of three years but shall be eligible for re-appointment;

(b) may at any time resign by instrument in

writing addressed to the Chairman.

(3) Notwithstanding the provisions of subsection (2) the Minister may, if at any time it appears to him that a member of the Board has failed to carry out his functions under this Act, revoke the appointment of that person and shall appoint another person under subsection (1) in place of that member for the remainder of the period of office of that member and if that member is nominated or elected by any other authority or body, his nomination or election shall be deemed to have been annulled on account of the revocation of his appointment to the Board.

(4) The Minister may appoint an appropriately qualified person to act temporarily in the place of any member of the Board other than the Chairman in the case of death, illness, resignation or absence from Kenya.

(5) The appointment, removal, death, resignation of any member shall be notified in the Gazette.

(6) The Board shall be a body corporate with perpetual succession and a common seal, and shall be capable in its corporate name of—

(*a*) suing and being sued;

(*b*) acquiring, holding and disposing of property;

(*c*) borrowing and lending money.

Subsection (4) of section 4 of the principal Act which it is proposed to amend—

(4) The quorum of the Board shall be five, of whom three shall be pharmacists.

Proceedings of Board.

Subsection (1) of section 5 of the principal Act which it is proposed to amend—

(1) There shall be a registrar of the Board who shall be the Chief Pharmacist.

The Registrar

Subsection (2) of section 19 of the principal Act which it is proposed to amend –

(2) A person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding thirty thousand shillings or to imprisonment for a term not exceeding three years or to both.

General restrictions as to unregistered persons.
3 of 1968, s. 4, 2 of 2002, Sch.

Section 20 of the principal Act which it is proposed to amend—

Pharmacist to display name and registration
7 of 1990, Sch,
9 of 2000, s. 79,
2 of 2002, Sch.

20. (1) No person shall carry on the business of pharmacist unless the name, certificate of registration and annual licence of the person having control of the business are conspicuously exhibited in the premises in which the business is carried on .

(1A) No person shall carry the business of a pharmaceutical technologist unless the name and certificate of enrolment of the person having control of the business are conspicuously exhibited in the premises in which the business is carried on.

(2) A person who contravenes the provisions of this section shall be guilty of an offence and liable to a fine not exceeding twenty thousand shillings, or to imprisonment for a term not exceeding one year, or to both.

Subsection (1) of section 23 of the principal Act which it is proposed to amend –

Premises to be registered

2 of 2002, Sch.

(1) No person shall carry on the business of a pharmacist except in premises registered in accordance with this section.

Subsection (6) of section 23 of the principal Act which it is proposed to amend –

(6) A person who contravenes the provisions of subsection (1) shall be guilty of an offence and liable to a fine not exceeding thirty thousand shillings or to imprisonment for a term not exceeding three years or to both.

Subsection (2) of section 26 of the principal Act which it is proposed to amend –

Possession of Part I poisons.
3 of 1968 ss. 5, 6,
2 of 2002, Sch.

(2) A person who is in possession of a Part I poison otherwise than in accordance with the provisions of this section shall be guilty of an offence and liable to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding three years or to both.

Subsection (5) of section 29 of the principal Act which it is proposed to amend –

Power to sell Part I poisons.
3 of 1968, ss. 6, 7, 8

(5) A person who sells a Part I poison except in accordance with the provisions of this section shall be guilty of an offence and liable to a fine not exceeding one

13 of 1980, Sch.

hundred thousand shillings or to imprisonment for a term not exceeding ten years or to both.

Section 35F of the principal Act which it is proposed to repeal and replace–

Board of management

35F. (1) There shall be a Board of management for the Laboratory which shall consist of nine members to be appointed by the Pharmacy and Poisons Board.

(2) A member of the Board of Management appointed under subsection (1) shall hold office for three years but shall be eligible for reappointment.

(3) A quorum of the Board of Management shall be five members.

(4) The Board of Management shall meet not lees than four times each calendar year.

(5) The Director shall be the secretary of the Board of Management.

(6) Subject to this subsection, the Board of Management may regulate its own procedure.

Section 35H of the principal Act which it is proposed to repeal and replace—

Director

35H. (1) The Board of Management shall appoint a Director who shall be the chief executive of the Laboratory responsible to the Board of Management for the day to day management of the Laboratory.

(2) The Director shall hold office on such terms and conditions of service as may be specified in the instrument of his appointment.