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REPUBLIC OF KENYA

THE NATIONAL ASSEMBLY

THIRTEENTH PARLIAMENT – SECOND SESSION

DEPARTMENTAL COMMITTEE ON HEALTH

REPORT ON THE

WINNOWING OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022 (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY THE HON. DR. ROBERT PUKOSE, MP

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CHAIRPERSON'S FOREWORD

This addendum report contains the Committee's proceedings on the consideration and winnowing of amendments from the Committee and individual Members to the Kenya Drugs Authority Bill, 2022 (National Assembly Bill No. 54 of 2022).

The Kenya Drugs Authority Bill, 2022 (National Assembly Bill No. 54 of 2022) sponsored by Hon. (Dr.) Robert Pukose, MP which was published on 6th October 2022 and went through First Reading on 3rd May 2023 and was thereafter committed to the Departmental Committee on Health for consideration and facilitation for public participation pursuant to Article 118 of the Constitution and reporting to the House pursuant to the provisions of Standing Order 127(1).

Second Reading of the Bill was concluded on 18th October 2023 and the Bill progressed to the Committee of the whole House. After the Second Reading of the Bill seven Honourable Members proposed further amendments to the Bill.

The Committee of the whole house stage on the Bill started on Tuesday 25th October, 2023 and progressed up to clause 22. In resumption of the Committee of the whole house during the morning sitting of Wednesday 26th October 2023 before proceeding to the said order the Hon. speaker stayed the consideration of the Bill and directed that the proposed amendments to the Bill be subjected to a winnowing process, pursuant to the provisions of Standing Order 131 before the Committee on Health for harmonization before consideration at the Committee of the whole house The outcome of winnowing would inform the Speaker on how best to guide the House before the Bill is considered at the Committee of whole House.

Further, for clarity the speaker directed that, the Committee of the whole house had concluded consideration of clauses 3 to 22 and in the event contestations arise with regard to those Clauses, the house will be at liberty to recommit the clauses in accordance with standing Order 136A.

The Hon. Speaker directed that the proposed amendments be committed to the Committee on Health for harmonization before consideration at the Committee of the Whole House

During consideration of the proposed amendments, the Committee held a total of six (6) sittings during which it heard submissions from the following Honourable Members who proposed amendments

The Committee is thankful to the Office of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings.

On behalf of the Committee, and pursuant to Standing Order 127(4), it is my pleasant duty to table the Report on the winnowing process of the Departmental Committee on Health on its Consideration of the Kenya Drugs Authority Bill, 2022 (National Assembly Bill No. 54 of 2022).

HON. PATRICK NTWIGA MUNENE, MP

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

CHAPTER ONE

1.0 PREFACE

1.1 ESTABLISHMENT AND MANDATE OF THE COMMITTEE

1. The Departmental Committee on Health is established pursuant to the provisions of Standing Order 216 of the National Assembly Standing Orders and in line with Article 124 of the Constitution which provides for the establishment of the Committees by Parliament. The mandate and functions of the Committee include:
   a) *To investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned ministries and departments;*
   b) *To study the programme and policy objectives of ministries and departments and the effectiveness of the implementation;*
   ba) on a quarterly basis, monitor and report on the implementation of the national budget in respect of its mandate;
   c) To study and review all legislation referred to it;
   d) *To study, assess and analyse the relative success of the ministries and departments as measured by the results obtained as compared with their stated objectives;*
   e) *To investigate and inquire into all matters relating to the assigned ministries and departments as they may deem necessary, and as may be referred to them by the House;*
   f) *Vet and report on all appointments where the constitution or any other law requires the national Assembly to approve, except those understanding Order 204 (Committee on appointments);*
   g) *To examine treaties, agreements and conventions;*
   h) *To make reports and recommendations to the House as often as possible, including recommendation of proposed legislation;*
   i) *To consider reports of Commissions and Independent Offices submitted to the House pursuant to the provisions of Article 254 of the Constitution; and*
   j) *To examine any questions raised by Members on a matter within its mandate.*

2. In accordance with the Second Schedule of the Standing Orders, the Committee is mandated to consider matters related to health, medical care and health insurance including universal health coverage.

3. In executing its mandate, the Committee oversights the Ministry of Health with its two State Departments namely the State Department for Medical Services and the State Department for Public Health and Professional Standards.

1.2 COMMITTEE MEMBERSHIP

4. The Departmental Committee on Health was constituted by the House on 27th October 2022 and comprises of the following Members:

Chairperson
Hon. (Dr.) Robert Pukose, MP
Endebes Constituency
UDA Party

Vice-Chairperson
Hon. Ntwiga, Patrick Munene, MP
Chuka/Igambang'ombe Constituency
UDA Party

Hon. Owino Martin Peters, MP
Ndhiwa Constituency
ODM Party

Hon. Muge Cynthia Jepkosgei, MP
Nandi (CWR)
UDA Party

Hon. Wanyonyi Martin Pepela, MP
Webuye East Constituency
Ford Kenya Party

Hon. Kipngok Reuben Kiborek , MP
Mogotio Constituency
UDA Party

Hon. (Dr.) Nyikal James Wambura, MP
Seme Constituency
ODM Party

Hon. Kibagendi Antoney, MP
Kitutu Chache South Constituency
ODM Party

Hon. Julius Ole Sunkuli Lekakeny, MP
Kilgoris Constituency
KANU

Hon. Maingi Mary, MP
Mwea Constituency
UDA Party

Hon. Mathenge Duncan Maina, MP
Nyeri Town Constituency
UDA Party

Hon. Lenguris Pauline, MP
Samburu (CWR)
UDA Party

Hon. Oron Joshua Odongo, MP
Kisumu Central Constituency
ODM Party

Hon. (Prof.) Jaldesa GuyoWaqo, MP
Moyale Constituency
UPIA Party

Hon. Mukhwana Titus Khamala, MP
Lurambi Constituency
ANC Party

1.3 COMMITTEE SECRETARIAT

5. The Committee is supported by the following secretariat:

Mr. Hassan Abdullahi Arale
Clerk Assistant I/Head of Secretariat

Ms. Gladys Jepkoech Kiprotich
Clerk Assistant III

Ms. Marlene Ayiro
Principal Legal Counsel II

Ms. Abigael Muinde
Research Officer III

Ms. Faith Chepkemoi
Legal Counsel II

Mr. Hiram Kimuhu
Fiscal Analyst III

Mr. Yakub Ahmed
Media Relations Officer II

Mr. Benson Kimanzi
Serjeant-At-Arms III

Ms. Rahab Chepkilim
Audio Recording Officer II

Mr. Salat Abdi Ali
Principal Serjeant-At-Arms

CHAPTER TWO

2.0 OVERVIEW OF THE KENYA DRUGS AUTHORITY BILL, 2022, NATIONAL ASSEMBLY BILL NO. 54 OF 2022

6. **PART I (Clause 1-3)** of the Bill contains the preliminary provisions on the short title, interpretation and application of the Act. The Bill seeks to regulate health products and technologies including:

   (a) chemical substances;

   (b) therapeutic cosmetics;

   (c) herbal medicines and products;

   (d) medical devices including radiation-emitting devices;

   (e) medicines; and

   (f) scheduled substances.

7. **PART II (Clause 4-21)** of the Bill establishes the Kenya Drugs Authority in Clause 4 with its headquarters in Nairobi. The Authority is to be managed by a Board, the Kenya Drugs Board established under clause 8 of the Bill. The Part also provides for:
   a) the powers of the Kenya Drugs Authority in clause 13.
   b) the composition and qualifications for appointment as a member of the Kenya Drugs Board. The Kenya Drugs Board comprises of twelve members namely the Principal Secretaries in the Ministry of Health and Ministry of Finance, the Director-General of Health, the Managing Director of KEBS, representatives of the Law Society of Kenya, Pharmaceutical Association, Council of County Governors, Kenya Association of Manufacturers and Consumer Federation of Kenya and a Chairperson appointed by the President.
   c) the functions of the Kenya Drugs Authority in clause 12- the main function of the Authority is the regulation, investigation, inspection and approval of health products and technologies and related matters in public interest. The Authority will therefore manage licences and registers under the Bill and prescribe standards of quality for products to be manufactured in the country among others.
   d) the appointment of a Director General in clause 6 by the Public Service Commission with the approval of Parliament for a term of four years. The Director General shall be the Chief Executive Officer, Accounting Officer and Registrar of the Authority as well as the Secretary to the Board.
   e) the power of the Cabinet Secretary, Ministry of Health under clause 21 to establish scientific advisory committees that will provide expert, independent advice to the Cabinet Secretary on complex scientific issues presented to the Kenya Drugs Authority.

8. **PART III (Clause 22-36)** of the Bill provides for the regulation of medicines. The Bill therefore:
   a) penalizes the sale of adulterated and substandard medicine and medicine which has not been registered by the Kenya Drugs Authority;

b) requires compliance with standards of manufacturing, labeling, packaging, sale or advertisement;
c) penalizes the manufacture, sale, preparation and storage of medicine including herbal medicine contrary to the prescribed standards;
d) sets out the factors to be met to warrant the issuance of a product licence;
e) provides for the establishment and management of a medicines register; and
f) provides the procedure for the registration of medicines.

9. **PART V (Clause 37-46)** of the Bill provides for the regulation of scheduled substances. Under this Part, the Kenya Drugs Authority is to prepare and submit the lists of scheduled substances to the Cabinet Secretary that shall only be sold by authorized sellers specially licensed to do so. The Bill therefore criminalizes the possession of scheduled substances by unlicensed persons. The Bill further makes provision for the licensing of the dealers of scheduled substances, labelling of containers that will be used to supply scheduled substances and the sale of such substances including through electronic or online means.

10. **PART VI (Clause 47-48)** of the Bill provides for the manufacture of medicinal substances upon the issuance of a manufacturing license, renewable annually, by the Kenya Drugs Authority and compliance with good manufacturing practices.

11. **PART VII (Clause 49-54)** of the Bill provides for the regulation of therapeutic cosmetics. It prohibits the sale of therapeutic cosmetics that contains a substance that may cause injury to a user's health when there is adherence to the directions on the label as well as the preparation of therapeutic cosmetics under unsanitary conditions. The Kenya Drugs Authority is also empowered to prohibit any ingredient in therapeutic cosmetics.

12. **PART VIII (Clause 55-59)** of the Bill provides for the regulation of medical devices. The Bill penalizes the sale of adulterated and substandard medical devices and medical devices which have not been registered by the Kenya Drugs Authority the Bill further requires compliance with standards of manufacturing, labeling, packaging, sale, or advertisement of medical devices.

13. **PART IX (Clause 60-61)** of the Bill establishes the National Quality Control Laboratory responsible for:
    a) the examination and testing of drugs and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;
    b) performing chemical, biological, biochemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
    c) conducting research and training; and
    d) testing the quality of locally manufactured and imported medicines or medicinal substances, medical devices or therapeutic cosmetics on behalf of the Kenya Drugs Authority, with a view to determining whether such drugs or medicinal substances comply with the Act.

The National Quality Control Laboratory is to issue a certificate of analysis in the prescribed format for every analysis undertaken.

14. **PART XII (Clause 62-70)** of the Bill provides for the standards of advertisement and labelling of health products and technologies. All advertisements must be authorized by the Kenya Drugs Authority especially those relating to the diseases listed in the Sixth Schedule to the Bill including HIV, leprosy, diabetes, pneumonia as well as drugs and appliances for procuring abortions.

15. **PART XIII (Clause 71-87)** of the Bill provides for the administration and enforcement of the Act. The Bill makes provision for the general power of the Cabinet Secretary on the recommendation of the Kenya Drugs Authority to prohibit or control certain medicines or medical devices and to request further information. The Bill further authorizes the Kenya Drugs Authority to:
    a) authorize the sale or supply of unregistered medicine or medical device for a specified period;
    b) request for information;
    c) inspect licences and books of licensed sellers;
    d) inspect animals intended for slaughter; and
    e) retain and dispose seized goods.

16. **PART XIV (Clause 88-94)** of the Bill provides for financial provisions. The Bill sets out the sources of funding for the Kenya Drugs Authority, the preparation of annual estimates, the preparation of annual report and special reports, the investment of the Kenya Drugs Authority's funds, accounts and audit. The source of funding of the Kenya Drugs Authority includes appropriations from the Consolidated Fund, monies accruing in the course of the performance of its functions and gifts, grants or donations given to the Kenya Drugs Authority.

17. **PART XV (Clause 95-97)** of the Bill provides for miscellaneous provisions. The Kenya Drugs Authority may make Regulations under the Bill on various matters including fees payable and prescribed forms under the Act, procedures of clinical trials and the electronic sale of medicines among others. The Bill also contains transition and savings provisions on what happens to the assets, liabilities, legal obligations and staff of the National Quality Control Laboratory and the Public Health (Standards) Board being repealed. Under this Part, the Pharmacy and Poisons Board shall continue to exist for purposes of regulating the pharmacy profession until Parliament enacts a law for the regulation of the pharmacy practice. The Part further provides that the Bill shall apply subject to the provisions of the Public Health Act.

18. **SCHEDULES-** the Bill has seven schedules:

a) **First Schedule-**which contains provisions on the conduct of business and affairs of the Board in terms of meetings, quorum, voting, committees, disclosure of interest among others;

b) **Second Schedule-**which provides the oath or affirmation of the Office of the Chairperson, Member and Director;

c) **Third Schedule-**which contains provisions relating to appointment of members of the Board;

d) **Fourth Schedule-**which provides for the establishment and membership of Scientific Advisory Committees such as the National Food Safety Committee, Human Medicines Committee, Veterinary Medicines Committee, Medical Devices Committee and National Quality Control Committee;

e) **Fifth Schedule-**which provides the specified publications on standards of medicines;

f) **Sixth Schedule**- which sets out the purposes for which drugs may not be advertised; and

g) **Seventh Schedule**- which sets out the repeals being made under the Bill.

CHAPTER TTHREE

3.0 CONSIDERATION AND WINNOWING OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

3.1 Referral of the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022)

The Kenya Drugs Authority Bill (National Assembly Bill No. 54) sponsored by Hon. (Dr.) Robert Pukose was read a First Time on 3rd May, 2023 and committed to the Departmental Committee on Health for facilitation of public participation pursuant to Article 118 of the Constitution and reporting to the House, pursuant to Standing Order 127(1).

The Second Reading of the Bill was done on 4th, 11th and concluded on 18th October, 2023. After the Second Reading of the Bill was concluded, the Committee and seven Honourable Members proposed further amendments to the Bill, namely: -

1. Hon. Peter Kaluma, MP;
2. Hon. Dr. Otiende Omollo, MP;
3. Hon. Millie Odhiambo, MP;
4. Hon. Irene Mayaka,MP;
5. Hon. Anthony Oluoch MP;
6. Hon. Dr. Jmaes Nyikal, MP.
7. Hon. Martin Owino Peters, MP

Pursuant to the provisions of Standing Order 131, the Speaker directed that all the amendments received be referred to the Departmental Committee on health and be subjected to the winnowing process for harmonization.

3.0 COMMITTEE CONSIDERATION OF THE SUBMISSIONS

All the members with proposed amendments were invited by the Committee to prosecute the same before the Committee. The Committee thereafter considered and made observations and recommendations on each of the proposed amendments.

3.1 Submission by the Committee

The Hon. Dr. Robert Pukose, MP the chairperson of the Committee presented the Committee on Health proposed amendments and appeared before the Committee on 2nd November, 2023 and made the following submission:

Long Title

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

> "AN ACT of Parliament to establish a comprehensive legal framework for the regulation of Health Products and Technologies; to safeguard public health through development of a regulatory system to ensure safety, quality, efficacy, effectiveness and performance of health products; to establish the Kenya Health Products and Technologies Authority and for connected purposes".

Justification: The amendment accords with international best practice and sets out the main purpose of the Bill which is to establish a centralized regulatory authority for health products and technologies.

Clause 1

THAT, Clause 1 of the Bill be amended by—

(a) deleting the phrase "Kenya Drugs Authority Act, 2022" and substituting therefor the phrase "Kenya Health Products and Technologies Regulatory Authority Act, 2022";

Justification: The amendment accords with international best practice and comprehensively covers the mandate of the proposed Authority.

(b) deleting the words "and commencement" in the marginal note.

Justification: To limit the marginal note to the content of clause 1 which only sets out the name of the Bill. The Clause does not make any provision as regards the commencement of the Bill.

Clause 2

THAT Clause 2 of the Bill be amended—

(a) in the definition of "article" by–

(i) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (a); and

(ii) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (b);

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(b) in the definition of "Authority" by deleting the words "Kenya Drugs Authority" and substituting therefor the words, "Kenya Health Products and Technologies Regulatory Authority";

Justification: To ensure harmony with the title of the Bill as proposed for amendment.

(c) in the definition of "chemical substance" by deleting the words "or detergent";

Justification: To exclude detergents which are used for cleaning inanimate objects and does not fall under the purview of the regulation of health products and technologies.

(d) in the definition of "drug" by deleting the word "if" appearing in paragraph (b)(ii) and substituting therefor the word "of";

Justification: To correct a minor typographical error.

(e) by deleting the definition of "enrolled pharmaceutical technologist";

Justification: The current definition cross references the Pharmacy and Poisons Act, cap. 244 which will be repealed as provided under clause 97. A new definition proposed.

(f) in the definition of "health products and technologies" by inserting the words, "dietary supplement" immediately after the words, "therapeutic cosmetics";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(g) by deleting the definition of "herbal medicine or product";
(h) by deleting the definition of "medical device";
(i) by deleting the definition of "medicinal substance";

Justification: New definitions provided for these terms. These new definitions expand the scope to cover all aspects of the use of medical devices and medicinal substances in relation to health and to include herbal materials and herbal combinations.

(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(k) by deleting the definition of "pharmacy";

Justification: The current definition is inadequate. The term to be defined in the proposed Pharmaceutical Practice Bill.

(l) by deleting the definition of "pharmaceutical technologist";

Justification: The Pharmacy and Poisons Act, cap. 244 provides that a pharmaceutical technologist must be enrolled in the roll established under this Act.

(m) by deleting the definition of "registered midwife";

Justification: The term is no longer used in the Bill in line with the proposed amendment of clause 43 (1)(c).

(n) in the definition of "scheduled substance" by deleting the words "in the relevant schedule under this Act" and substituting therefor the words "in the list published by the Cabinet Secretary under section 37 of this Act";
Justification: There is no Schedule on scheduled substances. The Cabinet Secretary will publish the list of scheduled substances in the *Gazette*.

(o) by deleting the definition of "therapeutic cosmetic"; and

Justification: The current definition defines cosmetics in general that are meant to provide the body with appropriate aesthetics, texture, pH, color and smell. It is not specific to special cosmetics.

(p) by inserting the following new definitions in their proper alphabetic sequence—

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"adverse event" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment;

"biologicals" means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies and includes products derived from human blood and plasma;

"Board" means the Board of the Authority established under section 8;

"Centre" means the National Pharmacovigilance Centre established under section 59B;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dietary supplement" means a product taken by mouth that is added to the diet to help meet daily requirements of essential nutrients, and which usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

"enrolled pharmaceutical technologist" means a person enrolled as such by the body for the time being responsible for the enrolment of pharmaceutical technologists;"

"falsified medical product" means a product that is deliberately or fraudulently misrepresented in relation to its identity, composition or source;

"Field Safety Corrective Action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, and includes—

(a) the return of a medical device to the product owner or its representative;

(b) device modification which may include—

(i) retrofit in accordance with the product owner's modification or design change;

(ii) permanent or temporary changes to the labelling or instructions for use;

(iii) software upgrades including those carried out by remote access;

(iv) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;

(v) device exchange;

(vi) device destruction; or
(vii) advice given by product owner regarding the use of the device.

"health product" includes a medicine, medical product, medicinal substance, vaccine, diagnostic, medical device, blood or blood product, traditional and alternative medicine, therapeutic feed and nutritional formulation, cosmetic and related products;

"health technology" means the application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives;

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations;

"in-vitro diagnostics medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector and who holds a minimum of a diploma in pharmacy;

"lot" or "sub-lot" means a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous; and in the case of continuous manufacture, the lot corresponds to a defined fraction of the production characterized by its intended homogeneity;

"lot release" means the process of the evaluation of an individual lot of a licensed biological product by the Authority before giving approval for its release onto the market;

"marketing authorization" means the certificate of registration issued by the competent health product regulatory authority in the country of origin for the purpose of marketing or free distribution of a health product after evaluation for safety, efficacy and quality;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;

(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies, and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importation" means importation into Kenya, by a licensed importer of a health product other than the marketing authorization holder or his or her technical representative, of the following health products which require marketing authorization in Kenya—

(a) patented health products under section 58(2) of the Industrial Property Act, 2001;
(b) non-patented health products; or
(c) branded generic health products;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;

"scheduling" means, in relation to a substance, the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;

"substandard medical product" means a registered medical product that fails to meet either its quality standards or specifications, or both;

"therapeutic cosmetic" means a cosmetic which—

(a) offers an additional benefit to a person over an ordinary cosmetic; or

(b) contains a bioactive product formulated from an animal ingredient that may have visible and measurable short or long-term effects on a person, and may include a product that may be absorbed through the skin or a mucous membrane;

"unregistered medical product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;

"vessel" means a truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;

Justification: The new definitions are internationally recognized by the World Health Organization and are critical for the execution of regulatory functions of the Authority.

To further identify the Board as used in the Bill.

To provide new definitions for the words: enrolled pharmaceutical technologist, therapeutic cosmetic, herbal medicine, medical device and medicinal substances.

Clause 3

THAT, Clause 3 of the Bill be amended by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) This Act applies to the regulation of—

(a) medicines, medical products and technologies;
(b) medical devices including radiation emitting products;
(c) radiopharmaceuticals;
(d) complementary, alternative or herbal medicines;
(e) cosmetics and Borderline Products;
(f) in-vitro diagnostics medical devices;
(g) therapeutic feeds;
(h) clinical trials;
(i) nutraceuticals and dietary supplements;
(j) digital health and technologies;
(k) scheduled substances;
(l) chemical substances; and
(m) biological products for use in humans and the starting materials used in their manufacture."

Justification: To comprehensively cover all aspects in the regulation of health products and technologies.

Clause 4

THAT, Clause 4 of the Bill be amended in sub-clause (1) by deleting the words "Kenya Drugs Authority" and substituting therefor the words "Kenya Health Products and Technologies Regulatory Authority".

Justification: This accords with international best practice on the establishment of a centralized regulatory authority for health products and technologies.

Clause 5

THAT, Clause 5 of the Bill be amended by deleting the words, "but the Authority may establish branches anywhere in Kenya" and substituting therefor the words "or in such other place as the board of the Authority may, by resolution, determine".

Justification: To give the Board discretion in determining the location of the Authority's headquarters.

Clause 6

THAT, Clause 6 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) There shall be a Director-General who shall be the chief executive officer of the Authority.

Justification: For proper drafting of the clause.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) The Director-General shall be appointed by the Board, through a transparent and competitive process, on such terms as may be specified in the instrument of appointment."

Justification: The Director General is not a State Officer and should therefore be appointed by the Authority without the approval by Parliament.

(c) in sub-clause (3) by deleting the word "four" and substituting therefor the word "three".

Justification: Appointments and term of service in State Corporations are normally capped at three (3) years which is renewable for one final term.

(d) by deleting sub-clause (4) and substituting the following new sub-clause (4)—

"(4) A person shall be qualified for appointment as a Director-General if such person—

(a) holds a bachelor's degree in pharmacy from a university recognized in Kenya;
(b) holds a masters' degree in pharmacy, medicine or any relevant field from a university recognized in Kenya;
(c) has at least ten years' experience in pharmacy or its equivalent;
(d) has served in a senior management position for at least five years;
(e) is a member of a professional body; and
(f) meets the requirements of Chapter six of the Constitution."; and

Justification: The Director General should be a qualified pharmacist as the regulation of health products and technologies requires specialized knowledge and technical expertise in the pharmaceutical field.

(e) by deleting sub-clause (5).

Justification: The fact that the Director-General shall be the CEO of the Authority is provided in the sub-clause (1) as proposed for amendment.

Clause 7

THAT, Clause 7 of the Bill be amended in paragraph (f) by deleting the words "Act. regulation under this" and substituting therefor the words "regulation under this Act.".

Justification: To correct a typographical error.

Clause 8

THAT, Clause 8 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "Kenya Drugs" and substituting therefor the words "Kenya Health Products and Technologies Regulatory';

Justification: The name of the Board should reflect the amended Title of the Bill and name of the Authority as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) The Board shall comprise—

(a) a non-executive Chairperson appointed by the President and who shall—

(i) be a registered pharmacist of good standing with a degree in pharmacy; and

(ii) have at least ten years' experience in the pharmaceutical sector, five of which shall be at senior management level;

(b) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing;

(c) the Principal Secretary the Ministry for the time being responsible for finance or a representative designated in writing;

(d) the Director-General for Health or a representative designated in writing;

(e) one person nominated by the Pharmaceutical Society of Kenya;

(f) one person nominated by the Kenya Pharmaceutical Association;

(g) one person nominated by the Kenya Medical Association;

(h) one person, not being a Governor, with knowledge and experience in health products and technologies nominated by the Council of County Governors to represent the interests of counties;

(i) one person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(j) the Director-General of the Authority who shall be the secretary and an *ex officio* member of the Board."; and

Justification: The composition of the Board should comply with the *Mwongozo* Code of Governance for State Corporations in terms of numbers, skill mix and professional

expertise which should include all relevant players involved in the matters of health products and technologies.

(c) by deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

"(3) The Cabinet Secretary shall appoint the members of the Board under subsection (e), (f), (g), (h) and (i) by notice in the *Gazette.*"

Justification: The members of the Board Members are not State Officers and hence their appointment does not require approval by Parliament. It is sufficient that the Cabinet Secretary notifies the public of the appointments in the Kenya Gazette.

Clause 9
THAT, the Bill be amended by deleting Clause 9.
Justification: The provision contradicts the legal framework for appointment of the Chairperson, Board Members and CEOs of State Corporations or Semi-Autonomous Government Agencies. The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

Clause 10
THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "section 12" appearing in paragraph (c) and substituting therefor the words "section 11".
Justification: To correct the cross reference as clause 11 makes provision for removal from office of the members of the Board of the Authority.

Clause 12
THAT, Clause 12 of the Bill be amended by—
(a) inserting the following paragraphs immediately after paragraph (e)—

"(ea) regulate the disposal of health products and technologies;
(eb) monitor the market for the presence of unregistered and illegal health products and technologies;
(ec) conduct analytical tests of health products and technologies";

Justification: To make provision for the functions of disposal, analytical testing and monitoring of the market by the Authority.

(b) deleting paragraph (f) and substituting therefor the following new paragraph (f) —
"(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act through analysis of reports on adverse reactions and events, including any other health product and technology use related issues and take appropriate regulatory actions when necessary";

Justification: To expressly align to the WHO requirement on the establishment of a national vigilance system.

(c) deleting paragraph (g) and substituting therefor the following new paragraph (g)—

"(g) regulate clinical trials and ensure that clinical trial protocols of health products and technologies are being assessed according to the prescribed ethical and professional criteria and defined standards including mandatory bioequivalence studies";

Justification: To anchor the oversight of clinical trials in the law as recommended by the WHO.

(d) inserting the following new paragraphs immediately after paragraph (g)—

"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials, emergency use and compassionate use;
(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements";

Justification: To provide for approval of health products and technologies during emergencies and to provide for pharmacovigilance which check the safety of health products and technologies.

(e) deleting paragraph (n) and substituting therefor the following new paragraph (n)—
"(n) appoint inspectors and order inspection of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act";

Justification: To specify the premises subject to inspection by the Authority.

(f) inserting the following new paragraphs after paragraph (o)—

"(oa) conduct national regulatory authority lot release, official authority batch release of specified biologicals to ensure the quality, safety and efficacy of biological products through a regulatory release system in compliance with established approaches, policies, guidelines, procedures and in line with World Health Organization and internationally recognized guidelines;

(ob) carry out and promote research related to medicines and health products";

Justification: To enable the conduct of research by the Authority and the conduct of lot releases which are a key component in the regulation of the production of vaccines.

(g) inserting the following paragraphs after paragraph (q)—

"(qa) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;
(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;
(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;
(qd) maintain a register of all authorized health products and technologies manually or electronically;

(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;
(qf) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

Justification: To include critical functions of the Authority based on best practice in regulation of import and export of health products and technologies that will enable the country attain WHO maturity level 3.

Clause 13

THAT, Clause 13 of the Bill be amended by—

(a) deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate for the furtherance of the purpose of the Act;"

(b) inserting the following new paragraphs immediately after paragraph (a)—

"(aa) adopt and implement any such internationally recognized good regulatory practices;
(ab) determine and implement effective and efficient reliance mechanisms;
(ac) issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;
(ad) levy, collect and utilize fees for services rendered;
(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; (af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

Justification: To comply with WHO requirements for regulatory functions in the Global Benchmarking Tool especially on control over imports and exports.

Clause 21

THAT Clause 21 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) The Board may establish such scientific advisory committees of the Authority, as may be necessary for the effective performance of the functions of the Authority".

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9) —

"(9) An advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary".

Justification: The Scientific Advisory Committees ought to offer technical advice and report to the Board (its appointing authority) which then advices the Cabinet Secretary accordingly.

Part Iv

THAT, Part IV of the Bill be amended by deleting the title and substituting therefor the following new title—

"PART III—HEALTH PRODUCTS AND TECHNOLOGIES"

Justification: To ensure harmony with the title of the Bill as proposed for amendment and to correct a minor error in numbering of the parts of the Bill.

Clause 22

THAT, Clause 22 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—

(i) deleting the words "sell any medicine" appearing in the opening sentence and substituting therefor the words "sell, manufacture, supply, distribute or dispense any health product or technology";

Justification: To broaden the scope of prohibited sale of health product and technologies to include manufacturing, dispensing, distribution and supply of health product and technologies.

(ii) deleting paragraph (d) and substituting therefore the following new paragraph (d)—

"(d) is falsified,";

Justification: For alignment with international best practice as the proposed terminology is recognized by the WHO.

(c) in sub-clause (3) by—

(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) deleting the words "pharmaceutical product" appearing in paragraph (b) and substituting therefor the words, "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 23

THAT, Clause 23 of the Bill be amended in sub-clause (1) by—

(a) deleting the word "medicines" appearing in paragraph (a) and substituting therefor the words, "health products or technologies";
(b) deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words, "health products or technologies"; and
(c) deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words, "health products or technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 24

THAT, Clause 24 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";
(b) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(c) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–

"(2) If a standard has not been prescribed for a health product or technology but a standard for the health product or technology is contained in any of the publications specified in the Fifth Schedule, any person who manufactures, labels, packages, sells or advertises any other substance or article in such a manner that is likely to be mistaken for the health product or technology having met any of the standards contained in any of the publications specified in the Fifth Schedule, commits an offence.";

(d) in sub-clause (3)–
  (i) by deleting the word "medicine" wherever it appears in the opening sentence and substituting therefor the words "health product or technology"; and
  (ii) by deleting the word "drug" appearing in paragraph (b) and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) in sub-clause (4)—
  (i) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three months" appearing in paragraph (a) and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years"; and

(ii) by deleting the words "two hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

Justification: To make the fines prohibitive and punitive due to the risk of the offences to public health.

Clause 25

THAT, the Bill be amended by deleting Clause 25.

Justification: The prohibition of sale of medicines of a quality not demanded is a practice issue and falls outside the ambit of the Bill.

Clause 26

THAT, Clause 26 of the Bill be amended by—

(a) deleting the word "medicine" appearing in the marginal note and substituting therefor the words "health product or technology"; and

(b) deleting the word "medicine" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 27

THAT, Clause 27 of the Bill be amended—

(a) by deleting the words "medicinal products" appearing in paragraph (a) and substituting therefor the words "health products or technologies";

(b) by deleting the words "medicinal products" appearing in paragraph (b) and substituting therefor the words "health products or technologies"; and

(c) by deleting paragraph (c) and substituting the following new paragraph (c)—

"(c) the quality of the health products or technologies of each such description, according to the specification and the method or proposed method of manufacture of the health products or technologies, and the provisions proposed for securing that the health products or technologies as sold or supplied will be of that quality; and"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

New Clauses

THAT, the Bill be amended by inserting the following new clauses immediately after clause 27–

Application for product licence.

27A. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Authority for the registration of the health product or health technology in the prescribed form.

(2) An applicant under subsection (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Authority in the declaration page of the application form; and

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—

(a) a proposed label for use on the health product or technology;

(b) a copy of the manufacturing licence of the health product or technology, where applicable;

(c) a copy of the good manufacturing practice certificate from the Authority and the regulatory authority of the country where the health product or technology is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognized by the Authority, where applicable;

(e) a copy of the marketing authorization or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product or technology;

(h) proof of ownership of the site for the manufacture of the health product or technology, where applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body—

(i) a copy of the certificate of registration;

(ii) the professional information relating to the health product or technology; and

(iii) the conditions of the registration of the health product or technology;

(k) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell poisons issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(4) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

Processing of application for registration of health product or technology.

27B. (1) The Authority shall consider the application made under section 27A, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in the prescribed form.

(2) The Authority may, while considering the application, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;

(b) the labelling of the health product or technology;

(c) the statement of the representations to be made for the promotion of the health product or technology regarding—

(i) the claim to be made for the health product or technology;

(ii) the route of administering the health product or technology;

(iii) the dosage of the health product or technology;

(iv) the storage conditions of the health product or technology;

(v) the contra-indications, the side effects and precautions, if any of the health product or technology; and

(vi) the package size of the health product or technology.

(3) When evaluating an application, the Authority may—

(a) subject a sample of the health product or technology to an evaluation by an analyst; and

(b) consider the evaluation report of the analyst that has evaluated the health product or technology.

(4) Where the Authority is not satisfied as to the quality, safety efficacy, performance or economic value of the health product or technology, it may, after providing an opportunity to the applicant to be heard, reject the application and inform the applicant the reasons for rejection in writing.

Registration during emergency.

27C. (1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to life or health, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subsection (1) shall apply to the Authority in the prescribed form.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(4) An application under subsection (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(5) When determining an application under this section, the Authority shall consider the facts established from the valid marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for health products and technologies, if available.

(6) The person to whom the certificate of registration is issued under this section, shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) A provisional certificate of registration issued under subsection (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked.

(8) Any variation to the agreement appointing the local representative to the application made under subsection (2) shall be notified to the Authority within seven days of the variation.

Authorization of unregistered health

27D. (1) The Authority may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product or technology that is not registered.

product or technology.

(2) A health product or technology distributed pursuant to authorization granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) A person who intends to obtain the authorization under subsection (1), for purposes other than a clinical trial, shall apply to the Authority in the prescribed form.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(5) The application made under subsection (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;
(b) written consent of the applicant, where applicable;
(c) details of registration or pending registration of the health product or technology with any other regulatory authority, where applicable;
(d) evidence of compliance by the manufacturer of the health product or technology with good manufacturing practice standards as determined by the Authority;
(e) reasons why a registered health product or technology cannot be used;
(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;
(g) proof that the applicant holds—
    (i) a valid practicing licence issued by the body responsible for the profession of pharmacy;
    (ii) a valid wholesale dealer's licence issued in accordance with this Act;
    (iii) a valid licence to sell health products or technologies issued in accordance with this Act; or
    (iv) a valid manufacturing licence issued in accordance with this Act; and
    (v) proof of payment of the application fees as prescribed by the Authority.

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—

(a) progress reports after every six months from the date of issuance of the authorization;

(b) any adverse event report, where an adverse event occurred; and
(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—

(a) impose any additional conditions;
(b) request additional information;
(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or
(d) withdraw the authorization to treat the patient.

(8) The Authority may, by notice in writing withdraw the authorization issued under subsection (1) if the any of purposes or the manner specified in subsection (2) is contravened.

(9) A health product or technology authorized under this section shall be labelled in accordance with this Act.

(10) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

(11) The requirements in this section shall apply to applications for donations of health products and technologies

Justification: To provide new clauses 27A, 27B, 27C and 27D for the handling of applications of product licences by the Authority.

Clause 28

THAT, Clause 28 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines register" and substituting therefor the words "health products and technologies register";
(b) in sub-clause (1) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register"; and
(c) in sub-clause (2) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 29

THAT, Clause 29 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines and medical devices" and substituting therefor the words "health products and technologies";
(b) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) Every application for registration of a health product or technology shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant health product or technology and by the prescribed registration fee."

(c) in sub-clause (3)–

(i) by deleting the word "medicine" appearing in paragraph (a) and substituting therefor the words "health product or technology";

(ii) by deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words "health product or technology";

(iii) by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology";

(d) in sub-clause (4) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

(e) by deleting sub-clause (6) and substituting therefor the following new sub-clause (6)—

"(6) Where the Authority has approved the registration of any health product or technology if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, the Registrar shall register that health product or technology and shall enter in the register such particulars in regard to the health product or technology as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that health product or technology."

(f) in sub-clause (7) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(g) in sub-clause (8) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(h) in sub-clause (9) by deleting the word "medicines" and substituting therefor the words "health products and technologies";

(i) in sub-clause (10) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(j) in sub-clause (11) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(k) in sub-clause (12) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(l) in sub-clause (14) by deleting paragraph (a) and substituting therefor the following new paragraph (a) —

"(a)Kenya Essential Medicines List, Kenya Essential Diagnostics list and Kenya Essential Medical Supplies list' means the list of essential medicines, diagnostics and medical supplies included in the latest editions of the official publications relating to guidelines for standard treatment which is compiled by the state department responsible for Health;"

Justification: To broaden the scope of HPTs considered under the clause.

New Clauses

THAT, the Bill be amended by inserting the following new clauses immediately after clause 29—

Authorization of health products and technologies.

29A. (1) A person shall not import any health product or technology unless—

(a) the imported health product or technology has been authorized through issuance of an import permit or a written authorization by the Authority; and

(b) the imported health product or technology is inspected and verified by an inspector of the Authority at the ports of entry prior to its release.

(2) No batch or lot of any registered product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in cases of biological therapeutics.

(3) Each applicable test conducted by the manufacturer under subsection (2) shall be made on each batch or lot after completion of all processes of manufacture and such test may affect compliance with the standard applicable to the product.

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

(5) Every batch or lot of a registered biological therapeutic imported into Kenya or manufactured in Kenya shall be evaluated and, on being satisfied of conformity with prescribed standards and payment of prescribed fees, the Director-General shall approve its release into the market and issue a certificate of official batch or lot release in the prescribed format.

(6) The Authority may recognize and accept official lot release certificates issued by other national regulatory authorities of other countries for a specific batch or lots of biological therapeutic manufactured within the territories of those national regulatory authorities, in issuance of a certificate under this section.

(7) A person who contravenes this section commits an offence and shall on conviction be liable—

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Justification: To provide for authorization of health products and technologies imported into the country including the requirement for batch or lot release in line with WHO requirements.

Parallel importation of health products and technologies.

29B. (1) A person shall not engage in the parallel importation of a health product or technology into Kenya unless—

(a) the person is incorporated as a limited liability company under the Companies Act;

(b) the person has been granted a certificate of parallel importation;

(c) the person is licensed to parallel import the health product or technology;

(d) the health product or technology has a valid registration in Kenya under this Act; and

(e) the health product or technology has a valid market authorization in the country of origin.

(2) A person who wishes to undertake parallel importation of a health product or technology shall apply to the Board for a certificate of parallel importation in the prescribed manner.

(3) The Board shall establish and maintain a system that ensures that a registered parallel imported health product or technology can be traced from its sourcing, manufacturing, packaging, storage, transport to its delivery to the health facility, institution or private practice where the health product or technology is intended to be used.

(4) A person who—

(a) is the holder of a certificate of parallel importation or licensee and fails to comply with any requirement or obligation in this Act;

(b) contravenes any prohibition prescribed by the Authority; or

(c) fails to comply with any requirement imposed on that person by the Board pursuant to this Act,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Justification: To make provision for parallel importation of health products and technologies.

Clause 30

THAT, Clause 30 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology"; and

(b) in sub-clause (3), by deleting the word "medicine" wherever it appears in paragraph (b) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 31

THAT, Clause 31 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" and substituting therefor the words "health product or technology"; and

(b) in sub-clause (3), by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 32

THAT, Clause 32 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) The Authority shall cancel the registration of a health product or technology if—

(a) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(b) a particular health product or technology does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular health product or technology available to the public."

(b) in sub-clause (2) by deleting the words "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology";

(c) in sub-clause (4)–

(i) by deleting the words "medicine or medical device" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) by deleting the words "medicine or medical device" appearing in paragraph (b) and substituting therefor the words "health product or technology"; and

(d) by deleting the words "medicine or medical device" wherever it appears in sub-clause (5) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 33

THAT, Clause 33 of the Bill be amended in sub-clause (1) by deleting the words "medicine or medical device" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 34

THAT, Clause 34 of the Bill be amended—

(a) by deleting the words "medicines" and "medicine" wherever it appears and substituting therefor the words "health product or technology"; and

(b) in the marginal note by deleting the words "medicines" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 35

THAT, Clause 35 of the Bill be amended —

(a) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";

(c) in sub-clause (2) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";

(d) in sub-clause (3) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist"; and

(e) in sub-clause (4) by inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist".

Justification: For inclusion of pharmaceutical technologists in the dispensing of interchangeable multi-source medicine.

Clause 36

THAT, the Bill be amended by deleting Clause 36

Justification: The provision is a practice related issues that is best handled through the proposed Pharmaceutical Practice Bill.

New Clause

THAT, the Bill be amended by inserting the following new clause immediately after clause 36—

Clinical trials.

36A. (1) A health product or technology shall not be used for clinical trial unless an approval is granted by the Authority with the approval of the relevant ethics body.

(2) A person who intends to commence a clinical trial on a health product or technology shall make an application to the Authority in the prescribed form and the application shall be accompanied by the study protocol in the prescribed format and the prescribed fee.

(3) The study protocol submitted under subsection (2) shall include a post-trial access program to ensure access of investigational medicinal substances by participants in the trial before grant of marketing authorization by the Authority.

(4) The Authority shall prescribe guidelines for evaluation of applications made under subsection (2) to be implemented for accelerated evaluations during emergency situations, epidemics and outbreaks.

(5) A person granted an approval under this section shall put in place a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated and the safety and well-being of the participants of the study.

(6) The Authority shall carry out inspection of the clinical trials and monitor compliance of the clinical trials with the prescribed requirements.

(7) Any amendments to clinical trials protocols shall be submitted to the Authority for approval before implementation.

Justification: To provide for effective regulation of clinical trials by the Authority.

Part V

THAT, the Bill be amended in the title to Part V by deleting the expression "PART V" and substituting therefor the expression "PART IV".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 37

THAT, Clause 37 of the Bill be amended—

(a) in sub-clause (2) by deleting the words "and dealers in mining, agricultural or horticultural accessories" appearing in paragraph (a);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)—
"(3) The Cabinet Secretary shall publish the list of scheduled substances prepared under subsection (1) in the *Gazette.*"

Justification: To provide for the publication of the list of scheduled substances.

(c) by renumbering sub-clause (3) as sub-clause (4);
(d) by deleting sub-clause (4) and substituting therefor the following new sub-clauses —

"(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.
(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsection (1), (2) and (3)."

Justification: To enhance the period of review of the lists of scheduled substances from one year to two years and provide for review in public interest where need arises. To ensure that the procedure set out in the clause in the preparation and publication of the list of scheduled substances is followed even when the lists are modified.

Clause 38

THAT, Clause 38 of the Bill be amended—
(a) in sub-clause (1) by—
(i) deleting the words "the Limitations prescribed by this sub-section" and substituting therefor the words "the following limitations";

Justification: For proper drafting. The words "prescribed by this sub-section" are unnecessary.

(ii) deleting paragraph (c)

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.
(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 2,000,000.

Clause 39

THAT, Clause 39 of the Bill be amended by deleting sub-clause (5) and substituting therefor the following new sub-clause (5)—

"(5) A license issued under this section shall be valid for a period of one year, renewable annually".

Justification: Annual expiry of the license is too punitive especially for persons who apply in the middle of the year.

Clause 40

THAT, the Bill be amended by deleting clause 40.

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

Clause 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraphs (c) and (e);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws. The National or County government cannot buy scheduled substances on its own, it must do so through a person licensed to do so under the Bill.

(b) in sub-clause (2) by deleting paragraph (b) and (c); and

Justification: The persons to whom a wholesaler dealer may sell scheduled substances to are set out in sub-clause (1).

(c) by deleting sub-clause (3).

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

Clause 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "paragraph (b) of Section 53(2)" appearing in paragraph (a) and substituting therefor the words "section 41(2)(b)"; and

Justification: To correct the cross reference as clause 41 makes reference to the written certificate contemplated under clause 42.

(b) in sub-clause (3) by deleting the words "three years" and substituting therefor the words "one year"

Justification: To reduce the penalty of imprisonment from three years to one year as the same is not commensurate to the fine of one hundred thousand shillings in relation to the offence of not making entries of sale of scheduled substances in a scheduled substances book.

Clause 43

THAT, Clause 43 of the Bill be amended in sub-clause (1)—

(a) by deleting the opening sentence and substituting therefor the following new opening sentence—

"(1) A qualified healthcare professional may supply or dispense a Scheduled Substance with therapeutic value for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following provisions—"

Justification: To rrestrict dispensing of scheduled substances to authorized persons.

(b) in paragraph (b) by—

(i) inserting the word "and" immediately after the word "supplied" appearing in sub-paragraph (iii); and

(ii) deleting the word "and" appearing in sub-paragraph (iv);

Justification: To correct a minor drafting error.

(c) by deleting paragraph (c).

Justification: Registered midwives are included in the qualified healthcare professional provided in the amended sub-clause (1).

Clause 45

THAT, the Bill be amended by deleting Clause 45 and substituting therefor the following new clause 45—

Automatic machines.

45. (1) An authorized seller may use an automatic machine to dispense over-the-counter scheduled substances.

(2) The Authority shall develop regulations on the—

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

Justification: To provide for the use of automatic machines in dispensing selected scheduled substances in an effort to leverage on technology.

Clause 46

THAT, the Bill be amended by deleting Clause 46 and substituting therefor the following new clause 46—

Electronic sale of health products and technologies.

46. (1) The Authority shall prescribe guidelines to provide for the electronic supply and dispensing of scheduled substances including through e-pharmacy, telemedicine, medication therapy management and online pharmacy.

(2) The regulations made under subsection (1) shall provide for—

(a) licensure of e-pharmacies;

(b) safety of patients;
(c) verification of the identity and traceability of patients;
(d) verification of the identity and traceability of prescribers; and
(e) integrity, legitimacy and authenticity of prescriptions including avoidance of multiple use of the same prescription.

(3) The electronic supply and dispensing of scheduled substances shall be permitted provided that the supply of such health products and technologies conforms with all requirements for the particular health product or technology in terms of its scheduling status and any other requirements as may be specified in regulations in relation to such supply or dispensing.

(4) In the case of a prescription-only medicine, the required prescription shall have been obtained as a result of at least one physical interaction between an authorised practitioner and the patient within a period of at least six months.

(5) Any person who contravenes this section shall be guilty of an offence, and shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding one year, or to both.

Justification: For proper regulation of electronic sale of medicine which is already a global phenomenon as many online platforms are selling medicines to consumers and to enhance the fines in relation to the sale of scheduled substances using electronic means to ensure that quality is guaranteed.

New Clause

THAT, the Bill be amended by inserting the following new clause immediately after clause 46—

Dietary supplements.

46A. (1) A dietary supplement shall—

(a) not contain scheduled substances; and
(b) have a stated or implied therapeutic purpose.

(2) Where a dietary supplement contains folic acid, the maximum daily dose for the dietary supplement shall be as per the guidelines prescribed by the Board of the Authority.

Justification: To provide for dietary supplements which will enhance the regulation of food supplements by the Authority.

Part Vi

THAT, the Bill be amended in the title of Part VI by deleting the expression "PART VI—MANUFACTURE OF MEDICINAL SUBSTANCES" and substituting therefor the expression "PART IV—MANUFACTURE OF HEALTH PRODUCTS".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 47

THAT, Clause 47 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A manufacturing licence issued under this section shall be valid for a period of one year, renewable annually."

Justification: To give the manufacturing licence validity for one year.

(c) in sub-clause (3) by deleting the words "medicinal substance" and substituting therefor the words "health product;

(d) in sub-clause (4) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) by inserting the following sub-clauses immediately after sub-clause (5)—

"(6) The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product regulated under this Act.

(7) The personnel qualified to conduct lot release of vaccines and batch release of health products shall submit their qualifications to the Authority.

(8) Any person who commits an offence under this section is on conviction, liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding ten years, or to both."

Justification: Substandard, falsified and falsely labelled health products occasion serious public health challenges.

Clause 48

THAT, Clause 48 of the Bill be amended—

(a) by renumbering the provision as sub-clause (1); and

(b) by inserting the following new sub-clauses immediately after sub-clause (1)—

"(2) The Authority shall have power to enter and inspect manufacturing premises to confirm compliance with prescribed good manufacturing practices and issue a certificate of compliance in the prescribed format upon payment of prescribed fees.

(3) The Cabinet Secretary shall make regulations for the better carrying out of the provisions of this section.

(4) Without prejudice to the generality of subsection (3), the Authority shall make regulations on—

(a) revocation and suspension of manufacturing licences;
(b) withdrawal of revocation of manufacturing licences upon request; and
(c) transfer of manufacturing licences."

Justification: To give the Authority power enforce compliance with good manufacturing practices as recommended by WHO which will in turn encourage continuous improvement of internal quality control systems and production processes by manufacturers.

PART VII

THAT, the Bill be amended in the title of Part VII by deleting the expression "PART VII" and substituting therefor the expression "PART VI".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 51

THAT, the Bill be amended by inserting the following new clauses immediately after clause 51—

Information that is required to be displayed on the pack.

51A. A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;
(b) the net weight;
(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;
(d) the name and address of manufacturer of the therapeutic cosmetic;
(e) a warning statement; and
(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

Justification: To enhance transparency on the ingredients used in therapeutic cosmetics in line with the Good Manufacturing Practices

Manufacturing of cosmetics.

51B. (1) The Cabinet Secretary shall make regulations for the effective implementation of this section.

(2) The regulations made under subsection (1) may—

(a) require manufacturers of cosmetics to register with the Authority; and

(b) impose restrictions, requirements or other conditions on manufacturers of cosmetics, if such restrictions, requirements or conditions are necessary to protect public health.

Justification: To enhance transparency on the ingredients used in therapeutic cosmetics in line with the Good Manufacturing Practices

Clause 52

THAT, Clause 52 of the Bill be amended by deleting the words "have a therapeutic effect or value" and substituting therefor the words "treat, diagnose or prevent disease, or affect the structure or functions of the body".

Justification: Using the term "therapeutic cosmetic" already indicates that the cosmetic has therapeutic effect hence there is no need to restate the same.

Clause 54

THAT, Clause 54 of the Bill be amended by—

(a) deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

"(3) Any person who manufactures, sells, supplies, imports or exports a therapeutic cosmetic which contains a prohibited ingredient commits an offence and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both."

Justification: To provide for a penalty for the offence of manufacturing or selling therapeutic cosmetics that contain prohibited ingredients.

(b) inserting the following new sub-clause immediately after sub-clause (3)—

"(4) The Authority shall make regulations exempting from any labelling requirement of this Part, therapeutic cosmetics which are, in accordance with the practice of the trade, to be processed, labelled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Part upon removal from such processing, labelling or repacking establishment."

Justification: To allow for the making of regulations on use of prohibited ingredients in relation to therapeutic cosmetics.

PART VIII

THAT, the Bill be amended in the title of Part VIII by deleting the expression "PART VIII" and substituting therefor the expression "PART VII".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 55

THAT, Clause 55 of the Bill be amended in sub-clause (1) by inserting the words ", in-vitro diagnostics medical devices register" immediately after the words "human medical devices register".

Justification: To make provision for in-vitro diagnostics.

Clause 56

THAT, Clause 56 of the Bill be amended in sub-clause (1) by inserting the words "falsified, falsely-labelled or counterfeited" immediately after the word "substandard" appearing in paragraph (c).

Justification: To incorporate internationally accepted terminology.

Clause 58

THAT, Clause 58 of the Bill be amended—

(a) in sub-clause (2) by inserting the words "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" immediately after the word "Authority";

Justification: This will enable the country to comply with WHO standards on manufacturing.

(b) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act, documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

(4) An importer, distributor or dealer shall establish and implement documented procedures for the maintenance of importation or distribution records and shall maintain an importation or distribution record of each medical device to be submitted to the Authority."

Justification: To allow the Authority to consult and receive advice from the Kenya Nuclear Regulatory Authority that exercises regulatory control over nuclear and radioactive materials and facilities under section 6(c)(i) of the Nuclear Regulatory Act, No. 29 of 2019. To require importers, distributors or dealers to keep records of medical devices submitted to the Authority.

Clause 59

THAT, Clause 59 of the Bill be amended in sub-clause (1) by inserting the words "unregistered establishments for medical devices and" immediately after the word "under".

Justification: To provide for the registration of establishments for medical devices by the Authority.

New Clause

THAT, the Bill be amended by inserting the following new clause immediately after clause 59—

Registration of medical devices establishment.

59A. (1) An application for registration of a medical devices establishment shall be submitted to the Authority in the prescribed format and shall be accompanied by the prescribed fees.

(2) An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority of such system.

(3) Where the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Director-General shall issue a registration certificate for the medical devices establishment in the prescribed format.

(4) A medical devices establishment registration certificate under this section shall be valid for a period of one year, renewable annually upon application in accordance with the prescribed conditions.

(5) The registration certificate for manufacturers shall be valid for five years following a successful reinspection.

(6) The Authority may refuse to issue a medical devices establishment registration certificate where—

(a) an applicant has made a false or misleading statement in the application;

(b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

(c) an applicant has failed to meet the prescribed conditions for medical devices establishment registration.

(7) Where the Authority does not issue a medical devices establishment registration certificate under subsection (6), the Authority shall—

(a) notify the applicant in writing of the reasons for refusing the registration of the establishment; and

(b) give the applicant an opportunity to respond to the Authority and provide relevant documentation or evidence in support of the application.

(8) After the issuance of a medical devices establishment registration certificate, where there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Authority within ten working days of the change.

Justification: To make provision for the registration of establishments for medical devices.

NEW PART

THAT, the Bill be amended by inserting the following new Part immediately after the new clause 59A—

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

59B. (1) The Authority shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system.

(2) The Centre established under subsection (1) shall receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority.

(3) The Authority shall conduct both passive surveillance and active surveillance of health products and technologies.

(4) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements.

(5) All entities responsible for placing a health product or technology in the market shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies.

(6) The entities referred to in subsection (5) shall submit safety information to the Authority in the prescribed manner.

(7) The consumers, general public and health care professionals shall report adverse reactions and adverse events to the Authority in the prescribed manner.

Justification: To anchor the role of the Authority in the regulation of pharmacovigilance in the country.

PART XI

THAT, the Bill be amended in the title of Part XI by deleting the expression "PART XI" and substituting therefor the expression "PART IX".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 60

THAT the Bill be amended by deleting Clause 60 and substituting therefor the following new clause 60—

Establishment of the National Quality Control Laboratory.

60. (1) There is established the National Quality Control Laboratory of the Authority which shall be used as a facility for—

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;
(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;
(d) field testing of regulated products using screening techniques;
(e) providing technical support to local manufacturers and building their capacity in matters pertaining to quality control of regulated products through on site and off site training and laboratory assessments;
(f) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;
(g) conducting research and training and providing high quality analytics and expert knowledge in the areas of medicinal products and active pharmaceutical ingredients; and
(h) developing and administering a data bank on quality assurance on behalf of the Authority.

(2) The National Quality Control Laboratory shall be the quality control laboratory of health products and technologies for the Authority.

(3) The Board of the Authority shall appoint a Director, National Quality Control Laboratory who shall be responsible to the Authority for the day to day management of the National Quality Control Laboratory.

(4) The Director National Quality Control Laboratory shall hold office on such terms and conditions of service as may be specified in the instrument of appointment by the Board of the Authority.

(5) The Director National Quality Control Laboratory shall be a registered pharmacist and shall possess a Master's degree in a science related field from a recognized university.

(6) The Director of the National Quality Control Laboratory shall—
(a) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;

(b) ensure timely quality control testing of all samples in conformity with national and international standards;
(c) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;
(d) collaborate with other laboratories, regulatory and law enforcement agencies, manufacturers of pharmaceutical and other health products to ensure quality in health products and technologies;
(e) handle appeals on test results;
(f) where the laboratory lacks capacity, subcontract laboratory testing services;
(g) advice the Authority on matters of testing and quality control over health products and technologies; and
(h) perform any other duties assigned by the Authority from time to time.

(7) The funds to be used for the management of the Laboratory shall consist of all moneys received or recovered under this Part and a portion of the moneys appropriated by Parliament to the Authority.

(8) Subject to subsection (7), monies generated by the Laboratory in the course of the performance of its functions under this section shall be solely expended on the Laboratory.

Justification: The NQCL, headed by a Director appointed by the Authority, to become a regulatory laboratory of the Authority as recommended by the WHO so that the country can achieve Maturity Level 3. To ringfence monies for the Laboratory such that monies generated by the Laboratory shall be solely expended on the Laboratory and the Authority ought to give a portion of the monies appropriated to it by Parliament to the Laboratory.

Clause 61

THAT, Clause 61 of the Bill be amended in sub-clause (1) by deleting the words "Director-General" and substituting therefor the words "Director of the National Quality Control Laboratory".

Justification: For compliance with WHO guidelines which requires that a certificate of analysis should be issued by a person capable of ensuring the authenticity of the test samples.

PART XII

THAT, the Bill be amended in the title of Part XII by deleting the expression "PART XII" and substituting therefor the expression "PART X".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 63

THAT, Clause 63 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicine, drug, appliance or article" wherever they appear and substituting therefor the words "health product or technology"; and

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (2) by inserting the words "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (d).

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on diseases listed in the Sixth Schedule.

Clause 64

THAT, Clause 64 of the Bill be amended by deleting the words "a medicine, drug, appliance or article" wherever it appears and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 65

THAT, Clause 65 of the Bill be amended—

(a) in paragraph (a) by—

(i) deleting the words "or similar article"; and

(ii) deleting the word "extravagant,".

Justification: To ensure objectivity.

(b) in paragraph (b) by deleting the word "an article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 66

THAT, Clause 66 of the Bill be amended—

(a) in sub-clause (1)—

(i) by deleting the words "drug, appliance or article" wherever they appear in paragraph (a) and substituting therefor the words "health product or technology"; and

(ii) by deleting the words "drug, appliance or article" appearing in paragraph (b) and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (3) by—

(i) renumbering the provision as clause (2); and

(ii) by inserting the words ", enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (ii)

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on abortion and false or misleading advertisements.

Clause 67

THAT Clause 67 of the Bill be amended—

(a) by deleting the word "articles" appearing in the marginal note and substituting therefor the words "health products and technologies";

(b) by deleting sub-clause (1) and substituting the following new sub-clause (1)–

"(1) Subject to this Act, a person shall not sell by retail a health product or technology consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the health product or technology or on a label affixed thereto, or if the health product or technology is sold or supplied in more than one container, on the inner container or on a label affixed thereto—

(a) the appropriate designation of the substance so recommended or of each of the active constituents, or of each of the ingredients from which it has been compounded; and

(b) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients; provided that this subsection shall not apply to a health product or technology made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person."

(c) in sub-clause (2) by deleting the word "article" wherever it appears in the definition of "appropriate quantitative particulars" and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(d) in sub-clause (3) by—

(i) deleting the word "an article" appearing in sub-clause (3) and substituting therefor the words "a health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(ii) deleting the words "two hundred thousand" appearing in paragraph (a) and substituting therefor the words "one million";
(iii) deleting the words "three hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million"

Justification: To make the fines payable commensurate to the offences relating to labeling of health products and technologies containing medicine.

Clause 68

THAT, the Bill be amended by deleting Clause 68.

Justification: It is preferable to make provision for valid exemptions through regulations as opposed to providing defences for offences relating to labeling of medicines.

Clause 69

THAT, Clause 69 of the Bill be amended by—
(a) deleting the word "article" and substituting therefor the words "health product or technology"; and
(b) deleting the word "articles" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIII

THAT, the Bill be amended in the title to Part XIII by deleting the expression "PART XIII" and substituting therefor the expression "PART XI".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 71

THAT, Clause 71 of the Bill be amended—
(a) in the marginal note by deleting the words "medicines or medical devices" and substituting therefor the words "health products and technologies"; and
(b) in sub-clause (1) by deleting the words "or homoeopathic medicine, preparation or medical device" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 72

THAT, Clause 72 of the Bill be amended—
(a) in the marginal note by deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by inserting the words "including a health product and technology for emergency use" immediately after the word "technology"; and

Justification: To make provision for supply of health products and technologies during emergency situations.

(c) in sub-clause (3) by deleting the words "medicine or medical device product" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 73

THAT, Clause 73 of the Bill be amended—

(a) in the marginal note by deleting the word "goods" and substituting therefor the words "health products and technologies".
(b) in sub-clause (1) by deleting the words "drug, article" wherever they appear and substituting therefor the words "health product or technology";
(c) in sub-clause (2) by deleting the words "drug or article" wherever they appear and substituting therefor the words "health product or technology";
(d) in sub-clause (3) by deleting the words "drug or article" and substituting therefor the words "health product or technology"; and
(e) in sub-clause (4) by deleting the words "drug or article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 78

THAT, Clause 78 of the Bill be amended in sub-clause (1) by inserting the words "or enrolled pharmaceutical technologist" immediately after the words "registered pharmacist" appearing in paragraph (b).

Justification: To provide for the application of penal sanctions to enrolled pharmaceutical technologists as regards body corporates.

Clause 79

THAT, the Bill be amended by deleting Clause 79 and substituting the following new clause 79—

Inspection and verification of health products and technologies at the ports of entry.

79. (1) A person who imports a health product or technology shall notify the inspectors of the Authority at the ports of entry to conduct pre-clearance inspection and verification.

(2) Any person who imports a health product or technology and causes it to be released to the market without authorization under subsection (1) shall be guilty of an offence.

(3) Any person who commits an offence under this section is upon conviction, liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

Justification: Clause 79 be deleted as the function of inspection of animals intended for slaughter is outside the regulatory purview of the Authority.

The new clause on inspection and verification of health products and technologies at the ports of entry enables the Authority to enforce compliance with the prescribed standards of quality, safety and efficacy of health products and technologies before release at the ports of entry so as to prevent concealment, misdeclaration, diversion and cross border smuggling of health products and technologies.

Clause 80

THAT, Clause 80 of the Bill be amended—

(a) by deleting the words "article" and "articles" wherever they appear and substituting therefor the words "health product or technology" and "health products and technologies" respectively in sub-clause (6), (7), (8), (9), (10), (11) and (12).

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—

(i) deleting the word "article" wherever it appears and substituting therefor the words "health product or technology"; and

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(ii) inserting the words "or any other vessel" immediately after the word "vehicle" appearing in paragraph (b).

Justification: To expand the scope to include all other means of conveying health products and technologies.

Clause 81

THAT, the Bill be amended by deleting Clause 81.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

Clause 82

THAT, the Bill be amended by deleting Clause 82.

Justification: Regulation is a function of National Government under the Fourth Schedule to the Constitution.

Clause 83

THAT, the Bill be amended by deleting Clause 83.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

Clause 85

THAT, Clause 85 of the Bill be amended by deleting the word "article" wherever it appears and and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

Clause 86

THAT, Clause 86 of the Bill be amended in sub-clause (1) by deleting paragraph (b) and substituting therefor the following new paragraph (b)—

"(b) in the case of a subsequent offence, to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both".

Justification: To make enhance the general penalty for offences committed in relation to this Bill and to make the fines payable commensurate to the imprisonment terms.

Clause 87

THAT, Clause 87 of the Bill be amended in sub-clause (1) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology" in paragraph (c)

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIV

THAT, the Bill be amended in the title of Part XIV by deleting the expression "PART XIV" and substituting therefor the expression "PART XII".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 88

THAT, Clause 88 of the Bill be amended by deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) such monies as may be appropriated by the National Assembly for the purposes of the Authority".

Justification: For proper drafting and consistency in the wording used in the Statute Book.

Clause 91

THAT, Clause 91 of the Bill be amended by—deleting the words "Kenya National Audit Office" wherever they appear and substituting therefor the words "Auditor-General".

Justification: For proper reference to the Auditor-General as designated under Article 229 of the Constitution and which is the successor of the Kenya National Audit Office.

PART XV

THAT, the Bill be amended in the title of Part XV by deleting the expression "PART XV" and substituting therefor the expression "PART XIII".

Justification: To correct a minor error in numbering of the parts of the Bill.

Clause 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—

(i) deleting the word "drugs," in paragraph (a)(i);

(ii) deleting the words "any drug" in paragraph (a)(ii);

(iii) deleting the word "product" and substituting therefor the word "products" in paragraph (d);

(iv) deleting the word "drugs" wherever it appears and substituting therefor the words "health products or technologies" in paragraph (h);

(v) deleting the word "article" and substituting therefor the words "health product or technology" in paragraph (k);

(vi) deleting the word "articles" and substituting therefor the words "health products and technologies" in paragraph (m);

(vii) deleting the words "drugs, medical devices" and substituting therefor the words "health products and technologies" in paragraph (o);

(viii) deleting the word "medicines" and substituting therefor the words "health products and technologies" in paragraph (v);

(ix) deleting paragraph (x) and substituting therefor the following new paragraph (x)—

"(x) governing administration of clinical trials of health products and technologies;"

(x) deleting the words "medicine, medical device" and substituting therefor the words "health product or technology" in paragraph (aa);

(xi) deleting the words "medicines or medical devices" and substituting therefor the words "health products or technologies" in paragraph (bb);

(xii) deleting paragraph (dd) and substituting therefor the following new paragraph (dd)—

"(dd) the compounding of health products and technologies and the dispensing of health products and technologies"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(xiii) inserting the words ", an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in paragraph (bb);

Justification: For inclusion of pharmaceutical technologists who are currently involved in the dispensing of medicines and medical devices pursuant to the Pharmacy and Poisons Act, Cap. 244 and their scope of training.

(xiv) deleting paragraph (ii);

Justification: The general provision on the making of regulations is set out in sub-clause (1).

(xv) inserting the following new paragraphs immediately after paragraph (ii)—

"(jj) on pharmacovigilance and post market surveillance;

(kk) official regulatory lot release of vaccines and other biological products imported and manufactured in Kenya;

(ll)pricing of health products and technologies;

(mm) good practices in the regulation of medical products;

(nn) inspections, licensure and certification of the manufacture of medical products by health facilities;

(oo) inspections, licensure and certification of manufacture of medical products and other regulated products by facilities not directly regulated by the Authority including steel industries, sugar industries;

(pp) inspection and recognition of pharmaceutical quality control laboratories;

(qq) to regulate licit use of narcotic and psychotropic substances; and

(rr) to regulate parallel importation of medicines;"

(b) by renumbering sub-clause (2) as sub-clause (3).

Justification: To provide for the making of regulations on licit use of narcotic and psychotropic substances, parallel importation of medicines, safety monitoring, pharmacovigilance and post market surveillance.

Clause 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the word "Board" and substituting therefor the word "Boards";

(ii) deleting paragraph (d) and substituting therefor the following new paragraph (d)—

"(d) all members and staff of the former Boards shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Boards."

(b) by deleting the sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) In this section, "the former Boards" means the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory established under the Pharmacy and Poisons Act, Cap. 244."

Justification: To provide for the transition of both the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory.

(c) in sub-clause (3) by deleting the word "twelve" appearing in the opening sentence and substituting therefor the words "twenty-four".

Justification: To provide sufficient time which will facilitate the conduct of extensive stakeholder participation on the regulation of pharmacy practice regulation.

Clause 97

THAT, Clause 97 of the Bill be amended by inserting the words "with reference to section 96 (3)" immediately after the words "that Schedule" in sub-clause (1).

Justification: To prevent a lacuna in respect of the regulation of the pharmaceutical practice.

Second Schedule

THAT, the Bill be amended by deleting the Second Schedule.

Justification: The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

Third Schedule

THAT, the Bill be amended by deleting the Third Schedule.

Justification: The matters of the tenure of office, allowances, protection from liability and disclosure of interest by Board members are already provided for in the main Bill. The issue of approval of the Board members by the Parliament has been proposed for deletion as the Authority's Board members are not State Officers.

Fourth Schedule

THAT, the Fourth Schedule of the Bill be amended by deleting paragraph (1), (2), (3), (4) and (5) and substituting therefor the following new paragraphs—

1. Biologics Committee.
2. Pharmacovigilance Committee.
3. Complementary, Alternative or Herbal Medicines Committee.
4. Radiopharmaceuticals Committee.
5. Cosmetics and Borderline Products Committee.
6. Clinical Trial Scientific Technical Advisory Committee.
7. Health Technology Assessment Committee.
8. Nutraceuticals and Dietary Supplements Committee.
9. Digital Health and Technologies Committee.
10. Medical Devices and Health Technologies Committee.
11. Veterinary Medicines Committee.

Justification: The scientific advisory committees amended to take into account all aspects of health products and technologies and to delete the Scientific Advisory Committees on food which is outside the scope of the Bill as amended.

Seventh Schedule

THAT, the Seventh Schedule of the Bill be amended by—

(a) deleting the word "Board" in the paragraph on Cap. 244

(b) deleting the phrase "(s. 116) and substituting the phrase ("s.97").

Justification: For proper cross referencing of the Pharmacy and Poisons Act, Cap. 244 and clause 97 on repeals.

(c) deleting the paragraph on Cap. 254.

Justification: Food is outside the purview of the Bill.

3.2 Submissions by Hon. Anthony Oluoch, MP

The Hon. Anthony Oluoch, MP appeared before the Committee on on 31st October, 2021, and made the following submission: -

The Hon. Anthony Oluoch, MP presented the following amendments to the Committee; -

Long Title

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

"AN ACT of Parliament to establish the Kenya Health Products and Technologies Authority to ensure safety, quality and efficacy or performance of drugs, poisons, therapeutic and biological products, therapeutic cosmetics, herbal medicines and products, chemical substances, medical devices, veterinary products and other health technologies; to provide for the harmonization and administration of the laws relating to the regulation of, drugs, poisons, therapeutic products, therapeutic cosmetics, chemical products, veterinary products and medical devices and the control and safe handling of poisons; to safeguard the security of the supply chains for, therapeutic products, cosmetics and veterinary products; to provide for measures to optimize the use of therapeutic products in health care in Kenya and for connected purposes."

Clause 2

THAT, the Clause 2 of the Bill be amended—

(a) in the definition of the term "advertisement" by deleting the words "herbal medicines and products";

(b) in the definition of the term "article" by—
  (i) deleting the words "herbal medicine" appearing in paragraph (a); and
  (ii) deleting the words "herbal medicine" appearing in paragraph (b);

(c) in the definition of "authorized seller of scheduled substances" by inserting the words "and enrolled as a pharmaceutical technologist or registered as a pharmacist" immediately after the word "Act";

(d) in the definition of the term "health products and technologies" by deleting the words "herbal medicines and products";

(e) by deleting the definition of the term "herbal medicine or product" and substituting therefor the following new definition—

> "herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations and excludes herbs, herbal materials, herbal preparations, finished herbal products sold or dispensed on a small scale by traditional health practitioners;"

(f) in the definition of the term "medicine" by inserting the words "other than herbal medicines or products" immediately after the words "or mixture of substances".

(g) in the definition of "pharmacy" by inserting the words "licensed and" immediately after the words "carried out by" appearing in paragraph (a);

(h) deleting the definition of "chemical substance" and substituting therefor the following new definition—

"chemical substance" means any substance or mixture of substances prepared, sold or represented for use as a germicide, antiseptic, disinfectant, pesticide, insecticide, rodenticide, vermicide, detergent or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;

(i) deleting the definition of "therapeutic cosmetic" and substituting therefor the following new definition—

"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, to target and repair skin issues, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;".

Clause 3

THAT, Clause 3 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraph (c); and

(b) by inserting the following new sub-clause immediately after sub-clause (2)—

(3) This Act shall not apply to the regulation of herbal medicines or products.

Clause 6

THAT, Clause 6 of the Bill be amended in sub-clause (4) by deleting the word "ten" in appearing in paragraph (c) and substituting therefor the word "fifteen".

Clause 8

THAT, Clause 8 of the Bill be amended in sub-clause (7) by inserting the words ", fair representation of persons with disabilities" immediately after the words "regional balance."

Clause 12

THAT, Clause 12 of the Bill be amended in paragraph (o) by deleting the words "and herbal drugs;"

Clause 23

THAT, Clause 23 of the Bill be amended in sub-clause (2) by —

(a) deleting the words "one million" appearing in paragraph (a) and substituting therefor the words "two million"; and

(b) deleting the words "two million" appearing in paragraph (b) and substituting therefor the words "five million".

Clause 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (9).

Clause 35

THAT, Clause 35 of the Bill be amended in sub- clause (2) by inserting the word "registered" immediately after the words "may prohibit a".

Clause 36

THAT, the Bill be amended by deleting Clause 36.

Clause 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the words "or pharmaceutical technologists" immediately after the words "a Registered Pharmacist"

Clause 41

THAT, Clause 41 of the Bill be amended in sub-clause (1) by inserting the words "or pharmaceutical technologists" immediately after the words "a pharmacist" appearing in paragraph (b)".

Clause 42

THAT, Clause 42 of the Bill be amended by—

(a) deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) An authorized seller shall enter a record of such particulars of the scheduled substance before delivery of the scheduled substance under this Act."

(b) inserting the following new sub-clause (2) immediately after the new sub-clause (1)—

"(2) A record under subsection (1) shall be in the format prescribed by the Authority and shall indicate —

(a) the date of the sale;
(b) the name and address of the purchaser;
(c) the quantity of the scheduled substances sold; and
(d) the purpose for which it is stated by the purchaser to be required."

(c) renumbering sub-clause (2) as sub-clause (3); and

(d) renumbering sub-clause (3) as sub-clause (4).

Clause 51

THAT, the Bill be amended in clause 51 by inserting the words "and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both" immediately after the word "offence".

Clause 54

THAT, the Bill be amended by deleting clause 54.

Clause 63-

THAT, Clause 63 of the Bill be amended by deleting sub-clause (3).

3.3 Submissions by the Hon. Irene Mayaka, MP

The Hon. Irene Mayaka, MP, appeared before the Committee on 31st October, 2023 and made her submission of the proposed amendments as follows: -

Under Clause 37

That clause 37 of the Bill be amended –

(a) By inserting the following new sub-clause immediately after sub-clause (2) – "(3) The Cabinet Secretary shall publish the list prepared under subsection (1) in the Gazette.

(4) the list published under subsection (3) shall include narcotic substances, prescription – only medications, over the Counter medicines, hazardous and prohibited substances".

(b) By renumbering sub-clause (5); and

(c) By renumbering sub-clause (4) as sub-clause (6);

3.4 Submission by the Hon. Dr. Otiende Omollo, MP

The Hon. Dr. Otiende Omollo, MP presented his proposed amendments through visual meeting on 1st November, 2023 and made the following submission: -

Under Clause 2

That, the Clause 2 of the Bill be amended by deleting the definition of "pharmacy" and substituting therefor the following new definition-

"pharmacy has the meaning assigned to it under the Pharmacy and poisons Act.

Clause 8

That, Clause 8 be amended in sub-clause (2) by deleting paragraph (j) and substituting therefor the following new paragraph-

"one person, not being a governor, who is a registered pharmacist of good standing, nominated by the Council of Governors"

Clause 39

That, clause 39 of the Bill be amended in the marginal note by deleting the words "Wholesale Dealers Licence" and substituting therefor the word "Local Technical Representative Licence"

The Honorable member also said clause 25 and 35 needs to be relooked.

3.5 Submission by the Hon. Millie Odhiambo, MP

The Hon. Millie Odhiambo, MP presented his proposed amendments through visual meeting on 1st November, 2023 and made the following submission: -

The Hon. Millie Odhiambo, MP was invited to the winnowing process of the Kenya Drug Authority Bill, 2022 through a letter ref. NA/DDC/DC-H/2023/ (099) dated 27th October, 2023 for a meeting on 31st October and 1st November, 2023 and attended the meeting through Visual on 1st November and presented the following proposed amendments to the Committee which she sent through email earlier as follows for consideration since she had travelled out of the Country;

PART I- PRELIMINARY: Add the definition of "alternative medicine" **"alternative medicine"** means alternative medicine as defined under the Health Act.

Definition of "drug"

(a) Add the words "herbal medicine" after the words "any medicine" and before the words "medicinal preparation, medicinal substance, therapeutic substance prepared, sold or represented for use in-"
(b) Add the word "herbal medicine"" after the words "any medicine" and before the words "medicinal preparation"

(b) (ii) delete the word "if" appearing after the words "restoring, correcting or modifying functioning" and after the words "organs in humans or animals" and replace with the word "of".

Definition of "falsified medicines" Put a semi colon (;) after the words "... of active or other ingredients" and before the words "or falsely labelled medicine"

Definition of health products and technologies Delete and replace with **"health products"** means chemical substances, therapeutic cosmetics, herbal medicines, medicines, scheduled substances and related products and substances.

"health technologies" means medical devices including radiation-emitting devices and related products.

Definition of herbal medicine or products Delete and replace with **"herbal medicine"** means *the use of plants to treat disease and enhance general health and wellbeing.*

"herbal product" means a plant derived material or preparations with claimed therapeutic or other human or veterinary health benefits, which contain either raw or processed ingredients from one or more plants, or material of inorganic or animal origin;

Definition of "insanitary condition" Add the words "herbal medicine" after the words "as might contaminate a drug or a therapeutic cosmetic" and before the words "with dirt or filth"

Definition of "Label" Add the words "herbal medicine" after the words "accompanying any drug" and before the words "therapeutic cosmetic"

NB: There appears to be something missing in this definition and I cannot tell what it is. The original drafter can assist.

Definition of "manufacture"

Delete the word "product or" appearing after the words "means any process carried out in the course of making" and add the words "or product" after the words "medicinal substance" and add the word "extracting" after the words "and includes" and before the words "packaging, blending, mixing"

Definition of "medicinal substance" Add the words "herbal medicine" after the words "medicine" and before the word "product"

Definition of "registered midwife" Delete the words "by law to practice the profession of midwife in Kenya" and replace with the words "to practice as such under the Nurses and Midwives' Act"

Definition of "registered pharmacist"

Delete the words "by the body for the time being responsible for registration of pharmacists" and replace with the words "under the Pharmacy and Poisons Act":

Definition of "substandard medicine"

Add the words "under this Act or any other written law" after the words "means medicines which do not meet defined standards and specifications" and before the words "and includes products that have been contaminated"

Definition of "therapeutic cosmetic"

Delete the words "or altering complexion" appearing after the words "sold or represented for use in cleaning, improving" and before the words "skin, hair, eyes or teeth"

Clause 6 (4) (a): Delete the word "engineering" appearing after the word "in either pharmacy, medicine", and before the words "or equivalent fields";

Clause 7 (a) and (b) - Delete sub clause (a) and (b) and then replace with the following:

(a) Is a State officer

Renumber the subsections consequently.

(e) delete subsection "e" and replace with the words "is a public officer"

(f) delete the words "Act", regulation under this" appearing at the end of the sentence and replace with "regulations under this Act"

Clause 8 (3)- Delete (e) appearing between "h" and "i"

(a) **Clause 8 (6)** Delete sub clauses (a) and (b) and replace with (a) Is a State officer

Clause 8 (7)

Add the word "youth representation" after the words "regard shall be had of the need for" and before the word "regional" and add the word "and ethnic" after the word "regional" and before the words "balance and the realization"

Clause 10 (1) (f) Delete the words "permission of the" and replace with "notifying the"

Clause 12 (o)- Add the words "chemicals, medicine" after the words "promote rational use of

Clause 12 (A) - Delete the word "ensure" and replace with the word "set"

Clause 12 (b) - Delete the word "that" appearing after the word "ensure" and before the words 'compliance with existing legislation" and replace with the words "that there is" and further delete the words "is being promoted and controlled"

Clause 12 (g) - Delete the word "being" after the word "products and technologies are" and before the words "assessed accordingly

Clause 13 (f)- Delete the words "co-opt in such committees" and replace with the words "hire as consultants"

Clause 17 (2) - Add the words "youth inclusion" after the words "The principles of" and after the words "ethnic, regional and gender"

Clause 21 (1) - Delete the words "Cabinet Secretary" appearing after the word "The" and before the word "may establish scientific" and further delete the word "Cabinet Secretary" appearing before the word "under this Act" and replace with the word "Authority".

Clause 21 (3) - Delete the word "Cabinet Secretary" and replace with "Board"

Clause 21 (4) - Delete the word "Cabinet Secretary" and replace with the "Board"

Clause 21 (9) - Delete the word "Cabinet Secretary" appearing before the words "with respect to its activities" and replace with the word "Board"; further delete the words "and the Cabinet Secretary shall lay a copy of each report before Parliament.

New Sub-Clause 21 (10)- The Board shall prepare and submit annually a report of its activities including that of any subcommittees to the Cabinet Secretary and the Cabinet Secretary shall submit the said report to parliament.

Clause 22 (2) (b)- Delete the words "five years" and replace with "three years".

Clause 22 (3) - Delete entire clause

Clause 24 (3) - Add sub clause (c) as follows:_(c) is herbal medicine

Clause 24 (4) (A) - Delete the words "one hundred" and replace with "five hundred"

Clause 24 (b) - Delete the words "two hundred thousand" and replace with "one million shillings" and further delete the words "five years" and replace with "three years"

Clause 27 - Add a new Clause 27 (1) as follows:

27 (1) "The Authority may issue product licences as provided under this Act

Renumber current 27 to 27 (2)

Clause 28 (1) - Add the words "and herbal medicines" before the word "register" and after the word "There is established a medicines"

Clause 28 (2) - Add the words "herbal medicine" after the words "content of the medicines" and before the word "register"

Clause 29 (1) - Add a new Clause 29 (1) as follows then renumber the subsequent subsections

29 (1) Any pharmacist may apply for the registration of a medicine, herbal medicine or medical device as provided for under this Act.

Clause 29 (1) - Add the word "herbal medicine" in sub clause 29 (1) in the Bill after the words "Every application for the registration of a medicine" and before the words "or medical device"

Clause 29 (3) (a) - Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

Clause 29 (3) (b) - Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

Clause 29 (3) (c) - Add the words "or herbal medicine" after the word "that medicine" and before the word "is in the public domain"

Clause 29 (4) - Add the words "herbal medicine" after the words "of a medicine" and before the words "it shall cause the applicant"

Clause 29 (4) (b) - Add the words "comment" after the words "with the applicant's" and after the words "on the Authority's reasons for not being so satisfied"

Clause 29 (6) - Add the words "herbal medicine" after the word "medicine" and before the words "the registrar shall register"; and further after the word "medicine" and before the words "as are required by this Act"; and further after the words "in the prescribed form in respect of that medicine"

Clause 29 (7) - Add the words "and herbal medicine" after the words "Every medicine" and before the words "shall be registered"

Clause 29 (8)- Add the words "and herbal medicine" after the words "allocate to every medicine" and before the words "registered under this Act"; and further after the words "name of such medicine" and before the words "and which shall be stated in the certificate"; and further after the words "issued in respect of that such medicine"

Clause 29 (9) - Add the words "and herbal medicine" after the words "registration of medicine" and before the words "already registered"; and further add the words "under this Act or any other written law" after the words "already registered" and before the words "shall be valid for a period of"

Clause 29 (12) Add the words "and herbal medicine" after the words "in respect of a medicine" and before the words "referred to in subsection (4)"

New Sub clause 29 (12) (A), (B) And (C) Provide for a new sub clause 29 (12) and renumber the current 29 (12) to 29 (13) and others consequently. Provide for the sub clause 29 (12) as follows:

(a) "The Authority may reject any application if the applicant fails to meet the standards as required by this Act or any other written law"
(b) A person dissatisfied with the decision of the Registrar may appeal to the Board within the period specified under subsection 14
(c) Where a person is dissatisfied with the decision of the Board, the applicant may appeal to the High Court within thirty days of the decision being communicated to him or her.

Clause 13 - Add the words "of appeal" after the words "expiry of the appropriate period"; and further delete the words "referred to in sixty days"

Clause 30 (1)

Add the words "or herbal medicine" after the words "on application by the holder" and before the words "a certificate of registration"; and further after the words "register with respect to that medicine"

Clause 30 (3) (B)

Add the words "or herbal medicine" after the words "in respect of the medicine" and before the words "after receiving the existing certificate of registration"; and further after the words "register with respect to that medicine"; and further after the words "in respect of that medicine" and before the words "for cancellation"

A New Sub clause 30 (3) - Provide a new sub clause 30 (3) and renumber the current (3) as (4) and provide for the new (3) as follows: (3) The applicant shall provide reasons for the proposed amendments

Clause 31 (1) Add the words "or herbal medicine" after the words "registration of a medicine"

Clause 32 (1) Add the words "herbal medicine" after the words "registration of a medicine" and before the words "" or medical device"

Clause 32 (1) (a) Add the words "herbal medicine" after the words "to which particular medicine" and before the words "" or medical device"

Clause 32 (1) (b) Add the words "herbal medicine" after the words "particular medicine" and before the words "" or medical device"

Clause 32 (1) (c) Add the words "herbal medicine" after the words "particular medicine" and before the words "" or medical device"

Clause 32 (2) Add the words "herbal medicine" after the words "any medicine" and before the words "" or medical device"; and further after the words "in respect of that medicine" and before the words "or medical device"

Clause 32 (4) Add the words "herbal medicine" after the words "registration of that medicine" and before the words "" or medical device"

Clause 32 (4) (b) Add the words "herbal medicine" after the words "that the registration of the medicine" and before the words "or medical device"

Clause 32 (5) Add the words "herbal medicine" after the words "in respect of a medicine" and before the words "" or medical device"; and further after the words "of the registration of that medicine" and before the words "or medical device".

Clause 33 (1) And (2)

(1) Add the words "herbal medicine" after the words "registration of a medicine" and before the words "" or medical device"
(2) Add the words "herbal medicine" after the words "registration of a medicine"

New Sub clause 33 (3) Provide for a new sub clause 3 and renumber current sub clause (3) to (4). Provide for the new sub clause (3) as follows:

(3) In the case of cancellation of registration of a herbal medicine the Registrar shall in such case specify-
(a) The name under which the herbal medicine is registered
(b) The active components of the herbal medicine
(c) The name of the applicant
(d) The name of the person who has propriety rights over the herbal medicine
(e) The registration number allocated to the herbal medicine;
(f) The conditions if any, subject to which that medicine is registered

Clause 35 (1) Delete the word "shall" appearing after the words "A pharmacist" and before the words "dispense and interchangeable" and replace with the word "may"

New Clause 35 (4) (d) Add a new sub-clause (4) (d) as follows:

34 (4) (d) unless the purchaser or patient is first informed of the same and agrees to the change.

Clause 36 (1) Delete the words "on a commercial scale"

Clause 38 (2) Delete "one hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment"

Clause 40 (4) Delete the words "whose decision thereon shall be final" appearing at the end of the sentence.

Clause 40 (7) Delete the words "two hundred thousand" appearing after the words "to a fine not exceeding" and replace with "one million"; and delete the words "two years" appearing after the words "imprisonment for a term not exceeding" and replace with "three years".

Clause 41(1) (d) Add the words "enrolled pharmaceutical technologist and registered pharmacist" after the word "practitioner"

Clause 42 (2) (A)

Delete the words "provided that where a person represents that he urgently requires a Schedule Substances for the purpose of his trade, business or profession and satisfies the seller that by reason of some emergency he is unable before delivery to furnish the order in writing, the seller may forthwith deliver the Scheduled Substances to the purchaser who will within twenty-four hours of the sale furnish the seller with the written order"

Clause 42 (3) Delete the words "one hundred thousand" appearing after the words "to a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

Clause 43 (3) Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 44 (3) Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 45 Delete the words "five hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 46 (1) Delete the word "This" appearing at the beginning of the sentence and replace with the words "The electronic supply of medicine"

Clause 59 (3) Add the word "who" between the words "A person" and the words "sells or supplies"

Clause 60 (1) (c) Add the words "medicinal herbs" after the words "manufactured and imported medicine" and after the words "or medicinal substances"

Clause 63 (1) Add the words "medical herbs" after the words "referring to a medicine" and before the words "drug, appliance or article"; and further before the words "to imply that the medicine" and before the words "drug, appliance or article".

Clause 67 (3) (a) Delete the words "two hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to an imprisonment" and replace with the words "one million".

Clause 67 (3) (b) Delete the words "three hundred thousand" appearing after the words "a fine of at least" and before the words "shillings or to an imprisonment" and replace with the words "two million".

Clause 68 (1) Add the words "or herbal medicine" after the words "recommended a medicine" and before the words "to prove".

Clause 71 Add the words "herbal medicine" after the words "homoeopathic medicine preparation" and before the words "or medical device"

Clause 72 (3) Add the words "herbal medicine" after the words "quantity of a particular medicine" and after the words "or medical device"

Clause 79 Delete Clause 79

Clause 86 Delete the words "seven hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

Clause 88 (v) Add the words "herbal medicine" at the end of the sentence.

Clause 88 (aa) Add the words "herbal medicine" after the words "a specified medicine" and before the words "medical device"

Clause 88 (bb) Add the words "herbal medicine" after the words "dispense medicine" and before the words "medical device"

Clause 88 (dd) Add the words "herbal medicine" after the words "compounding of medicine" and before the words "medical device"

Fourth Schedule Section (1) (1) replace Cabinet Secretary with "the Board"

Section (4) (2) (1) Add the words "herbal medicine" after the words "human medicinal products" and before the words "giving advice"

TITLE - Change the Title to the **KENYA DRUG AND HEALTH TECHNOLOGIES BILL.**

3.6 Submission by the Hon. Dr. James Nyikal, MP

The Hon. Dr. James Nyikal, MP appeared before the Committee and presented his proposed amendments in a meeting held on 2nd November, 2023 as follows: -

Clause 2

THAT, Clause 2 of the Bill be amended by inserting the following new definitions in the proper alphabetic sequence—

No. 21 of 2017.

"Director-General for Health" has the meaning assigned to it under the Health Act;

"wholesaler dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

Justification: To distinguish the Director-General for Health with the Director-General of the Authority and for consistency with the amendment proposed below to clause 81 of the Bill. To define a wholesaler dealer as the term is used in the Bill under clause 39 of the Bill

Clause 12

THAT, Clause 12 of the Bill be amended by deleting paragraph (t).

Justification: The provision relates to an administrative function as regards human resource management and development and need not be in the Bill.

Clause 21

THAT, Clause 21 of the Bill be amended—

(a) by deleting sub-clause (4); and

(b) in sub-clause (9) by deleting the words "Cabinet Secretary, with respect to its activities and the Cabinet Secretary shall lay a copy of each report before Parliament" and substituting therefor the following words "Board of the Authority which shall submit a copy of the report to the Cabinet Secretary who shall transmit the report to Parliament".

Justification: Sub-clause (4) provides for the co-option of members into the scientific advisory committees. This is unnecessary as the appointing authority needs to appoint the relevant skills to the Committee in the first instance.

Amendment of sub-clause (9) to require that the scientific advisory committees shall submit its report to the Board of the Authority which shall submit the same to the Cabinet Secretary who

must transmit it to Parliament. The Committee report had not provided for the transmittal of the reports of the scientific advisory committees to Parliament.

Clause 22

THAT, Clause 22 of the Bill be amended in sub-clause (3) by deleting the words "sub-section (1)" and substituting therefor the words "The provisions of subsection(1)(a)".

Justification: Sub-clause (3) should not only apply where a medicine is not registered by the Authority and not in instances where a medicines is adulterated, substandard or fails to comply with the specifications in law.

Clause 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (4) and substituting therefor the following new sub-clause (4)—

"(4) Where the Authority finds that an application for registration of a medicine or medical device does not satisfy the requirements provided in subsection (3), it shall notify the applicant in writing of the reasons why that medicine or medical device should not be registered and invite the applicant to make comments on its finding within a period of one month from the date of the notification."

Justification: For proper drafting of the sub-clause (4) as the provision is currently not clear.

Clause 31

THAT, the Bill be amended by deleting clause 31.

Justification: To remove the aspect of transfer of certificate of registration of health products and technologies.

Clause 35

THAT, Clause 35 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "upon consultation and concurrence with the person who prescribed the medicine," immediately after the word "shall";
(b) by deleting sub-clause (2);
(c) by renumbering sub-clause (3) as sub-clause (2); and
(d) by deleting sub-clause (4).

Justification: To require that a prescriber of a medicine is consulted before medicine is substitution with a generic medicine. With the amendment to sub-clause (1), sub-clause (2) and (4) are unnecessary as the factors will be discussed by the Prescriber and the Pharmacist at the point of consultation.

Clause 38

THAT, Clause 38 of the Bill be amended by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 1,000,000.

Clause 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances".

Justification: To insert a missing word which will make the sub-clause much clearer.

Clause 42

THAT, Clause 42 of the Bill be amended in sub-clause (3) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three years" and substituting therefor the words "five hundred thousand shillings or to imprisonment for a term not exceeding one year".

Justification: To enhance the fine for the offence of failure to record the sale or suplly of scheduled substances in a Schedules Substances Book as is required in clause 42 from Kshs. 100,000 to Kshs. 500,000. To reduce the jail term from three years to one year as 3 years is too punitive.

Clause 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "five hundred thousand".

Justification: To enhance the penalty for the offence of failure to label a container of scheduled substances in the manner set out in clause 44 from Kshs. 200,000 to Kshs. 500,000

Clause 79

THAT, the Bill be amended by deleting Clause 79.
Justification: The regulation of meat is outside the ambit of the regulation of the Authority.

Clause 81

THAT, Clause 81 of the Bill be amended by deleting the words "Director of Medical Services" and substituting therefor the words "Director-General for Health".
Justification: The Health Act, No. 21 of 2017 makes provision for the office of the Director-General for Health which replaced the office of the Director of Medical Services.

Clause 83

THAT, Clause 83 of the Bill be amended by deleting the words "Cabinet Secretary" wherever they appear and substituting therefor the words "the Authority".
Justification: The function of regulation of HPTs is a preserve of the Authority and the power provided in clause 83 is utilized administratively in the performance of this function. The Cabinet secretary responsible for matters of health is only responsible for policy.

Clause 90

THAT, Clause 90 of the Bill be amended in sub-clause (2) by deleting the words "think fit" appearing in paragraph (f) and substituting therefor the words "deem appropriate".
Justification: For proper drafting.

Clause 92

THAT, Clause 92 of the Bill be amended in sub-clause (2) by inserting the words "with the approval of the Cabinet Secretary" immediately after the word "determine".
Justification: For checks and balances in the investment of the funds of the Authority which will ensure prudent use of the funds by the Authority.

Fourth Schedule
THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);

Justification: Amendment of paragraph (1) is necessary for consistency with sub-paragraph (1) which establishes the National Food Safety Committee.

(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;
(g)the Director-General for Health or a representative designated in writing;"

Justification: For inclusion of KMA in the Human Medicines Committee as prescribers of medicines are crucial in ensuring patient safety.

For inclusion of the Director-General for Health in view of his technical expertise on matters of health generally.

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

Justification: The words "in consultation with the Cabinet Secretary responsible for health," are superfluous as it is already indicated that the Chairperson of the Medical Devices Committee will be appointed by the Cabinet Secretary.

3.7 Submission by the Hon. Martin Owino Peters, MP

The Hon. Martin Owino Peters, MP appeared the Committee presented his proposed amendments to the Committee in a meeting held on 2nd November, 2023 as follows: -

That Clause 72 of the Bill be amended in sub clause (1) by deleting the word "person" appearing immediately after the words "The Authority may authorize a" and substituting therefor the words "registered pharmacist".

3.8 Submission by the Hon. Peter Kaluma, MP

The Hon. Peter Kaluma, MP was invited to the winnowing process of the Kenya Drug Authority Bill, 2022 through a letter ref. NA/DDC/DC-H/2023/ (099) dated 27th October, 2023 for a meeting on 31st October and 1st November, 2023 but sent the following written proposed amendments to the Committee for consideration since he had travelled out of the Country;

General views:

1. We exclude anything to do with the practice of veterinary medicine from the Bill as this is dealt with under a law whose repeal has not been proposed here;
2. The manufacture of drugs be left to graduate Pharmacists;
3. Sale and dispensing of drugs once prescribed by a qualified medical practitioner or Dentist be allowed not only to pharmacists but also to holders of diploma in pharmaceutical technology, pharmacy or equivalent qualifications;
4. Proposed repeal of some sections of the Narcotic Drugs and Psychotropic Substances Act be avoided. The Act is dealing with a different category of drugs the possession, use or consumption of which is punished differently.
5. Measures be taken to ensure good provisions of the laws proposed to be repealed are incorporated into Bill. These include Part II of the Pharmacy and Poisons Act.
6. This is serious law. while it seeks to repeal two existing laws, the Memorandum states that it's purposed to comply with some WHO requirements. It would be good to involve the Ministry of Health and key stakeholders in the harmonization process. This would secure that the government position is presented, understood and carried forth into the proposed law and the requirements of WHO specified and met.
7. Amendments proposed by the Committee infringe S.O 133 as they derogate from the substratum of the various clauses of the Bill they seek to alter. It would be better the whole Bill be withdrawn and a new Bill be presented by the Government.

Specific Amendment Proposals:

Clause 2

Veterinary medicine - delete

"enrolled pharmaceutical technologist" - refers to definition in law being repealed. Pick definition from the law and insert it here. "means a pharmaceutical technologist whose name appears on the Roll of pharmaceutical technologists

"herbal medicine or product" - insert full stop (.) after "plants" in*second last line and delete all words following.

Insert:

"traditional medicines or products" means a plant or animal derived material or preparations with claimed therapeutic or other human benefits, which contain either raw or processed ingredients from one or more plants or animals, or material of inorganic origin."

Clause 3(2) - delete.
Clause 6(3) substitute "four" with "three"
Clause 6(4) (a) - insert full stop after "engineering" and delete the words following "or equivalent fields".
Clause 6(4)(d) insert "established for regulation of pharmacy, medicine or engineering profession."
Delete clause 6(6) - it conflicts with the lawful mandate of the Board in Clause 8(1).
Delete Clause 6(8)
Delete Clause 6(9)
Delete Clause 7 (a) and (b)
Delete "is" in 7(d) and substitute "has been"
8(2)(a)(i) insert, "medical practitioner or medical engineer" after the word "pharmacist"
Amend 8(2)(a)(ii) by inserting medical or medical engineering" after "pharmaceutical"
Delete 8(2)(f)8(2)(j) - delete "County" before "Governor"
Delete 8(3)
Delete 8(6)(a) and (b)
Substitute "is" with "has been" in clause 8(6)(e)
Clause 8(7) delete all words after "Board" and insert ", regard shall be had to the need for ethnic and regional balance and the need to ensure that persons of same biological sex shall not comprise more than two thirds of the members of the Board."
Delete Clause 9
Delete 10(2).
Clause 12 (f) substitute "events" with "effects"
13(a) substitute "association" with "collaboration
13(c) - delete "any" and substitute "lawful".
Delete Clause 21 and the Fourth schedule. Establishment of Committees already provided for inn Clause 13(e). The Clause contradicts Clause 12(i) and (j) which vest the duty to advise CS in the Authority and Clause 34.

Insert new 22(4) subsection (1) shall not apply to traditional medicines or products"
Clause 31 - insert full stop after "person" and delete all words following.
Delete clause 32(5)
Clause 38(1)(b) insert semi colon (;) after "substances" and delete the words following thereafter.
Clause 13(c) delete "for mining, agricultural or horticultural purposes"
13(e)*delete "by a qualified medical practitioner, dentist, or veterinary surgeon or by a hospital, or dispensary or similar institution"
39(4) amend by inserting "is a qualified pharmacist, medical practitioner or medical engineering practitioner or holder of diploma in pharmacy, pharmaceutical technology"
Clause 41(1)(b) insert "or pharmaceutical technologist or dispensing chemist" after "pharmacist"
Clause 41 (1)(d) delete "or veterinary".
Clause 41(1)(f) - insert full stop (.) immediately after the word "behalf" and delete all words appearing thereafter as they are repetitions of earlier provisions.
Clause 41(2)(a) - delete "?or veterinary surgeon"
Clause 43 (1) - delete veterinary surgeon"
Clause 46 (1) substitute "This" with "Electronic sale of medicines"

Delete Clause 79
Clause 81 - Delete "or the Director of Veterinary Services, in relation to any matter appearing to affect the general interests of agriculture in Kenya,"
Clause 95 (aa) delete "or veterinary surgeon "Subject the regulations to approval by Parliament.
Second Schedule – Delete
Fourth Schedule - Delete.
Seventh Schedule - Delete Narcotic Drugs and Psychotropic Substances Act and its provisions.

NB: Ensure all good provisions of the Acts proposed to be repealed are carried into the new law by way of substitutive provisions. These include sections 6,7,8,9 of PPA.

CHAPTER FOUR

3.0 COMMITTEE OBSERVATIONS ON THE WINNOWING OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

Having considered the all the proposed amendments as proposed to the Kenya Drugs Authority Bill, 2022, by the Committee and individual Honourable Members submissions the Committee made the following observations on each of the proposed amendment: -

1. There is need to retain the regulation of herbal medicines in the Bill, and to this effect, the Committee proposes the amendment of the definition of "health products" to include herbal medicine. Further, there is need to exclude traditional and alternative medicine from the ambit of the Bill. The Committee notes that there will be need to come up with legislation to give effect to the provisions of the Health at, No. 21 of 2017, which mandates Parliament to establish a regulatory body to regulate the practice of traditional medicine and alternative medicine.
2. The Committee notes that the Registrar was not defined in the Bill, and to this end, there is need to introduce the definition of the term "Registrar" to mean the Director-General of the Authority.
3. There is need to ensure a smooth transition from the Pharmacy and Poisons Board to the Health Products and Technologies Regulatory Authority. The Committee notes that during the transition period, the staff of the Pharmacy and Poisons Board dealing with the regulation of health products and technologies would have to move to the Authority immediately upon the enactment of the Bill, while the Pharmacy and Poisons Board will continue to exist for a period of two years to regulate the pharmacy practice. The Committee further notes that within the two-year transition period, Parliament will have to enact a legislative framework for the regulation of the pharmacy profession.

CHAPTER FIVE

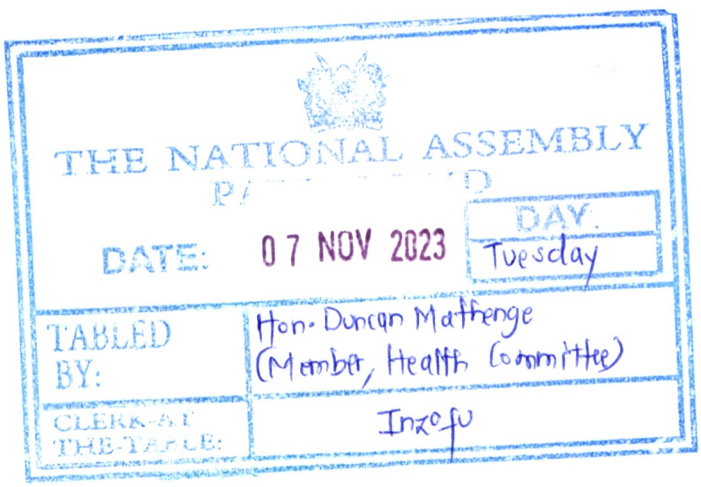
4.0 COMMITTEE RECOMMENDATIONS ON THE WINNOWING OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

Having considered all the proposed amendments as proposed by the Committee and the honourable members, the Committee agreed upon the following harmonized version of amendments. The Committee therefore, recommends that, the house adopts the report of the winnowing process of the proposed amendments to the Kenya Drugs Authority Bill, (National Assembly Bill, No. 54 of 2022).

SIGNED ..... **DATE** 2/11/2023 .....

HON. PATRICK NTWIGA MUNENE, MP

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH



CHAPTER SIX

SCHEDULE OF AMENDMENTS

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

> "AN ACT of Parliament to establish a comprehensive legal framework for the regulation of health products and technologies; to safeguard public health through development of a regulatory system to ensure safety, quality, efficacy, effectiveness and performance of health products; to establish the Kenya Health Products and Technologies Regulatory Authority and for connected purposes".

Justification: The amendment accords with international best practice and sets out the main purpose of the Bill which is to establish a centralized regulatory authority for health products and technologies.

CLAUSE 1

THAT, Clause 1 of the Bill be amended by—

(a) deleting the phrase "Kenya Drugs Authority Act, 2022" and substituting therefor the phrase "Kenya Health Products and Technologies Regulatory Authority Act, 2022";

Justification: The amendment accords with international best practice and comprehensively covers the mandate of the proposed Authority.

(b) deleting the words "and commencement" in the marginal note.

Justification: To limit the marginal note to the content of clause 1 which only sets out the name of the Bill. The Clause does not make any provision as regards the commencement of the Bill.

CLAUSE 2

THAT Clause 2 of the Bill be amended—

(a) in the definition of "article" by–

(i) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (a); and

(ii) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (b);

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(b) in the definition of "Authority" by deleting the words "Kenya Drugs Authority" and substituting therefor the words, "Kenya Health Products and Technologies Regulatory Authority";

Justification: To ensure harmony with the title of the Bill as proposed for amendment.

(c) in the definition of "chemical substance" by deleting the words "or detergent";

Justification: To exclude detergents which are used for cleaning inanimate objects and does not fall under the purview of the regulation of health products and technologies.

(d) in the definition of "drug" by deleting the word "if" appearing in paragraph (b)(ii) and substituting therefor the word "of";

Justification: To correct a minor typographical error.

(e) by deleting the definition of "enrolled pharmaceutical technologist";

Justification: The current definition cross references the Pharmacy and Poisons Act, Cap. 244 which will be repealed as provided under clause 97. A new definition proposed.

(f) in the definition of "health products and technologies" by inserting the words, "dietary supplements" immediately after the words, "therapeutic cosmetics";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(g) by deleting the definition of "herbal medicine or product";
(h) by deleting the definition of "medical device";
(i) by deleting the definition of "medicinal substance";

Justification: New definitions provided for these terms. These new definitions expand the scope to cover all aspects of the use of medical devices and medicinal substances in relation to health and to include herbal materials and herbal combinations.

(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(k) by deleting the definition of "pharmacy";

Justification: The current definition is inadequate. The term is to be defined in the proposed Pharmaceutical Practice Bill.

(l) by deleting the definition of "pharmaceutical technologist";

Justification: The Pharmacy and Poisons Act, Cap. 244 provide that a pharmaceutical technologist must be enrolled in the roll established under this Act.

(m)by deleting the definition of "registered midwife";

Justification: The term is no longer used in the Bill in line with the proposed amendment of clause 43 (1)(c).

(n) in the definition of "scheduled substance" by deleting the phrase "in the relevant schedule under this Act" and substituting therefor the phrase "in the list published by the Cabinet Secretary under section 37";

Justification: There is no Schedule on scheduled substances. The Cabinet Secretary will publish the list of scheduled substances in the *Gazette.*

(o) by deleting the definition of "therapeutic cosmetic"; and

Justification: The current definition defines cosmetics in general that are meant to provide the body with appropriate aesthetics, texture, pH, color and smell. It is not specific to special cosmetics.

(p) by inserting the following new definitions in their proper alphabetical sequence—

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"adverse event" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment;

"alternative medicine" means complementary medicine and includes a broad set of health care practices that are not part of Kenya's tradition and are not integrated into dominant health care system;

"biologicals" means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies and includes products derived from human blood and plasma;

"Board" means the Board of the Authority established under section 8;

"Centre" means the National Pharmacovigilance Centre established under section 59B;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dietary supplement" means a product taken by mouth that is added to the diet to help meet daily requirements of essential nutrients, and which usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

"enrolled pharmaceutical technologist" means a person enrolled as such by the body for the time being responsible for the enrolment of pharmaceutical technologists;

"falsified medical product" means a product that is deliberately or fraudulently misrepresented in relation to its identity, composition or source;

"Field Safety Corrective Action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, and includes—

(c) the return of a medical device to the product owner or its representative;

(d) device modification which may include—

(viii) retrofit in accordance with the product owner's modification or design change;
(ix) permanent or temporary changes to the labelling or instructions for use;
(x) software upgrades including those carried out by remote access;
(xi) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;
(xii) device exchange;
(xiii) device destruction; or
(xiv) advice given by product owner regarding the use of the device.

"health product" includes a medicine, medical product, medicinal substance, vaccine, diagnostic, medical device, blood or blood product, herbal medicine, therapeutic feed and nutritional formulation, cosmetic and related products;

"health technology" means the application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives, and includes radiation-emitting devices and related products;

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations;

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector under this Act;

"lot" or "sub-lot" means a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous; and in the case of continuous manufacture, the lot corresponds to a defined fraction of the production characterized by its intended homogeneity;

"lot release" means the process of the evaluation of an individual lot of a licensed biological product by the Authority before giving approval for its release onto the market;

"marketing authorization" means the certificate of registration issued by the competent health product regulatory authority in the country of origin for the

purpose of marketing or free distribution of a health product after evaluation for safety, efficacy and quality;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;
(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importation" means importation into Kenya, by a licensed importer of a health product other than the marketing authorization holder or his or her technical representative, of the following health products which require marketing authorization in Kenya—

(a) patented health products under the applicable law;
(b) non-patented health products; or
(c) branded generic health products;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;

"Registrar" means the Director-General of the Authority appointed under section 6;

"scheduling" means, in relation to a substance, the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;

"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, skin, eyes or teeth, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;

"traditional medicine" includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness;

"unregistered medical product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;

"vessel" means a truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;

"wholesale dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

Justification: The new definitions are internationally recognized by the World Health Organization and are critical for the execution of regulatory functions of the Authority.

To further identify the Board as used in the Bill.

To provide new definitions for the words: enrolled pharmaceutical technologist, therapeutic cosmetic, herbal medicine, medical device and medicinal substances.

The amendment also introduces the definition of the Registrar to mean the Director-General of the Authority, as the term is used in various clauses in the Bill.

CLAUSE 3

THAT, Clause 3 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(l) This Act applies to the regulation of—

(a) medicines, medical products and technologies;
(b) medical devices including radiation emitting devices;
(c) radiopharmaceuticals;
(d) complementary, alternative or herbal medicines;
(e) cosmetics and borderline products;
(f) in-vitro diagnostics medical devices;
(g) therapeutic feeds;
(h) clinical trials;
(i) nutraceuticals and dietary supplements;
(j) digital health and technologies;
(k) scheduled substances;
(l) chemical substances; and
(m) biological products for use in humans and the starting materials used in their manufacture."

(b) by inserting the following new sub-clause immediately after sub-clause (2)—

"(3) This Act shall not apply to the regulation of traditional medicine and alternative medicine."

Justification: To comprehensively cover all aspects in the regulation of health products and technologies.

Further, the amendment seeks to expressly exempt the regulation of traditional and alternative medicine from the Bill, as this will be dealt with by the enactment of legislation to provide for the regulation of traditional medicine and alternative medicine as envisaged under section 75 of the Health Act.

CLAUSE 4

THAT, Clause 4 of the Bill be amended in sub-clause (1) by deleting the words "Kenya Drugs Authority" and substituting therefor the words "Kenya Health Products and Technologies Regulatory Authority".

Justification: This accords with international best practice on the establishment of a centralized regulatory authority for health products and technologies.

CLAUSE 5

THAT, Clause 5 of the Bill be amended by deleting the words, "but the Authority may establish branches anywhere in Kenya" and substituting therefor the words "or in such other place as the Board of the Authority may, by resolution, determine".

Justification: To give the Board discretion in determining the location of the Authority's headquarters.

CLAUSE 6

THAT, Clause 6 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) There shall be a Director-General of the Authority who shall be the chief executive officer of the Authority."

Justification: For proper drafting of the clause.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) The Director-General shall be appointed by the Board, through a transparent and competitive process, on such terms as may be specified in the instrument of appointment."

Justification: The Director-General is not a State Officer and should therefore be appointed by the Authority without the approval by Parliament.

(c) in sub-clause (3) by deleting the word "four" and substituting therefor the word "three".

Justification: Appointments and term of service in State Corporations are normally capped at three (3) years which is renewable for one final term.

(d) by deleting sub-clause (4) and substituting the following new sub-clause (4)—

"(4) A person shall be qualified for appointment as a Director-General if such person—

(a) holds a bachelor's degree in pharmacy from a university recognized in Kenya;
(b) holds a masters' degree in pharmacy, medicine or any relevant field from a university recognized in Kenya;
(c) has at least ten years' experience in pharmacy or its equivalent;
(d) has served in a senior management position for at least five years;

(e) is a member of a professional body; and
(f) meets the requirements of Chapter six of the Constitution."; and

Justification: The Director-General should be a qualified pharmacist as the regulation of health products and technologies requires specialized knowledge and technical expertise in the pharmaceutical field.

(e) by deleting sub-clause (5).

Justification: The fact that the Director-General shall be the CEO of the Authority is provided in the sub-clause (1) as proposed for amendment.

CLAUSE 7
THAT, Clause 7 of the Bill be amended in paragraph (f) by deleting the phrase "Act. regulation under this" and substituting therefor the phrase "regulation under this Act."

Justification: To correct a typographical error.

CLAUSE 8
THAT, Clause 8 of the Bill be amended—
(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause—
"(1) The management of the Authority shall vest in a Board appointed under this section."

Justification: The name of the Board should reflect the amended Title of the Bill and name of the Authority as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–
"(2) The Board shall comprise—
(a) a non-executive Chairperson appointed by the President and who shall—
(iii)be a registered pharmacist of good standing with a degree in pharmacy; and
(iv)have at least ten years' experience in the pharmaceutical sector, five of which shall be at senior management level;
(b) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing;
(c) the Principal Secretary the Ministry for the time being responsible for finance or a representative designated in writing;
(d) the Director-General for Health or a representative designated in writing;
(e) one person nominated by the Pharmaceutical Society of Kenya;
(f) one person nominated by the Kenya Pharmaceutical Association;
(g) one person nominated by the Kenya Medical Association;

(h) one person, not being a Governor, with knowledge and experience in health products and technologies nominated by the Council of County Governors to represent the interests of counties;

(i) one person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(j) the Director-General of the Authority who shall be the secretary and an *ex officio* member of the Board."; and

Justification: The composition of the Board should comply with the *Mwongozo* Code of Governance for State Corporations in terms of numbers, skill mix and professional expertise which should include all relevant players involved in the matters of health products and technologies.

(c) by deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

"(3) The Cabinet Secretary shall appoint the members of the Board under subsection (2) (e), (f), (g), (h) and (i) by notice in the *Gazette*."

Justification: The members of the Board Members are not State Officers and hence their appointment does not require approval by Parliament. It is sufficient that the Cabinet Secretary notifies the public of the appointments in the Kenya Gazette.

CLAUSE 9
THAT, the Bill be amended by deleting Clause 9.

Justification: The provision contradicts the legal framework for appointment of the Chairperson, Board Members and CEOs of State Corporations or Semi-Autonomous Government Agencies. The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

CLAUSE 10
THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "section 12" appearing in paragraph (c) and substituting therefor the words "section 11".

Justification: To correct the cross reference as clause 11 makes provision for removal from office of the members of the Board of the Authority.
CLAUSE 12
THAT, Clause 12 of the Bill be amended by—
(a) inserting the following paragraphs immediately after paragraph (e)—

"(ea) regulate the disposal of health products and technologies;
(eb) monitor the market for the presence of unregistered and illegal health products and technologies;
(ec) conduct analytical tests of health products and technologies";

Justification: To make provision for the functions of disposal, analytical testing and monitoring of the market by the Authority.

(b) deleting paragraph (f) and substituting therefor the following new paragraph (f) —
"(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act through analysis of reports on adverse reactions and events, including any other health product and technology use related issues and take appropriate regulatory actions when necessary";

Justification: To expressly align to the WHO requirement on the establishment of a national vigilance system.

(c) deleting paragraph (g) and substituting therefor the following new paragraph (g)—
"(g) regulate clinical trials and ensure that clinical trial protocols of health products and technologies are being assessed according to the prescribed ethical and professional criteria and defined standards including mandatory bioequivalence studies";

Justification: To anchor the oversight of clinical trials in the law as recommended by the WHO.

(d) inserting the following new paragraphs immediately after paragraph (g)—

"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials, emergency use and compassionate use;
(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements";

Justification: To provide for approval of health products and technologies during emergencies and to provide for pharmacovigilance which check the safety of health products and technologies.

(e) deleting paragraph (n) and substituting therefor the following new paragraph (n)—

"(n) appoint inspectors who hold a minimum of a diploma in pharmacy and conduct inspection, either by itself or through its agents, of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act";

Justification: To specify the premises subject to inspection by the Authority.

(f) inserting the following new paragraphs after paragraph (o)—

"(oa) conduct national regulatory authority lot release, official authority batch release of specified biologicals to ensure the quality, safety and efficacy of biological products

through a regulatory release system in compliance with established approaches, policies, guidelines, procedures and in line with World Health Organization and internationally recognized guidelines;
(ob)carry out and promote research related to medicines and health products";

Justification: To enable the conduct of research by the Authority and the conduct of lot releases which are a key component in the regulation of the production of vaccines.

(g) inserting the following paragraphs after paragraph (q)—

"(qa) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;
(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;
(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;
(qd) maintain a register of all authorized health products and technologies manually or electronically;
(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;
(qf) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

Justification: To include critical functions of the Authority based on best practice in regulation of import and export of health products and technologies that will enable the country attain WHO maturity level 3.

CLAUSE 13

THAT, Clause 13 of the Bill be amended by—

(a) deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate for the furtherance of the purpose of the Act;"

(b) inserting the following new paragraphs immediately after paragraph (a)—

"(aa) adopt and implement any such internationally recognized good regulatory practices;
(ab) determine and implement effective and efficient reliance mechanisms;

(ac)issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;
(ad) levy, collect and utilize fees for services rendered;
(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors;
(af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

Justification: To comply with WHO requirements for regulatory functions in the Global Benchmarking Tool especially on control over imports and exports.

CLAUSE 21

THAT Clause 21 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) The Board may establish such scientific advisory committees of the Authority, as may be necessary for the effective performance of the functions of the Authority".

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9) —
"(9) A scientific advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary".

Justification: The Scientific Advisory Committees ought to offer technical advice and report to the Board (its appointing authority) which then advices the Cabinet Secretary accordingly.

PART IV

THAT, Part IV of the Bill be amended by deleting the title and substituting therefor the following new title–

"PART III—HEALTH PRODUCTS AND TECHNOLOGIES"

Justification: To ensure harmony with the title of the Bill as proposed for amendment and to correct a minor error in numbering of the parts of the Bill.

CLAUSE 22

THAT, Clause 22 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—

(i) deleting the words "sell any medicine" appearing in the opening sentence and substituting therefor the words "sell, manufacture, supply, distribute or dispense any health product or technology";

Justification: To broaden the scope of prohibited sale of health product and technologies to include manufacturing, dispensing, distribution and supply of health product and technologies.

(ii) deleting paragraph (d) and substituting therefore the following new paragraph (d)—

"(d) is falsified,";

Justification: For alignment with international best practice as the proposed terminology is recognized by the WHO.

(c) in sub-clause (3) by—

(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology"; and
(ii) deleting the words "pharmaceutical product" appearing in paragraph (b) and substituting therefor the words, "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 23

THAT, Clause 23 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the word "medicines" appearing in paragraph (a) and substituting therefor the words, "health products or technologies";
(ii) deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words, "health product or technology"; and
(iii) deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words, "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (2) by—
(i) deleting the words "one million" appearing in paragraph (a) and substituting therefor the words "two million"; and
(ii) deleting the words "two million" appearing in paragraph (b) and substituting therefor the words "five million".

Justification: To enhance the penalty imposed for the offence of deception and falsification of health products and technologies, since the commission of the offence poses serious ramifications.

CLAUSE 24

THAT, Clause 24 of the Bill be amended—

(a) in the marginal noteby deleting the word "medicines" and substituting therefor the words "health products and technologies";
(b) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(c) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–
"(2) If a standard has not been prescribed for a health product or technology but a standard for the health product or technology is contained in any of the publications specified in the Fifth Schedule, any person who manufactures, labels, packages, sells or advertises any other substance or article in such a manner that is likely to be mistaken for the health product or technology having met any of the standards contained in any of the publications specified in the Fifth Schedule, commits an offence.";

(d) in sub-clause (3) by–
(iii)deleting the word "medicine" wherever it appears in the opening sentence and substituting therefor the words "health product or technology"; and
(iv)deleting the word "drug" appearing in paragraph (b) and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) in sub-clause (4) by—

(i) deleting the phrase "one hundred thousand shillings or to imprisonment for a term not exceeding three months" appearing in paragraph (a) and substituting therefor the phrase "one million shillings or to imprisonment for a term not exceeding three years"; and

(ii) deleting the words "two hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

Justification: To make the fines prohibitive and punitive due to the risk of the offences to public health.

CLAUSE 25

THAT, the Bill be amended by deleting Clause 25.

Justification: The prohibition of sale of medicines of a quality not demanded is a practice issue and falls outside the ambit of the Bill.

CLAUSE 26

THAT, Clause 26 of the Bill be amended by—

(a) deleting the word "medicine" appearing in the marginal note and substituting therefor the words "health product or technology"; and

(b) deleting the word "medicine" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 27

THAT, Clause 27 of the Bill be amended by—

(a) deleting the words "medicinal products" appearing in paragraph (a) and substituting therefor the words "health products or technologies";

(b) deleting the words "medicinal products" appearing in paragraph (b) and substituting therefor the words "health products or technologies"; and

(c) deleting paragraph (c) and substituting the following new paragraph (c)—

"(c) the quality of the health products or technologies of such description, according to the specification and the method or proposed method of manufacture of the health products or technologies, and the provisions proposed for securing that the health products or technologies as sold or supplied shall be of that quality; and"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

NEW CLAUSES

THAT, the Bill be amended by inserting the following new clauses immediately after clause 27–

Application for product licence.

27A. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Authority for the registration of the health product or health technology, in the prescribed form.

(2) An applicant under subsection (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Authority in the declaration page of the application form; and

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—

(a) a proposed label for use on the health product or technology;

(b) a copy of the manufacturing licence of the health product or technology, where applicable;

(c) a copy of the good manufacturing practice certificate from the Authority and the regulatory authority of the country where the health product or technology is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognized by the Authority, where applicable;

(e) a copy of the marketing authorization or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product or technology;

(h) proof of ownership of the site for the manufacture of the health product or technology, where applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body—

(iv)a copy of the certificate of registration;

(v) the professional information relating to the health product or technology; and

(vi)the conditions of the registration of the health product or technology;

(k) proof that the applicant holds—

(vi)a valid practising licence issued by the body responsible for the profession of pharmacy;

(vii) a valid wholesale dealer's licence issued in accordance with this Act;

(viii) a valid licence to sell poisons issued in accordance with this Act; or

(ix)a valid manufacturing licence issued in accordance with this Act; and

(x) proof of payment of the application fees as prescribed by the Authority.

(4) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

Processing of application for registration of health product or technology.

27B. (1) The Authority shall consider the application made under section 27A, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in the prescribed form.

(2) The Authority may, while considering the application, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;

(b) the labelling of the health product or technology;

(c) the statement of the representations to be made for the promotion of the health product or technology regarding—

(vii) the claim to be made for the health product or technology;

(viii)the route of administering the health product or technology;

(ix)the dosage of the health product or technology;

(x) the storage conditions of the health product or technology;

(xi)the contra-indications, the side effects and precautions, if any of the health product or technology; and

(xii) the package size of the health product or technology.

(3) When evaluating an application, the Authority may—

(a) subject a sample of the health product or technology to an evaluation by an analyst; and

(b) consider the evaluation report of the analyst that has evaluated the health product or technology.

(4) Where the Authority is not satisfied as to the quality, safety efficacy, performance or economic value of the health product or technology, it may, after

providing an opportunity to the applicant to be heard, reject the application and inform the applicant the reasons for rejection in writing.

Registration during emergency.

27C. (1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to life or health, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subsection (1) shall apply to the Authority in the prescribed form.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(4) An application under subsection (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds—

(i) a valid practising licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

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(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(5) When determining an application under this section, the Authority shall consider the facts established from the valid marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for health products and technologies, if available.

(6) The person to whom the certificate of registration is issued under this section, shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) A provisional certificate of registration issued under subsection (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked.

(8) Any variation to the agreement appointing the local representative to the application made under subsection (2) shall be notified to the Authority within seven days of the variation.

Authorization of unregistered health product or technology.

27D. (1) The Authority may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product or technology that is not registered.

(2) A health product or technology distributed pursuant to authorization granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) A person who intends to obtain the authorization under subsection (1), for purposes other than a clinical trial, shall apply to the Authority in the prescribed form.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who

shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(5) The application made under subsection (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;

(b) written consent of the applicant, where applicable;

(c) details of registration or pending registration of the health product or technology with any other regulatory authority, where applicable;

(d) evidence of compliance by the manufacturer of the health product or technology with good manufacturing practice standards as determined by the Authority;

(e) reasons why a registered health product or technology cannot be used;

(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(g) proof that the applicant holds—

(i) a valid practising licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii)a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv)a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—

(a) progress reports after every six months from the date of issuance of the authorization;

(b) any adverse event report, where an adverse event occurred; and

(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or

(d) withdraw the authorization to treat the patient.

(8) The Authority may, by notice in writing withdraw the authorization issued under subsection (1) if any of the purposes or the manner specified in subsection (2) is contravened.

(9) A health product or technology authorized under this section shall be labelled in accordance with this Act.

(10) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

(11) The requirements in this section shall apply to applications for donations of health products and technologies.

Justification: To provide new clauses 27A, 27B, 27C and 27D for the handling of applications of product licences by the Authority.

CLAUSE 28

THAT, Clause 28 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines register" and substituting therefor the words "health products and technologies register";
(b) in sub-clause (1) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register"; and
(c) in sub-clause (2) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 29

THAT, Clause 29 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines and medical devices" and substituting therefor the words "health products and technologies";
(b) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) Every application for registration of a health product or technology shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant health product or technology and by the prescribed registration fee."

(c) in sub-section (2) by deleting the phrase "Essential Medicines List or Essential Veterinary Medicines List" and substituting therefor the phrase "Kenya Essential Medicines List, Kenya Essential Diagnostics List, Kenya Essential Medical Supplies List and Kenya Essential Veterinary Medicine List";
(d) in sub-clause (3) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(e) in sub-clause (4) by—
(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";
(ii) deleting paragraph (b) and inserting the following new paragraph—
"(b) that the applicant may, within a period of three months after the date of the notification, furnish the Registrar with the comments on the Authority's reasons for not being so satisfied."

Justification: To afford adequate time and to increase the period within which an applicant may submit their comments on the Authority's reasons for its decision, from one month to three months.

(f) by deleting sub-clause (6) and substituting therefor the following new sub-clause (6)—

"(6) Where the Authority has approved the registration of any health product or technology if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, the Registrar shall register that health product or technology and shall enter in the register such particulars in regard to the health product or technology as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that health product or technology."

(g) in sub-clause (7) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(h) in sub-clause (8) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(i) in sub-clause (9) by deleting the word "medicines" and substituting therefor the words "health products and technologies";
(j) in sub-clause (10) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(k) in sub-clause (11) by deleting the word "medicine" and substituting therefor the words "health product or technology";
in sub-clause (12) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(l) in sub-clause (14) by—

(i) deleting paragraph (a) and substituting therefor the following new paragraph (a) —
"(a)Kenya Essential Medicines List, Kenya Essential Diagnostics List and Kenya Essential Medical Supplies List means the list of essential medicines, diagnostics and medical supplies included in the latest editions of the official publications relating to guidelines for standard treatment which is compiled by the state department responsible for Health;"
(ii) inserting the word "Kenya" immediately before the phrase "Essential Veterinary Medicines List" appearing in paragraph (b).

Justification: To broaden the scope of HPTs considered under the clause.

NEW CLAUSES

THAT, the Bill be amended by inserting the following new clauses immediately after clause 29–

Authorization of health products and technologies.

29A. (1) A person shall not import any health product or technology unless—

(c) the imported health product or technology has been authorized through issuance of an import permit or a written authorization by the Authority; and
(d) the imported health product or technology is inspected and verified by an inspector of the Authority at the ports of entry prior to its release.

(2) A batch or lot of any registered product shall not be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in cases of biological therapeutics.

(3) Each applicable test conducted by the manufacturer under subsection (2) shall be made on each batch or lot after completion of all processes of manufacture and such test may affect compliance with the standard applicable to the product.

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

(5) Every batch or lot of a registered biological therapeutic imported into Kenya or manufactured in Kenya shall be evaluated and, on being satisfied of conformity with prescribed standards and payment of prescribed fees, the Director-General shall approve its release into the market and issue a certificate of official batch or lot release in the prescribed format.

(6) The Authority may recognize and accept official lot release certificates issued by other national regulatory authorities of other countries for a specific batch or lots of biological therapeutic manufactured within the territories of those national regulatory authorities, in issuance of a certificate under this section.

(7) A person who contravenes this section commits an offence and shall on conviction be liable—

(c) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both; or

(d) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Justification: To provide for authorization of health products and technologies imported into the country including the requirement for batch or lot release in line with WHO requirements.

Parallel importation of health products and technologies.

29B. (1) A person shall not engage in the parallel importation of a health product or technology into Kenya unless—

No. 17 of 2015.

(a) the person is incorporated as a limited liability company under the Companies Act;
(b) the person has been granted a certificate of parallel importation;
(c) the person is licensed to parallel import the health product or technology;
(d) the health product or technology has a valid registration in Kenya under this Act; and
(e) the health product or technology has a valid market authorization in the country of origin.

(2) A person who wishes to undertake parallel importation of a health product or technology shall apply to the Board for a certificate of parallel importation in the prescribed manner.

(3) The Board shall establish and maintain a system that ensures that a registered parallel imported health product or technology can be traced from its sourcing, manufacturing, packaging, storage, transport to its delivery to the health facility, institution or private practice where the health product or technology is intended to be used.

(4) A person who—

(d) is the holder of a certificate of parallel importation or licensee and fails to comply with any requirement or obligation in this Act;
(e) contravenes any prohibition prescribed by the Authority; or
(f) fails to comply with any requirement imposed on that person by the Board pursuant to this Act,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Justification: To make provision for parallel importation of health products and technologies.

CLAUSE 30

THAT, Clause 30 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";
(b) by inserting the following new sub-clause immediately after subclause (2)—

"(2A) A person who makes an application under this section shall provide reasons for the proposed amendments to the register."

(c) in sub-clause (3), by deleting the word "medicine" wherever it appears in paragraph (b) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

The amendment further seeks to ensure that a person who makes an application for the amendment of the register provides reasons for such proposed amendments.

CLAUSE 31

THAT, Clause 31 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" and substituting therefor the words "health product or technology"; and
(b) in sub-clause (3), by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 32

THAT, Clause 32 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) The Authority shall cancel the registration of a health product or technology if—

(d) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(e) a particular health product or technology does not comply with a prescribed requirement; or

(f) it is not in the public interest to make a particular health product or technology available to the public."

(b) in sub-clause (2) by deleting the phrase "medicine or medical device" wherever it appears and substituting therefor the phrase "health product or technology";
(c) in sub-clause (4)–

(iii)by deleting the words "medicine or medical device" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(iv)by deleting the words "medicine or medical device" appearing in paragraph (b) and substituting therefor the words "health product or technology"; and

(d) by deleting the words "medicine or medical device" wherever it appears in sub-clause (5) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 33

THAT, Clause 33 of the Bill be amended in sub-clause (1) by deleting the words "medicine or medical device" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 34

THAT, Clause 34 of the Bill be amended—

(a) by deleting the words "medicines" and "medicine" wherever they appear and substituting therefor the words "health product or technology"; and

(b) in the marginal note by deleting the words "medicines" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) A pharmacist or an enrolled pharmaceutical technologist may, in consultation with the person prescribing the health product or technology and the patient, dispense an interchangeable multi-source health product or technology instead of the health product or technology prescribed by a medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals."

(c) in sub-clause (2) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(d) in sub-clause (3) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist"; and
(e) in sub-clause (4) by inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist".

Justification: For inclusion of pharmaceutical technologists in the dispensing of interchangeable multi-source medicine.

The amendment to sub-clause (1) seeks to ensure that the consent of both the patient and the person who makes the initial prescription is obtained before such a change of prescription is made.

CLAUSE 36

THAT, Clause 36 of the Bill be amended—
(a) in sub-clause (1) by inserting the words "or products" immediately after the words "herbal medicine"; and
(b) in sub-clause (3) by inserting the phrase "and shall, on conviction be liable to a fine not exceeding one million shillings or imprisonment for a term not exceeding one year, or to both" immediately after the phrase "commits an offence".

Justification: The amendment seeks to ensure that herbal medicines and products as defined in the proposed new definition in clause 2 shall fall within the ambit of regulation of the Bill.

The amendment further seeks to impose a penalty for the offence of dealing in herbal medicines and products without registration.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 36—

Clinical trials.

36A. (1) A health product or technology shall not be used for clinical trial unless an approval is granted by the Authority.

(2) An approval under subsection (1) shall only be granted by the Authority after approval by the relevant ethics body has been granted.

(3) A person who intends to commence a clinical trial on a health product or technology shall make an application to the Authority in the prescribed form and the application shall be accompanied by the study protocol in the prescribed format and the prescribed fee.

(4) The study protocol submitted under subsection (2) shall include a post-trial access programme to ensure access of investigational medicinal substances by participants in the trial before grant of marketing authorization by the Authority.

(5) The Authority shall prescribe guidelines for evaluation of applications made under subsection (2) to be implemented for accelerated evaluations during emergency situations, epidemics and outbreaks.

(6) A person granted an approval under this section shall put in place a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated and the safety and well-being of the participants of the study.

(7) The Authority shall carry out inspection of the clinical trials and monitor compliance of the clinical trials with the prescribed requirements.

(8) Any amendments to clinical trials protocols shall be submitted to the Authority for approval before implementation.

Justification: To provide for effective regulation of clinical trials by the Authority.

PART V

THAT, the Bill be amended in the title to Part V by deleting the expression "PART V" and substituting therefor the expression "PART IV".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 37

THAT, Clause 37 of the Bill be amended—

(a) in sub-clause (2) by deleting the words "and dealers in mining, agricultural or horticultural accessories" appearing in paragraph (a);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)—
"(3) The Cabinet Secretary shall publish in the *Gazette* the list of scheduled substances prepared under subsection (1)."

Justification: To provide for the publication of the list of scheduled substances.

(c) by renumbering sub-clause (3) as sub-clause (4);
(d) by deleting sub-clause (4) and substituting therefor the following new sub-clauses —

"(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.
(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsections (1), (2) and (3)."

Justification: To enhance the period of review of the lists of scheduled substances from one year to two years and provide for review in public interest where need arises. To ensure that the procedure set out in the clause in the preparation and publication of the list of scheduled substances is followed even when the lists are modified.

CLAUSE 38

THAT, Clause 38 of the Bill be amended—

(a) in sub-clause (1) by—

(iii)deleting the phrase "the Limitations prescribed by this sub-section" and substituting therefor the phrase "the following limitations";

Justification: For proper drafting. The words "prescribed by this sub-section" are unnecessary.

(iv)deleting paragraph (c)

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 2,000,000.

CLAUSE 39

THAT, Clause 39 of the Bill be amended—

(a) in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances";

Justification: This is to provide proper grammatical flow.

(b) by deleting sub-clause (5) and substituting therefor the following new sub-clause (5)—

"(5) A licence issued under this section shall be valid for a period of one year, renewable annually."

Justification: Annual expiry of the licence is too punitive especially for persons who apply in the middle of the year.

CLAUSE 40

THAT, the Bill be amended by deleting clause 40.

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1)—

(i) by deleting paragraph (c);

(ii) by deleting paragraph (e);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws. The National or County government cannot buy scheduled substances on its own, it must do so through a person licensed to do so under the Bill.

(b) in sub-clause (2) —

(i) by deleting paragraph (b)

(ii) by deleting paragraph (c); and

Justification: The persons to whom a wholesaler dealer may sell scheduled substances to are set out in sub-clause (1).

(c) by deleting sub-clause (3).

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (1) by deleting the expression "paragraph (b) of Section 53(2)" appearing in paragraph (a) and substituting therefor the expression "section 41(2)(b)"; and

Justification: To correct the cross reference as clause 41 makes reference to the written certificate contemplated under clause 42.

(b) in sub-clause (3) by deleting the words "three years" and substituting therefor the words "one year".

Justification: To reduce the penalty of imprisonment from three years to one year as the same is not commensurate to the fine of one hundred thousand shillings in relation to the offence of not making entries of sale of scheduled substances in a scheduled substances book.

CLAUSE 43

THAT, Clause 43 of the Bill be amended in sub-clause (1)—

(a) by deleting the opening sentence and substituting therefor the following new opening sentence—

"(1) A qualified healthcare professional may supply or dispense a Scheduled Substance with therapeutic value for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following provisions—

Justification: To restrict dispensing of scheduled substances to authorized persons.

(b) in paragraph (b) by—

(iii)inserting the word "and" immediately after the word "supplied" appearing in sub-paragraph (iii); and

(iv)deleting the word "and" appearing in sub-paragraph (iv);

Justification: To correct a minor drafting error.

(c) by deleting paragraph (c).

Justification: Registered midwives are included in the qualified healthcare professional provided in the amended sub-clause (1).

CLAUSE 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "five hundred thousand".

Justification: To enhance the penalty for the offence of supply of non-labelled scheduled substances.

CLAUSE 45

THAT, the Bill be amended by deleting Clause 45 and substituting therefor the following new clause 45—

Automatic machines.

45. (1) An authorized seller may use an automatic machine to dispense over-the-counter scheduled substances.

(2) The Authority shall develop regulations on the—

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

Justification: To provide for the use of automatic machines in dispensing selected scheduled substances in an effort to leverage on technology.

CLAUSE 46

THAT, the Bill be amended by deleting Clause 46 and substituting therefor the following new clause 46—

Electronic sale of health products and technologies.

46. (1) The Authority shall prescribe regulations to provide for the electronic supply and dispensing of scheduled substances including through e-pharmacy, telemedicine, medication therapy management and online pharmacy.

(2) The regulations made under subsection (1) shall provide for—

(a) licensure of e-pharmacies;

(b) safety of patients;

(c) verification of the identity and traceability of patients;

(d) verification of the identity and traceability of prescribers; and

(e) integrity, legitimacy and authenticity of prescriptions including avoidance of multiple use of the same prescription.

(3) The electronic supply and dispensing of scheduled substances shall be permitted provided that the supply of such health products and technologies

conforms with all requirements for the particular health product or technology in terms of its scheduling status and any other requirements as may be specified in regulations in relation to such supply or dispensing.

(4) In the case of a prescription-only medicine, the required prescription shall have been obtained as a result of atleast one physical interaction between an authorised practitioner and the patient within a period of at least six months.

(5) A person who contravenes this section shall be guilty of an offence, and shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding one year, or to both.

Justification: For proper regulation of electronic sale of medicine which is already a global phenomenon as many online platforms are selling medicines to consumers and to enhance the fines in relation to the sale of scheduled substances using electronic means to ensure that quality is guaranteed.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 46—

Dietary supplements.

46A. (1) A dietary supplement shall—

(c) have a stated or implied therapeutic purpose; and

(d) not contain a scheduled substance.

(2) Where a supplement contains a dietary ingredient, the maximum daily dose for the dietary ingredient shall be as per the guidelines prescribed by the Authority.

Justification: To provide for dietary supplements which will enhance the regulation of food supplements by the Authority.

PART VI

THAT, the Bill be amended in the title of Part VI by deleting the expression "PART VI—MANUFACTURE OF MEDICINAL SUBSTANCES" and substituting therefor the expression "PART V—MANUFACTURE OF HEALTH PRODUCTS".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 47

THAT, Clause 47 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A manufacturing licence issued under this section shall be valid for a period of one year, renewable annually."

Justification: To give the manufacturing licence validity for one year.

(c) in sub-clause (3) by deleting the words "medicinal substance" and substituting therefor the words "health product;
(d) in sub-clause (4) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) by inserting the following sub-clauses immediately after sub-clause (5)—
"(6) The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product regulated under this Act.

(7) The personnel qualified to conduct lot release of vaccines and batch release of health products shall submit their qualifications to the Authority.

(8) A person who commits an offence under this section shall on conviction, be liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding ten years, or to both."

Justification: Substandard, falsified and falsely labelled health products occasion serious public health challenges.

CLAUSE 48

THAT, Clause 48 of the Bill be amended by—

(a) renumbering the existing provision as sub-clause (1); and
(b) inserting the following new sub-clauses immediately after the renumbered sub-clause (1)—

"(2) The Authority shall have power to enter and inspect manufacturing premises to confirm compliance with prescribed good manufacturing practices and issue a certificate of compliance in the prescribed format upon payment of prescribed fees.

(3) The Cabinet Secretary shall make regulations for the better carrying out of the provisions of this section.

(4) Without prejudice to the generality of subsection (3), the Cabinet Secretary shall make regulations on—

(d) revocation and suspension of manufacturing licences;
(e) withdrawal of revocation of manufacturing licences upon request; and
(f) transfer of manufacturing licences."

Justification: To give the Authority power to enforce compliance with good manufacturing practices as recommended by WHO which will in turn encourage continuous improvement of internal quality control systems and production processes by manufacturers.

The amendment also seeks to provide the specific instances in which the Cabinet Secretary shall have power to make regulations in regards to compliance with good manufacturing practice.

PART VII

THAT, the Bill be amended in the title of Part VII by deleting the expression "PART VII" and substituting therefor the expression "PART VI".

Justification: To correct a minor error in numbering of the parts of the Bill.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 50—

Information that is required to be displayed on the pack.

50A. (1) A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;

(b) the net weight of the theraupetic cosmetic;

(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;

(d) the name and address of the manufacturer of the therapeutic cosmetic;

(e) a warning statement; and

(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

(2) The Cabinet Secretary shall make regulations for the effective implementation of this section.

(3) The regulations made under subsection (1) may—

(a) require manufacturers of cosmetics to register with the Authority; and

(b) impose restrictions, requirements or other conditions on manufacturers of cosmetics, if such restrictions, requirements or conditions are necessary to protect public health.

Justification: To enhance transparency on the ingredients used in therapeutic cosmetics in line with the Good Manufacturing Practices

CLAUSE 51

THAT, Clause 51 of the Bill be amended by inserting the phrase "and shall on conviction be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both" immediately after the word "offence".

Justification: To expressly provide the penalty for the sale of therapeutic cosmetics under insanitary conditions.

CLAUSE 52

THAT, Clause 52 of the Bill be amended by deleting the phrase "have a therapeutic effect or value shall be treated as a medicine" and substituting therefor the phrase "treat, diagnose or prevent disease, or affect the structure or functions of the body shall be treated as a health product or technology".

Justification: Using the term "therapeutic cosmetic" already indicates that the cosmetic has therapeutic effect hence there is no need to restate the same.

The amendment also seeks to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 54

THAT, Clause 54 of the Bill be amended bydeleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

> "(3) A person who manufactures, sells, supplies, imports or exports a therapeutic cosmetic which contains a prohibited ingredient commits an offence and, shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both."

Justification: To provide for a penalty for the offence of manufacturing or selling therapeutic cosmetics that contain prohibited ingredients.

PART VIII

THAT, the Bill be amended in the title of Part VIII by deleting the expression "PART VIII" and substituting therefor the expression "PART VII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 55

THAT, Clause 55 of the Bill be amended by deleting sub-clause (1) and substituting therefor the following new sub-clause—

> "(1) The Registrar shall keep in the prescribed form a register of all medical devices approved by the Authority."

Justification: To make provision for the inclusion in the register of all medical devices as defined in clause 2 and approved by the Authority.

CLAUSE 56

THAT, Clause 56 of the Bill be amended by deleting sub-clause (1) and substituted therefor the following new sub-clause—

"(1) A person shall not sell any medical device that is—
(a) not registered by the Authority;

(b) adulterated;
(c) substandard, falsified, falsely labelled or counterfeited; or
(d) which fails to comply in any way with specifications of this Act or any other law."

Justification: To incorporate internationally accepted terminology, and to redraft for proper grammatical flow.

CLAUSE 57

THAT, Clause 57 of the Bill be amended by inserting the phrase "and shall, on conviction be liable to a fine not exceeding two million shillings, or imprisonment for a term not exceeding three years, or to both" immediately after the words "commits an offence".

Justification: To specifically provide a penalty for the offence of deceptive labelling, packaging and sale of medical devices.

CLAUSE 58

THAT, Clause 58 of the Bill be amended—

(a) in sub-clause (2) by inserting the phrase "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" immediately after the word "Authority";

Justification: This will enable the country to comply with WHO standards on manufacturing.

(b) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act, 2019 documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

(4) An importer, distributor or dealer shall establish and implement documented procedures for the maintenance of importation or distribution records and shall maintain an importation or distribution record of each medical device to be submitted to the Authority."

Justification: To allow the Authority to consult and receive advice from the Kenya Nuclear Regulatory Authority that exercises regulatory control over nuclear and radioactive materials and facilities under section 6(c)(i) of the Nuclear Regulatory Act, No. 29 of 2019. To require importers, distributors or dealers to keep records of medical devices submitted to the Authority.

CLAUSE 59

THAT, Clause 59 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "unregistered establishments for medical devices and" immediately after the word "under"; and

(b) by deleting sub-clause (3) and substituting therefor the following new sub-clause—

"(3) A person who sells or supplies unapproved medical devices commits an offence and shall, on conviction be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both."

Justification: To provide for the registration of establishments for medical devices by the Authority.

The amendment further seeks to amend sub-clause (3) for proper grammatical flow and to provide a penalty for the offence of supply of unapproved medical devices.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 59—

Registration of medical devices establishment.

59A. (1) An application for registration of a medical devices establishment shall be submitted to the Authority in the prescribed format and shall be accompanied by the prescribed fees.

(2) An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority of such system.

(3) Where the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Director-General shall issue a registration certificate for the medical devices establishment in the prescribed format.

(4) A medical devices establishment registration certificate issued under this section shall be valid for a period of one year, renewable annually upon application in accordance with the prescribed conditions.

(5) The registration certificate for manufacturers shall be valid for five years following a successful reinspection.

(6) The Authority may refuse to issue a medical devices establishment registration certificate where—

(a) an applicant has made a false or misleading statement in the application;

(b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

(c) an applicant has failed to meet the prescribed conditions for medical devices establishment registration.

(7) Where the Authority does not issue a medical devices establishment registration certificate under subsection (6), the Authority shall—

(c) notify the applicant in writing of the reasons for refusing the registration of the establishment; and

(d) cause the applicant to be notified that the applicant may, within a period of three months from the date of notification, furnish the Authority with additional relevant documentation or evidence in support of the application.

(8) After the issuance of a medical devices establishment registration certificate, where there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Authority within ten working days of the change.

Justification: To make provision for the registration of establishments for medical devices.

NEW PART

THAT, the Bill be amended by inserting the following new Part immediately after the new clause 59A—

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

59B. (1) The Authority shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system.

(2) The Centre established under subsection (1) shall receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority.

(3) The Authority shall conduct both passive surveillance and active surveillance of health products and technologies.

(4) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements.

(5) All entities responsible for placing a health product or technology in the market shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies.

(6) The entities referred to in subsection (5) shall submit safety information to the Authority in the prescribed manner.

(7) The consumers, general public and health care professionals shall report adverse reactions and adverse events to the Authority in the prescribed manner.

Justification: To anchor the role of the Authority in the regulation of pharmacovigilance in the country.

PART XI

THAT, the Bill be amended in the title of Part XI by deleting the expression "PART XI" and substituting therefor the expression "PART IX".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 60

THAT the Bill be amended by deleting Clause 60 and substituting therefor the following new clause 60—

Establishment of the National Quality Control Laboratory.

60. (1) There is established the National Quality Control Laboratory of the Authority which shall be used as a facility for—

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;

(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;

(d) providing technical support to local manufacturers and building their capacity in matters pertaining to quality control of regulated products through on site and off site training and laboratory assessments;

(e) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;

(f) conducting research and training and providing high quality analytics and expert knowledge in the areas of health products and technologies and active pharmaceutical ingredients; and

(g) developing and administering a data bank on quality assurance on behalf of the Authority.

(2) The National Quality Control Laboratory shall be the quality control laboratory of health products and technologies for the Authority.

(3) The Board shall appoint a Director of the National Quality Control Laboratory who shall be responsible to the Authority for the day to day management of the National Quality Control Laboratory.

(4) The Director of the National Quality Control Laboratory shall hold office on such terms and conditions of service as may be specified in the instrument of appointment by the Board.

(5) The Director of the National Quality Control Laboratory shall be a registered pharmacist and shall possess a Master's degree in a science related field from a recognized university.

(6) The Director of the National Quality Control Laboratory shall—

(a) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;
(b) ensure timely quality control testing of all samples in conformity with national and international standards;
(c) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;
(d) collaborate with other laboratories, regulatory and law enforcement agencies to ensure quality in health products and technologies;
(e) handle appeals on test results;
(f) where the laboratory lacks capacity, subcontract laboratory testing services;

(g) advice the Authority on matters of testing and quality control over health products and technologies; and
(h) perform any other duties assigned by the Authority from time to time.

(7) The funds to be used for the management of the National Quality Control Laboratory shall consist of all moneys received or recovered under this Part and a portion of the moneys appropriated by the National Assembly to the Authority.

(8) Subject to subsection (7), the monies generated by the National Quality Control Laboratory in the course of the performance of its functions under this section shall be solely expended on the Laboratory.

Justification: The NQCL, headed by a Director appointed by the Authority, to become a regulatory laboratory of the Authority as recommended by the WHO so that the country can achieve Maturity Level 3. To ringfence monies for the Laboratory such that monies generated by the Laboratory shall be solely expended on the Laboratory and the Authority ought to give a portion of the monies appropriated to it by Parliament to the Laboratory.

CLAUSE 61

THAT, Clause 61 of the Bill be amended in sub-clause (1) by deleting the words "Director-General" and substituting therefor the words "Director of the National Quality Control Laboratory".

Justification: For compliance with WHO guidelines which requires that a certificate of analysis should be issued by a person capable of ensuring the authenticity of the test samples.

PART XII

THAT, the Bill be amended in the title of Part XII by deleting the expression "PART XII" and substituting therefor the expression "PART X".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 63

THAT, Clause 63 of the Bill be amended—

(c) in sub-clause (1) by deleting the phrase "medicine, drug, appliance or article" wherever it appears and substituting therefor the words "health product or technology"; and

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(d) in sub-clause (2) by inserting the words "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (d).

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on diseases listed in the Sixth Schedule.

CLAUSE 64

THAT, Clause 64 of the Bill be amended by—

(a) deleting the phrase "a medicine, drug, appliance or article" and substituting therefor the phrase "health product or technology"; and

(b) deleting the phrase "drug, appliance or article" and substituting therefor the phrase "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 65

THAT, Clause 65 of the Bill be amended—

(a) in paragraph (a) by—

(iii)deleting the words " or similar article"; and

(iv)deleting the word "extravagant,".

Justification: To ensure objectivity.

(b) in paragraph (b) by deleting the word " an article" and substituting therefor the words "a health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 66

THAT, Clause 66 of the Bill be amended—

(a) in sub-clause (1) by—

(iii)deleting the phrase "drug, appliance or article" wherever they appear in paragraph (a) and substituting therefor the phrase "health product or technology"; and

(iv)deleting the phrase "medicine, drug, appliance or article" appearing in paragraph (b) and substituting therefor the phrase "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (3) by—

(iii)renumbering the provision as sub-clause (2); and

(iv)by inserting the phrase ", enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (ii).

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on abortion and false or misleading advertisements.

CLAUSE 67

THAT Clause 67 of the Bill be amended—

(a) by deleting the word "articles" appearing in the marginal note and substituting therefor the words "health products and technologies";

(b) by deleting sub-clause (1) and substituting the following new sub-clauses–

"(1) Subject to this Act, a person shall not sell by retail a health product or technology consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the health product or technology or on a label affixed thereto, or if the health product or technology is sold or supplied in more than one container, on the inner container or on a label affixed thereto—

(c) the appropriate designation of the substance so recommended or of each of the active constituents, or of each of the ingredients from which it has been compounded; and

(d) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients:

(1A) Subsection (1) shall not apply to a health product or technology made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person."

(c) in sub-clause (2) by deleting the word "article" wherever it appears in the definition of "appropriate quantitative particulars" and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(d) in sub-clause (3) by—

(i) deleting the word "an article" appearing in the opening statement and substituting therefor the words "a health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(ii) deleting the words "two hundred thousand" appearing in paragraph (a) and substituting therefor the words "one million";

(iii)deleting the words "three hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

Justification: To make the fines payable commensurate to the offences relating to labeling of health products and technologies containing medicine.

CLAUSE 68

THAT, the Bill be amended by deleting Clause 68.

Justification: It is preferable to make provision for valid exemptions through regulations as opposed to providing defences for offences relating to labeling of medicines.

CLAUSE 69

THAT, Clause 69 of the Bill be amended by—

(c) deleting the word "article" and substituting therefor the words "health product or technology"; and
(d) deleting the word "articles" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIII

THAT, the Bill be amended in the title to Part XIII by deleting the expression "PART XIII" and substituting therefor the expression "PART XI".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 71

THAT, Clause 71 of the Bill be amended—
(a) in the marginal note by deleting the phrase "medicines or medical devices" and substituting therefor the phrase "health products and technologies"; and
(b) in sub-clause (1) by deleting the phrase "or homoeopathic medicine, preparation or medical device" and substituting therefor the phrase "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 72

THAT, Clause 72 of the Bill be amended—
(a) in the marginal note by deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—
(i) deleting the words "a person" and substituting therefor the words "a registered pharmacist"; and
(ii) inserting the phrase "including a health product and technology for emergency use" immediately after the word "technology"; and

Justification: To make provision for supply of health products and technologies during emergency situations.

The amendment also seeks to ensure that supply of health products and technologies shall only be undertaken by registered pharmacists.

(c) in sub-clause (3) by deleting the words "medicine or medical device product" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 73

THAT, Clause 73 of the Bill be amended—

(a) in the marginal note by deleting the word "goods" and substituting therefor the words "health products and technologies".
(b) in sub-clause (1) by deleting the words "drug, article" wherever they appear and substituting therefor the words "health product or technology";
(c) in sub-clause (2) by deleting the words "drug or article" wherever they appear and substituting therefor the words "health product or technology";
(d) in sub-clause (3) by deleting the words "drug or article"and substituting therefor the words "health product or technology"; and
(e) in sub-clause (4) by deleting the words "drug or article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 79

THAT, the Bill be amended by deleting Clause 79 and substituting therefor the following new clause 79—

Inspection and verification of health products and technologies at the ports of entry.

79. (1) A person who imports a health product or technology shall notify the inspectors of the Authority at the ports of entry to conduct pre-clearance inspection and verification.

(2) A person who imports a health product or technology and causes it to be released to the market without inspection and verification under subsection (1) commits an offence.

(3) A person who commits an offence under this section shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

Justification: Clause 79 be deleted as the function of inspection of animals intended for slaughter is outside the regulatory purview of the Authority.

The new clause on inspection and verification of health products and technologies at the ports of entry enables the Authority to enforce compliance with the prescribed standards of quality, safety and efficacy of health products and technologies before release at the ports of entry so as to prevent concealment, misdeclaration, diversion and cross border smuggling of health products and technologies.

CLAUSE 80

THAT, Clause 80 of the Bill be amended—

(a) in sub-clause (1) by—

(iii)deleting the word "article" wherever it appears and substituting therefor the words "health product or technology"; and

(iv)inserting the words "or any other vessel" immediately after the word "vehicle" appearing in paragraph (b).

(b) in sub-clause (6) by deleting the word "article" and substituting therefor the words "health product or technology";

(c) in sub-clause (7) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(d) in sub-clause (8) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(e) in sub-clause (9) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(f) in sub-clause (10) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(g) in sub-clause (11) by deleting the word "article" and substituting therefor the words "health product or technology";

(h) in sub-clause (12) by deleting the word "article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

To expand the scope to include all other means of conveying health products and technologies.

CLAUSE 81

THAT, the Bill be amended by deleting Clause 81.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

CLAUSE 82

THAT, the Bill be amended by deleting Clause 82.

Justification: Regulation is a function of National Government under the Fourth Schedule to the Constitution.

CLAUSE 83

THAT, the Bill be amended by deleting Clause 83.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

CLAUSE 85

THAT, Clause 85 of the Bill be amended by deleting the word "article" wherever it appears and and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 86

THAT, Clause 86 of the Bill be amended in sub-clause (1) by deleting paragraph (b) and substituting therefor the following new paragraph (b)—

"(b) in the case of a subsequent offence, to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both."

Justification: To make enhance the general penalty for offences committed in relation to this Bill and to make the fines payable commensurate to the imprisonment terms.

CLAUSE 87

THAT, Clause 87 of the Bill be amended in sub-clause (1) by deleting the word "article" wherever it appears in paragraph (c) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIV

THAT, the Bill be amended in the title of Part XIV by deleting the expression "PART XIV" and substituting therefor the expression "PART XII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 88

THAT, Clause 88 of the Bill be amended by deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) such monies as may be appropriated by the National Assembly for the purposes of the Authority".

Justification: For proper drafting and consistency in the wording used in the Statute Book.

CLAUSE 90

THAT, Clause 90 of the Bill be amended in sub-clause (2) by deleting the words "think fit" appearing in paragraph (f) and substituting therefor the words "consider appropriate".

Justification: The amendment is necessary for proper grammatical flow.

CLAUSE 91

THAT, Clause 91 of the Bill be amended—

(a) in sub clause (3) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General"; and

(b) in sub clause (4) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General".

Justification: For proper reference to the Auditor-General as designated under Article 229 of the Constitution and which is the successor of the Kenya National Audit Office.

CLAUSE 92

THAT, Clause 92 of the Bill be amended in sub-clause (2) by inserting the phrase ", with the approval of the Cabinet Secretary of the National Treasury" immediately after the word "may".

Justification: This amendment provides that the Authority may invest its funds only with the approval of the Cabinet Secretary for the National Treasury.

PART XV

THAT, the Bill be amended in the title of Part XV by deleting the expression "PART XV" and substituting therefor the expression "PART XIII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—

(i) deleting the word "drugs," in paragraph (a)(i);

(ii) deleting the words "any drug" in paragraph (a)(ii);

(iii) deleting the word "product" and substituting therefor the word "products" in paragraph (d);

(iv) deleting the word "drugs" wherever it appears and substituting therefor the words "health products or technologies" in paragraph (h);

(v) deleting the word "article" and substituting therefor the words "health product or technology" in paragraph (k);

(vi) deleting the word "articles" and substituting therefor the words "health products and technologies" in paragraph (m);

(vii) deleting the words "drugs, medical devices" and substituting therefor the words "health products and technologies" in paragraph (o);

(viii) deleting the word "medicines" and substituting therefor the words "health products and technologies" in paragraph (v);

(ix)deleting paragraph (x) and substituting therefor the following new paragraph (x)—

"(x) governing administration of clinical trials of health products and technologies;"

(x) deleting the words "medicine, medical device" and substituting therefor the words "health product or technology" in paragraph (aa);

(xi)deleting paragraph (bb) and substituting therefor the following new paragraph—

"(bb) providing for the manner in which a pharmacist, an enrolled pharmaceutical technologist or a person otherwise authorized under this Act may dispense health products or technologies";

Justification: For inclusion of pharmaceutical technologists who are currently involved in the dispensing of medicines and medical devices pursuant to the Pharmacy and Poisons Act, Cap. 244 and their scope of training.

(xii) deleting paragraph (dd) and substituting therefor the following new paragraph (dd)—

"(dd) the compounding of health products and technologies and the dispensing of health products and technologies"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(xiii) deleting the words "generally, for giving effect to this Act" appearing in paragraph (ii);

Justification: The general provision on the making of regulations is set out in sub-clause (1).

(xiv) inserting the following new paragraphs immediately after paragraph (ii)—

"(jj) on pharmacovigilance and post market surveillance;

(kk) official regulatory lot release of vaccines and other biological products imported and manufactured in Kenya;

(ll)pricing of health products and technologies;

(mm) good practices in the regulation of health products and technologies;

(nn) inspections, licensure and certification of the manufacture of health products and technologies by health facilities;

(oo) inspections, licensure and certification of manufacture of health products and technologies and other regulated products by facilities not directly regulated by the Authority including steel industries, sugar industries;

(pp) inspection and recognition of pharmaceutical quality control laboratories;

(qq) to regulate licit use of narcotic and psychotropic substances; and
(rr) to regulate parallel importation of health products and technologies;"

(b) by renumbering sub-clause (2) as sub-clause (3).

Justification: To provide for the making of regulations on licit use of narcotic and psychotropic substances, parallel importation of medicines, safety monitoring, pharmacovigilance and post market surveillance.

CLAUSE 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting paragraph (d) and substituting therefor the following new paragraph (d)—

"(d) all members and staff of the former Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Board."

(ii) inserting the following new paragraph immediately after paragraph (d)—

"(e) the staff of the Pharmacy and Poisons Board for the time being working in the directorate responsible for the regulation of health products and technologies shall be deemed to be staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as staff of the Pharmacy and Poisons Board."

(b) by deleting the sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) In this section, "the former Board" means the Board of the National Quality Control Laboratory established under the Pharmacy and Poisons Act, Cap. 244."

Justification: To provide for the transition of both the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory.

(c) in sub-clause (3)—

(a) by deleting the word "twelve" appearing in the opening sentence and substituting therefor the words "twenty-four";

(b) by inserting the following new paragraph immediately after paragraph (b)—

"(c) after the expiry of the period of twenty four months—

(i) the Pharmacy and Poisons Board shall be dissolved, and the provisions of subsection (1)(a), (b) and (c) shall, with the necessary modifications, apply; and

(ii) the remaining members and staff of the Pharmacy and Poisons Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the Pharmacy and Poisons Board."

Justification: To provide sufficient time which will facilitate the conduct of extensive stakeholder participation on the regulation of pharmacy practice regulation.

The amendment further seeks to ensure that the Pharmacy and Poisons Board shall continue to exist for a period of two years after the enactment of the Bill, for purposes of regulation of the pharmacy profession and pending the enactment of legislation by Parliament of a law to regulate the pharmacy profession.

CLAUSE 97

THAT, Clause 97 of the Bill be amended by inserting the words "with reference to section 96 (3)" immediately after the words "that Schedule" in sub-clause (1).

Justification: To prevent a lacuna in respect of the regulation of the pharmaceutical practice.

SECOND SCHEDULE

THAT, the Bill be amended by deleting the Second Schedule.

Justification: The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

THIRD SCHEDULE

THAT, the Bill be amended by deleting the Third Schedule.

Justification: The matters of the tenure of office, allowances, protection from liability and disclosure of interest by Board members are already provided for in the main Bill. The issue of approval of the Board members by the Parliament has been proposed for deletion as the Authority's Board members are not State Officers.

FOURTH SCHEDULE

THAT, the Bill be amended by deleting the Fourth Schedule and substituting therefor the following new Schedule—

FOURTH SCHEDULE (s. 21 (2))

SCIENTIFIC ADVISORY COMMITTEES

1. Human Health Products and Technologies Committee.
2. Pharmacovigilance Committee.
3. Cosmetics and Borderline Products Committee.
4. Clinical Trial Scientific Technical Advisory Committee.
5. Dietary Supplements Committee.
6. Digital Health and Technologies Committee.
7. Veterinary Health Products and Technologies Committee.

Justification: The scientific advisory committees amended to take into account all aspects of health products and technologies and to delete the Scientific Advisory Committees on food which is outside the scope of the Bill as amended.

SEVENTH SCHEDULE

THAT, the Seventh Schedule of the Bill be amended by—

(a) deleting the word "Board" in the paragraph on Cap. 244
(b) deleting the phrase "(s. 116) and substituting the phrase ("s.97").

Justification: For proper cross referencing of the Pharmacy and Poisons Act, Cap. 244 and clause 97 on repeals.

(c) deleting the paragraph on Cap. 254.

Justification: Food is outside the purview of the Bill.

ANNEXURE 1- MINUTES OF THE COMMITTEE SITTINGS

MINUTES OF HUNDRED AND TWENTIHY NINETH (129TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON THURSDAY 2ND NOVEMBER, 2023 AT 2.00 P.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P -**Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha	- Principal Clerk Assistant II
2.	Mr. Hassan A. Arale	- Clerk Assistant I
3.	Ms. Christine Odhiambo	- Senior Legal Counsel
4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant at Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

MIN. NO. NA/DC-H/2023/493: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 2.30 p.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/494: CONSIDERATION AND ADOPTION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) DURING THE WINNOWING PROCESS

Having considered all the proposed amendments as proposed by the Committee and the honourable members, the Committee agreed upon the harmonized version of amendments (attached schedule of amendments)

The Committee adopted the report of the proposed amendments to the Kenya Drugs Authority Bill (NA Bill No. 54 of 2022) during the winnowing process as the true reflection of the

Committee deliberations after it was proposed by the Hon. Mary Maingi, MP and seconded by Hon. Dr. Jamaes Nyikal, MP and made the following observations.

Having considered all the proposed amendments as proposed to the Kenya Drugs Authority Bill, 2022, by the Committee and individual Honourable Members submissions the Committee made the following observations on each of the proposed amendment: -

1. There is need to retain the regulation of herbal medicines in the Bill, and to this effect, the Committee proposes the amendment of the definition of "health products" to include herbal medicine. Further, there is need to exclude traditional and alternative medicine from the ambit of the Bill. The Committee notes that there will be need to come up with legislation to give effect to the provisions of the Health at, No. 21 of 2017, which mandates Parliament to establish a regulatory body to regulate the practice of traditional medicine and alternative medicine.
2. The Committee notes that the Registrar was not defined in the Bill, and to this end, there is need to introduce the definition of the term "Registrar" to mean the Director-General of the Authority.
3. There is need to ensure a smooth transition from the Pharmacy and Poisons Board to the Health Products and Technologies Regulatory Authority. The Committee notes that during the transition period, the staff of the Pharmacy and Poisons Board dealing with the regulation of health products and technologies would have to move to the Authority immediately upon the enactment of the Bill, while the Pharmacy and Poisons Board will continue to exist for a period of two years to regulate the pharmacy practice. The Committee further notes that within the two-year transition period, Parliament will have to enact a legislative framework for the regulation of the pharmacy profession.

MIN. NO. NADC-H/2023/495: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 4.30 p.m.

Sign.....Date 2/11/2023

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

MINUTES OF HUNDRED AND TWENTIHY EIGHTH (128TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON THURSDAY 2ND NOVEMBER, 2023 AT 9.00 A.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P **-Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha	- Principal Clerk Assistant II
2.	Mr. Hassan A. Arale	- Clerk Assistant I
3.	Ms. Christine Odhiambo	- Senior Legal Counsel
4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant At Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

MIN. NO. NA/DC-H/2023/490: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 9.30 a.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/491: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY THE HON. DR. ROBERT PUKOSE, MP CHAIRPERSON DEPARTMENTAL COMMITTEE ON HEALTH

Long Title

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

> "AN ACT of Parliament to establish a comprehensive legal framework for the regulation of Health Products and Technologies; to safeguard public health through development of

a regulatory system to ensure safety, quality, efficacy, effectiveness and performance of health products; to establish the Kenya Health Products and Technologies Authority and for connected purposes".

Justification: The amendment accords with international best practice and sets out the main purpose of the Bill which is to establish a centralized regulatory authority for health products and technologies.

CLAUSE 1

THAT, Clause 1 of the Bill be amended by

(a) deleting the phrase "Kenya Drugs Authority Act, 2022" and substituting therefor the phrase "Kenya Health Products and Technologies Regulatory Authority Act, 2022";

Justification: The amendment accords with international best practice and comprehensively covers the mandate of the proposed Authority.

(b) deleting the words "and commencement" in the marginal note.

Justification: To limit the marginal note to the content of clause 1 which only sets out the name of the Bill. The Clause does not make any provision as regards the commencement of the Bill.

CLAUSE 2

THAT Clause 2 of the Bill be amended

(a) in the definition of "article" by

(i) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (a); and

(ii) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (b);

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(b) in the definition of "Authority" by deleting the words "Kenya Drugs Authority" and substituting therefor the words, "Kenya Health Products and Technologies Regulatory Authority";

Justification: To ensure harmony with the title of the Bill as proposed for amendment.

(c) in the definition of "chemical substance" by deleting the words "or detergent";

Justification: To exclude detergents which are used for cleaning inanimate objects and does not fall under the purview of the regulation of health products and technologies.

(d) in the definition of "drug" by deleting the word "if" appearing in paragraph (b)(ii) and substituting therefor the word "of";

Justification: To correct a minor typographical error.

(e) by deleting the definition of "enrolled pharmaceutical technologist";

Justification: The current definition cross references the Pharmacy and Poisons Act, cap. 244 which will be repealed as provided under clause 97. A new definition proposed.

(f) in the definition of "health products and technologies" by inserting the words, "dietary supplement" immediately after the words, "therapeutic cosmetics";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(g) by deleting the definition of "herbal medicine or product";
(h) by deleting the definition of "medical device";
(i) by deleting the definition of "medicinal substance";

Justification: New definitions provided for these terms. These new definitions expand the scope to cover all aspects of the use of medical devices and medicinal substances in relation to health and to include herbal materials and herbal combinations.

(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";

Justification: For inclusion of dietary supplements which are part of health products and technologies.

(k) by deleting the definition of "pharmacy";

Justification: The current definition is inadequate. The term to be defined in the proposed Pharmaceutical Practice Bill.

(l) by deleting the definition of "pharmaceutical technologist";

Justification: The Pharmacy and Poisons Act, cap. 244 provides that a pharmaceutical technologist must be enrolled in the roll established under this Act

(m) by deleting the definition of "registered midwife";

Justification: The term is no longer used in the Bill in line with the proposed amendment of clause 43 (1)(c).

(n) in the definition of "scheduled substance" by deleting the words "in the relevant schedule under this Act" and substituting therefor the words "in the list published by the Cabinet Secretary under section 37 of this Act";

Justification: There is no Schedule on scheduled substances. The Cabinet Secretary will publish the list of scheduled substances in the *Gazette*.

(o) by deleting the definition of "therapeutic cosmetic"; and

Justification: The current definition defines cosmetics in general that are meant to provide the body with appropriate aesthetics, texture, pH, color and smell. It is not specific to special cosmetics.

(p) by inserting the following new definitions in their proper alphabetic sequence

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"adverse event" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment;

"biologicals" means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies and includes products derived from human blood and plasma;

"Board" means the Board of the Authority established under section 8;

"Centre" means the National Pharmacovigilance Centre established under section 59B;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dietary supplement" means a product taken by mouth that is added to the diet to help meet daily requirements of essential nutrients, and which usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

"enrolled pharmaceutical technologist" means a person enrolled as such by the body for the time being responsible for the enrolment of pharmaceutical technologists;"

"falsified medical product" means a product that is deliberately or fraudulently misrepresented in relation to its identity, composition or source;

"Field Safety Corrective Action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, and includes

(a) the return of a medical device to the product owner or its representative;

(b) device modification which may include

(i) retrofit in accordance with the product owner's modification or design change;

(ii) permanent or temporary changes to the labelling or instructions for use;
(iii) software upgrades including those carried out by remote access;
(iv) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;
(v) device exchange;
(vi) device destruction; or
(vii) advice given by product owner regarding the use of the device.

"health product" includes a medicine, medical product, medicinal substance, vaccine, diagnostic, medical device, blood or blood product, traditional and alternative medicine, therapeutic feed and nutritional formulation, cosmetic and related products;

"health technology" means the application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives;

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations;

"in-vitro diagnostics medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector and who holds a minimum of a diploma in pharmacy;

"lot" or "sub-lot" means a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous; and in the case of continuous manufacture, the lot corresponds to a defined fraction of the production characterized by its intended homogeneity;

"lot release" means the process of the evaluation of an individual lot of a licensed biological product by the Authority before giving approval for its release onto the market;

"marketing authorization" means the certificate of registration issued by the competent health product regulatory authority in the country of origin for the purpose of marketing or free distribution of a health product after evaluation for safety, efficacy and quality;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;
(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importation" means importation into Kenya, by a licensed importer of a health product other than the marketing authorization holder or his or her technical representative, of the following health products which require marketing authorization in Kenya

(a) patented health products under section 58(2) of the Industrial Property Act, 2001;
(b) non-patented health products; or
(c) branded generic health products;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;

"scheduling" means, in relation to a substance, the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;

"substandard medical product" means a registered medical product that fails to meet either its quality standards or specifications, or both;

"therapeutic cosmetic" means a cosmetic which—

(a) offers an additional benefit to a person over an ordinary cosmetic; or

(b) contains a bioactive product formulated from an animal ingredient that may have visible and measurable short or long-term effects on a person, and may include a product that may be absorbed through the skin or a mucous membrane;

"unregistered medical product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;

"vessel" means a truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;

Justification: The new definitions are internationally recognized by the World Health Organization and are critical for the execution of regulatory functions of the Authority.

To further identify the Board as used in the Bill.

To provide new definitions for the words: enrolled pharmaceutical technologist, therapeutic cosmetic, herbal medicine, medical device and medicinal substances.

CLAUSE 3

THAT, Clause 3 of the Bill be amended by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(l) This Act applies to the regulation of—

(a) medicines, medical products and technologies;
(b) medical devices including radiation emitting products;
(c) radiopharmaceuticals;
(d) complementary, alternative or herbal medicines;
(e) cosmetics and Borderline Products;
(f) in-vitro diagnostics medical devices;
(g) therapeutic feeds;
(h) clinical trials;
(i) nutraceuticals and dietary supplements;
(j) digital health and technologies;
(k) scheduled substances;
(l) chemical substances; and
(m) biological products for use in humans and the starting materials used in their manufacture."

Justification: To comprehensively cover all aspects in the regulation of health products and technologies.

CLAUSE 4

THAT, Clause 4 of the Bill be amended in sub-clause (1) by deleting the words "Kenya Drugs Authority" and substituting therefor the words "Kenya Health Products and Technologies Regulatory Authority".

Justification: This accords with international best practice on the establishment of a centralized regulatory authority for health products and technologies.

CLAUSE 5

THAT, Clause 5 of the Bill be amended by deleting the words, "but the Authority may establish branches anywhere in Kenya" and substituting therefor the words "or in such other place as the board of the Authority may, by resolution, determine".

Justification: To give the Board discretion in determining the location of the Authority's headquarters.

CLAUSE 6

THAT, Clause 6 of the Bill be amended

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)

"(1) There shall be a Director-General who shall be the chief executive officer of the Authority."

Justification: For proper drafting of the clause.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)

"(2) The Director-General shall be appointed by the Board, through a transparent and competitive process, on such terms as may be specified in the instrument of appointment."

Justification: The Director General is not a State Officer and should therefore be appointed by the Authority without the approval by Parliament.

(c) in sub-clause (3) by deleting the word "four" and substituting therefor the word "three".

Justification: Appointments and term of service in State Corporations are normally capped at three (3) years which is renewable for one final term.

(d) by deleting sub-clause (4) and substituting the following new sub-clause (4)—

"(4) A person shall be qualified for appointment as a Director-General if such person

(a) holds a bachelor's degree in pharmacy from a university recognized in Kenya;
(b) holds a masters' degree in pharmacy, medicine or any relevant field from a university recognized in Kenya;
(c) has at least ten years' experience in pharmacy or its equivalent;
(d) has served in a senior management position for at least five years;
(e) is a member of a professional body; and
(f) meets the requirements of Chapter six of the Constitution."; and

Justification: The Director General should be a qualified pharmacist as the regulation of health products and technologies requires specialized knowledge and technical expertise in the pharmaceutical field.

(e) by deleting sub-clause (5).

Justification: The fact that the Director-General shall be the CEO of the Authority is provided in the sub-clause (1) as proposed for amendment.

CLAUSE 7

THAT, Clause 7 of the Bill be amended in paragraph (f) by deleting the words "Act. regulation under this" and substituting therefor the words "regulation under this Act.".

Justification: To correct a typographical error.

CLAUSE 8

THAT, Clause 8 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "Kenya Drugs" and substituting therefor the words "Kenya Health Products and Technologies Regulatory';

Justification: The name of the Board should reflect the amended Title of the Bill and name of the Authority as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–

"(2) The Board shall comprise—

(a) a non-executive Chairperson appointed by the President and who shall—

(i) be a registered pharmacist of good standing with a degree in pharmacy; and

(ii) have at least ten years' experience in the pharmaceutical sector, five of which shall be at senior management level;

(b) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing;

(c) the Principal Secretary the Ministry for the time being responsible for finance or a representative designated in writing;

(d) the Director-General for Health or a representative designated in writing;

(e) one person nominated by the Pharmaceutical Society of Kenya;

(f) one person nominated by the Kenya Pharmaceutical Association;

(g) one person nominated by the Kenya Medical Association;

(h) one person, not being a Governor, with knowledge and experience in health products and technologies nominated by the Council of County Governors to represent the interests of counties;

(i) one person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(j) the Director-General of the Authority who shall be the secretary and an *ex officio* member of the Board."; and

Justification: The composition of the Board should comply with the *Mwongozo* Code of Governance for State Corporations in terms of numbers, skill mix and professional expertise which should include all relevant players involved in the matters of health products and technologies.

(c) by deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—
"(3) The Cabinet Secretary shall appoint the members of the Board under subsection (e), (f), (g), (h) and (i) by notice in the *Gazette*."

Justification: The members of the Board Members are not State Officers and hence their appointment does not require approval by Parliament. It is sufficient that the Cabinet Secretary notifies the public of the appointments in the Kenya Gazette.

CLAUSE 9
THAT, the Bill be amended by deleting Clause 9.

Justification: The provision contradicts the legal framework for appointment of the Chairperson, Board Members and CEOs of State Corporations or Semi-Autonomous Government Agencies. The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

CLAUSE 10
THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "section 12" appearing in paragraph (c) and substituting therefor the words "section 11".
Justification: To correct the cross reference as clause 11 makes provision for removal from office of the members of the Board of the Authority.

CLAUSE 12
THAT, Clause 12 of the Bill be amended by
(a) inserting the following paragraphs immediately after paragraph (e)
"(ea) regulate the disposal of health products and technologies;
(eb) monitor the market for the presence of unregistered and illegal health products and technologies;
(ec) conduct analytical tests of health products and technologies";
Justification: To make provision for the functions of disposal, analytical testing and monitoring of the market by the Authority.

(b) deleting paragraph (f) and substituting therefor the following new paragraph (f)
"(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act through analysis of reports on adverse reactions and events, including any other health product and technology use related issues and take appropriate regulatory actions when necessary";
Justification: To expressly align to the WHO requirement on the establishment of a national vigilance system.

(c) deleting paragraph (g) and substituting therefor the following new paragraph (g)—
"(g) regulate clinical trials and ensure that clinical trial protocols of health products and technologies are being assessed according to the prescribed ethical and professional criteria and defined standards including mandatory bioequivalence studies";

Justification: To anchor the oversight of clinical trials in the law as recommended by the WHO.

(d) inserting the following new paragraphs immediately after paragraph (g)—
"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials, emergency use and compassionate use;
(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements";

Justification: To provide for approval of health products and technologies during emergencies and to provide for pharmacovigilance which check the safety of health products and technologies.

(e) deleting paragraph (n) and substituting therefor the following new paragraph (n)—
"(n) appoint inspectors and order inspection of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act";

Justification: To specify the premises subject to inspection by the Authority.

(f) inserting the following new paragraphs after paragraph (o)—
"(oa) conduct national regulatory authority lot release, official authority batch release of specified biologicals to ensure the quality, safety and efficacy of biological products through a regulatory release system in compliance with established approaches, policies, guidelines, procedures and in line with World Health Organization and internationally recognized guidelines;
(ob) carry out and promote research related to medicines and health products";

Justification: To enable the conduct of research by the Authority and the conduct of lot releases which are a key component in the regulation of the production of vaccines.

(g) inserting the following paragraphs after paragraph (q)—
"(qa) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;
(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;
(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;
(qd) maintain a register of all authorized health products and technologies manually or electronically;
(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the

Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;
(qf) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

Justification: To include critical functions of the Authority based on best practice in regulation of import and export of health products and technologies that will enable the country attain WHO maturity level 3.

CLAUSE 13

THAT, Clause 13 of the Bill be amended by—

(a) deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate for the furtherance of the purpose of the Act;"

(b) inserting the following new paragraphs immediately after paragraph (a)

"(aa) adopt and implement any such internationally recognized good regulatory practices;
(ab) determine and implement effective and efficient reliance mechanisms;
(ac) issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;
(ad) levy, collect and utilize fees for services rendered;
(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; (af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

Justification: To comply with WHO requirements for regulatory functions in the Global Benchmarking Tool especially on control over imports and exports.

CLAUSE 21

THAT Clause 21 of the Bill be amended

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)
"(1) The Board may establish such scientific advisory committees of the Authority, as may be necessary for the effective performance of the functions of the Authority".

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9)
"(9) An advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary".

Justification: The Scientific Advisory Committees ought to offer technical advice and report to the Board (its appointing authority) which then advices the Cabinet Secretary accordingly.

PART IV

THAT, Part IV of the Bill be amended by deleting the title and substituting therefor the following new title–

"PART III—HEALTH PRODUCTS AND TECHNOLOGIES"

Justification: To ensure harmony with the title of the Bill as proposed for amendment and to correct a minor error in numbering of the parts of the Bill.

CLAUSE 22

THAT, Clause 22 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—

(i) deleting the words "sell any medicine" appearing in the opening sentence and substituting therefor the words "sell, manufacture, supply, distribute or dispense any health product or technology";

Justification: To broaden the scope of prohibited sale of health product and technologies to include manufacturing, dispensing, distribution and supply of health product and technologies.

(ii) deleting paragraph (d) and substituting therefore the following new paragraph (d)—

"(d) is falsified,";

Justification: For alignment with international best practice as the proposed terminology is recognized by the WHO.

(c) in sub-clause (3) by—

(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) deleting the words "pharmaceutical product" appearing in paragraph (b) and substituting therefor the words, "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 23

THAT, Clause 23 of the Bill be amended in sub-clause (1) by—

(a) deleting the word "medicines" appearing in paragraph (a) and substituting therefor the words, "health products or technologies";

(b) deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words, "health products or technologies"; and

(c) deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words, "health products or technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 24

THAT, Clause 24 of the Bill be amended

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";

(b) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(c) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) If a standard has not been prescribed for a health product or technology but a standard for the health product or technology is contained in any of the publications specified in the Fifth Schedule, any person who manufactures, labels, packages, sells or advertises any other substance or article in such a manner that is likely to be mistaken for the health product or technology having met any of the standards contained in any of the publications specified in the Fifth Schedule, commits an offence.";

(d) in sub-clause (3)—

(i) by deleting the word "medicine" wherever it appears in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) by deleting the word "drug" appearing in paragraph (b) and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) in sub-clause (4)

(i) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three months" appearing in paragraph (a) and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years"; and

(ii) by deleting the words "two hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

Justification: To make the fines prohibitive and punitive due to the risk of the offences to public health.

CLAUSE 25

THAT, the Bill be amended by deleting Clause 25.

Justification: The prohibition of sale of medicines of a quality not demanded is a practice issue and falls outside the ambit of the Bill.

CLAUSE 26

THAT, Clause 26 of the Bill be amended by—

(a) deleting the word "medicine" appearing in the marginal note and substituting therefor the words "health product or technology"; and
(b) deleting the word "medicine" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 27

THAT, Clause 27 of the Bill be amended—

(a) by deleting the words "medicinal products" appearing in paragraph (a) and substituting therefor the words "health products or technologies";
(b) by deleting the words "medicinal products" appearing in paragraph (b) and substituting therefor the words "health products or technologies"; and
(c) by deleting paragraph (c) and substituting the following new paragraph (c)—

"(c) the quality of the health products or technologies of each such description, according to the specification and the method or proposed method of manufacture of the health products or technologies, and the provisions proposed for securing that the health products or technologies as sold or supplied will be of that quality; and"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

NEW CLAUSES

THAT, the Bill be amended by inserting the following new clauses immediately after clause 27–

Application for product licence.

27A. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Authority for the registration of the health product or health technology in the prescribed form.

(2) An applicant under subsection (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Authority in the declaration page of the application form; and
(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—

(a) a proposed label for use on the health product or technology;
(b) a copy of the manufacturing licence of the health product or technology, where applicable;
(c) a copy of the good manufacturing practice certificate from the Authority and the regulatory authority of the

country where the health product or technology is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognized by the Authority, where applicable;

(e) a copy of the marketing authorization or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product or technology;

(h) proof of ownership of the site for the manufacture of the health product or technology, where applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body

(i) a copy of the certificate of registration;

(ii) the professional information relating to the health product or technology; and

(iii) the conditions of the registration of the health product or technology;

(k) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell poisons issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(4) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

Processing of application for registration of health

27B. (1) The Authority shall consider the application made under section 27A, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in the prescribed form.

product or technology.

(2) The Authority may, while considering the application, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;

(b) the labelling of the health product or technology;

(c) the statement of the representations to be made for the promotion of the health product or technology regarding—

(i) the claim to be made for the health product or technology;

(ii) the route of administering the health product or technology;

(iii) the dosage of the health product or technology;

(iv) the storage conditions of the health product or technology;

(v) the contra-indications, the side effects and precautions, if any of the health product or technology; and

(vi) the package size of the health product or technology.

(3) When evaluating an application, the Authority may—

(a) subject a sample of the health product or technology to an evaluation by an analyst; and

(b) consider the evaluation report of the analyst that has evaluated the health product or technology.

(4) Where the Authority is not satisfied as to the quality, safety efficacy, performance or economic value of the health product or technology, it may, after providing an opportunity to the applicant to be heard, reject the application and inform the applicant the reasons for rejection in writing.

Registration during emergency.

27C. (1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to life or health, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subsection (1) shall apply to the Authority in the prescribed form.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(4) An application under subsection (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(5) When determining an application under this section, the Authority shall consider the facts established from the valid marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for health products and technologies, if available.

(6) The person to whom the certificate of registration is issued under this section, shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) A provisional certificate of registration issued under subsection (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked.

(8) Any variation to the agreement appointing the local representative to the application made under subsection (2) shall be notified to the Authority within seven days of the variation.

Authorization of unregistered health product or technology.

27D. (1) The Authority may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product or technology that is not registered.

(2) A health product or technology distributed pursuant to authorization granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) A person who intends to obtain the authorization under subsection (1), for purposes other than a clinical trial, shall apply to the Authority in the prescribed form.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative

who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(5) The application made under subsection (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;
(b) written consent of the applicant, where applicable;
(c) details of registration or pending registration of the health product or technology with any other regulatory authority, where applicable;
(d) evidence of compliance by the manufacturer of the health product or technology with good manufacturing practice standards as determined by the Authority;
(e) reasons why a registered health product or technology cannot be used;
(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;
(g) proof that the applicant holds—
    (i) a valid practicing licence issued by the body responsible for the profession of pharmacy;
    (ii) a valid wholesale dealer's licence issued in accordance with this Act;
    (iii) a valid licence to sell health products or technologies issued in accordance with this Act; or
    (iv) a valid manufacturing licence issued in accordance with this Act; and
    (v) proof of payment of the application fees as prescribed by the Authority.

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—

(a) progress reports after every six months from the date of issuance of the authorization;
(b) any adverse event report, where an adverse event occurred; and
(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—

(a) impose any additional conditions;
(b) request additional information;

(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or
(d) withdraw the authorization to treat the patient.

(8) The Authority may, by notice in writing withdraw the authorization issued under subsection (1) if the any of purposes or the manner specified in subsection (2) is contravened.

(9) A health product or technology authorized under this section shall be labelled in accordance with this Act.

(10) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

(11) The requirements in this section shall apply to applications for donations of health products and technologies

Justification: To provide new clauses 27A, 27B, 27C and 27D for the handling of applications of product licences by the Authority.

CLAUSE 28

THAT, Clause 28 of the Bill be amended

(a) in the marginal note by deleting the words "medicines register" and substituting therefor the words "health products and technologies register";
(b) in sub-clause (1) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register"; and
(c) in sub-clause (2) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 29

THAT, Clause 29 of the Bill be amended

(a) in the marginal note by deleting the words "medicines and medical devices" and substituting therefor the words "health products and technologies";
(b) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) Every application for registration of a health product or technology shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant health product or technology and by the prescribed registration fee."

(c) in sub-clause (3)
(i) by deleting the word "medicine" appearing in paragraph (a) and substituting therefor the words "health product or technology";

(ii) by deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words "health product or technology";
(iii) by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology";

(d) in sub-clause (4) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

(e) by deleting sub-clause (6) and substituting therefor the following new sub-clause (6)—

"(6) Where the Authority has approved the registration of any health product or technology if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, the Registrar shall register that health product or technology and shall enter in the register such particulars in regard to the health product or technology as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that health product or technology."

(f) in sub-clause (7) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(g) in sub-clause (8) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(h) in sub-clause (9) by deleting the word "medicines" and substituting therefor the words "health products and technologies";

(i) in sub-clause (10) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(j) in sub-clause (11) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(k) in sub-clause (12) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(l) in sub-clause (14) by deleting paragraph (a) and substituting therefor the following new paragraph (a) —

"(a)Kenya Essential Medicines List, Kenya Essential Diagnostics list and Kenya Essential Medical Supplies list' means the list of essential medicines, diagnostics and medical supplies included in the latest editions of the official publications relating to guidelines for standard treatment which is compiled by the state department responsible for Health;"

Justification: To broaden the scope of HPTs considered under the clause.

NEW CLAUSES

THAT, the Bill be amended by inserting the following new clauses immediately after clause 29

Authorization of health products and technologies.

29A. (1) A person shall not import any health product or technology unless

(a) the imported health product or technology has been authorized through issuance of an import permit or a written authorization by the Authority; and

(b) the imported health product or technology is inspected and verified by an inspector of the Authority at the ports of entry prior to its release.

(2) No batch or lot of any registered product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in cases of biological therapeutics.

(3) Each applicable test conducted by the manufacturer under subsection (2) shall be made on each batch or lot after completion of all processes of manufacture and such test may affect compliance with the standard applicable to the product.

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

(5) Every batch or lot of a registered biological therapeutic imported into Kenya or manufactured in Kenya shall be evaluated and, on being satisfied of conformity with prescribed standards and payment of prescribed fees, the Director-General shall approve its release into the market and issue a certificate of official batch or lot release in the prescribed format.

(6) The Authority may recognize and accept official lot release certificates issued by other national regulatory authorities of other countries for a specific batch or lots of biological therapeutic manufactured within the territories of those national regulatory authorities, in issuance of a certificate under this section.

(7) A person who contravenes this section commits an offence and shall on conviction be liable

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Justification: To provide for authorization of health products and technologies imported into the country including the requirement for batch or lot release in line with WHO requirements.

Parallel importation of health products and technologies.

29B. (1) A person shall not engage in the parallel importation of a health product or technology into Kenya unless—

(a) the person is incorporated as a limited liability company under the Companies Act;

(b) the person has been granted a certificate of parallel importation;

(c) the person is licensed to parallel import the health product or technology;

(d) the health product or technology has a valid registration in Kenya under this Act; and

(e) the health product or technology has a valid market authorization in the country of origin.

(2) A person who wishes to undertake parallel importation of a health product or technology shall apply to the Board for a certificate of parallel importation in the prescribed manner.

(3) The Board shall establish and maintain a system that ensures that a registered parallel imported health product or technology can be traced from its sourcing, manufacturing, packaging, storage, transport to its delivery to the health facility, institution or private practice where the health product or technology is intended to be used.

(4) A person who—

(a) is the holder of a certificate of parallel importation or licensee and fails to comply with any requirement or obligation in this Act;

(b) contravenes any prohibition prescribed by the Authority; or

(c) fails to comply with any requirement imposed on that person by the Board pursuant to this Act,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Justification: To make provision for parallel importation of health products and technologies.

CLAUSE 30

THAT, Clause 30 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology"; and

(b) in sub-clause (3), by deleting the word "medicine" wherever it appears in paragraph (b) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 31

THAT, Clause 31 of the Bill be amended

(a) in sub-clause (1) by deleting the word "medicine" and substituting therefor the words "health product or technology"; and

(b) in sub-clause (3), by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 32

THAT, Clause 32 of the Bill be amended

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)

"(1) The Authority shall cancel the registration of a health product or technology if

(a) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(b) a particular health product or technology does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular health product or technology available to the public."

(b) in sub-clause (2) by deleting the words "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology";

(c) in sub-clause (4)

(i) by deleting the words "medicine or medical device" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) by deleting the words "medicine or medical device" appearing in paragraph (b) and substituting therefor the words "health product or technology"; and

(d) by deleting the words "medicine or medical device" wherever it appears in sub-clause (5) and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 33

THAT, Clause 33 of the Bill be amended in sub-clause (1) by deleting the words "medicine or medical device" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 34

THAT, Clause 34 of the Bill be amended—

(a) by deleting the words "medicines" and "medicine" wherever it appears and substituting therefor the words "health product or technology"; and

(b) in the marginal note by deleting the words "medicines" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";

(c) in sub-clause (2) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";

(d) in sub-clause (3) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist"; and

(e) in sub-clause (4) by inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist".

Justification: For inclusion of pharmaceutical technologists in the dispensing of interchangeable multi-source medicine.

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36

Justification: The provision is a practice related issues that is best handled through the proposed Pharmaceutical Practice Bill.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 36—

Clinical trials.

36A. (1) A health product or technology shall not be used for clinical trial unless an approval is granted by the Authority with the approval of the relevant ethics body.

(2) A person who intends to commence a clinical trial on a health product or technology shall make an application to the Authority in the prescribed form and the application shall be accompanied by the study protocol in the prescribed format and the prescribed fee.

(3) The study protocol submitted under subsection (2) shall include a post-trial access program to ensure access of investigational medicinal substances by participants in the trial before grant of marketing authorization by the Authority.

(4) The Authority shall prescribe guidelines for evaluation of applications made under subsection (2) to be implemented for accelerated evaluations during emergency situations, epidemics and outbreaks.

(5) A person granted an approval under this section shall put in place a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated and the safety and well-being of the participants of the study.

(6) The Authority shall carry out inspection of the clinical trials and monitor compliance of the clinical trials with the prescribed requirements.

(7) Any amendments to clinical trials protocols shall be submitted to the Authority for approval before implementation.

Justification: To provide for effective regulation of clinical trials by the Authority.

PART V

THAT, the Bill be amended in the title to Part V by deleting the expression "PART V" and substituting therefor the expression "PART IV".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 37

THAT, Clause 37 of the Bill be amended

(a) in sub-clause (2) by deleting the words "and dealers in mining, agricultural or horticultural accessories" appearing in paragraph (a);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)
"(3) The Cabinet Secretary shall publish the list of scheduled substances prepared under subsection (1) in the *Gazette.*"

Justification: To provide for the publication of the list of scheduled substances.

(c) by renumbering sub-clause (3) as sub-clause (4);

(d) by deleting sub-clause (4) and substituting therefor the following new sub-clauses

"(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.
(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsection (1), (2) and (3)."

Justification: To enhance the period of review of the lists of scheduled substances from one year to two years and provide for review in public interest where need arises. To ensure that the procedure set out in the clause in the preparation and publication of the list of scheduled substances is followed even when the lists are modified.

CLAUSE 38

THAT, Clause 38 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the words "the Limitations prescribed by this sub-section" and substituting therefor the words "the following limitations";

Justification: For proper drafting. The words "prescribed by this sub-section" are unnecessary.

(ii) deleting paragraph (c)

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 2,000,000.

CLAUSE 39

THAT, Clause 39 of the Bill be amended by deleting sub-clause (5) and substituting therefor the following new sub-clause (5)—

"(5) A licence issued under this section shall be valid for a period of one year, renewable annually".

Justification: Annual expiry of the licence is too punitive especially for persons who apply in the middle of the year.

CLAUSE 40

THAT, the Bill be amended by deleting clause 40.

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraphs (c) and (e);

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws. The National or County government cannot buy scheduled substances on its own, it must do so through a person licensed to do so under the Bill.

(b) in sub-clause (2) by deleting paragraph (b) and (c); and

Justification: The persons to whom a wholesaler dealer may sell scheduled substances to are set out in sub-clause (1).

(c) by deleting sub-clause (3).

Justification: Scheduled substances used in mining, agriculture and horticulture are regulated under other laws.

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "paragraph (b) of Section 53(2)" appearing in paragraph (a) and substituting therefor the words "section 41(2)(b)"; and

Justification: To correct the cross reference as clause 41 makes reference to the written certificate contemplated under clause 42.

(b) in sub-clause (3) by deleting the words "three years" and substituting therefor the words "one year"

Justification: To reduce the penalty of imprisonment from three years to one year as the same is not commensurate to the fine of one hundred thousand shillings in relation to the offence of not making entries of sale of scheduled substances in a scheduled substances book.

CLAUSE 43

THAT, Clause 43 of the Bill be amended in sub-clause (1)

(a) by deleting the opening sentence and substituting therefor the following new opening sentence

"(1) A qualified healthcare professional may supply or dispense a Scheduled Substance with therapeutic value for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following provisions "

Justification: To restrict dispensing of scheduled substances to authorized persons.

(b) in paragraph (b) by

(i) inserting the word "and" immediately after the word "supplied" appearing in sub-paragraph (iii); and

(ii) deleting the word "and" appearing in sub-paragraph (iv);

Justification: To correct a minor drafting error.

(c) by deleting paragraph (c).

Justification: Registered midwives are included in the qualified healthcare professional provided in the amended sub-clause (1).

CLAUSE 45

THAT, the Bill be amended by deleting Clause 45 and substituting therefor the following new clause 45—

Automatic machines.

45. (1) An authorized seller may use an automatic machine to dispense over-the-counter scheduled substances.

(2) The Authority shall develop regulations on the

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

Justification: To provide for the use of automatic machines in dispensing selected scheduled substances in an effort to leverage on technology.

CLAUSE 46

THAT, the Bill be amended by deleting Clause 46 and substituting therefor the following new clause 46—

Electronic sale of health products and technologies.

46. (1) The Authority shall prescribe guidelines to provide for the electronic supply and dispensing of scheduled substances including through e-pharmacy, telemedicine, medication therapy management and online pharmacy.

(2) The regulations made under subsection (1) shall provide for—

(a) licensure of e-pharmacies;
(b) safety of patients;
(c) verification of the identity and traceability of patients;
(d) verification of the identity and traceability of prescribers; and
(e) integrity, legitimacy and authenticity of prescriptions including avoidance of multiple use of the same prescription.

(3) The electronic supply and dispensing of scheduled substances shall be permitted provided that the supply of such health products and technologies conforms with all requirements for the particular health product or technology in terms of its scheduling status and any other requirements as may be specified in regulations in relation to such supply or dispensing.

(4) In the case of a prescription-only medicine, the required prescription shall have been obtained as a result of at least one physical interaction between an authorised practitioner and the patient within a period of at least six months.

(5) Any person who contravenes this section shall be guilty of an offence, and shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding one year, or to both.

Justification: For proper regulation of electronic sale of medicine which is already a global phenomenon as many online platforms are selling medicines to consumers and to enhance the fines in relation to the sale of scheduled substances using electronic means to ensure that quality is guaranteed.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 46—

Dietary supplements.

46A. (1) A dietary supplement shall —

(a) not contain scheduled substances; and
(b) have a stated or implied therapeutic purpose.

(2) Where a dietary supplement contains folic acid, the maximum daily dose for the dietary supplement shall be as per the guidelines prescribed by the Board of the Authority.

Justification: To provide for dietary supplements which will enhance the regulation of food supplements by the Authority.

PART VI

THAT, the Bill be amended in the title of Part VI by deleting the expression "PART VI — MANUFACTURE OF MEDICINAL SUBSTANCES" and substituting therefor the expression "PART IV — MANUFACTURE OF HEALTH PRODUCTS".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 47

THAT, Clause 47 of the Bill be amended

(a) in sub-clause (1) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)

"(2) A manufacturing licence issued under this section shall be valid for a period of one year, renewable annually."

Justification: To give the manufacturing licence validity for one year.

(c) in sub-clause (3) by deleting the words "medicinal substance" and substituting therefor the words "health product;

(d) in sub-clause (4) by deleting the words "medicinal substance" and substituting therefor the words "health product";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) by inserting the following sub-clauses immediately after sub-clause (5) —

"(6) The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product regulated under this Act.

(7) The personnel qualified to conduct lot release of vaccines and batch release of health products shall submit their qualifications to the Authority.

(8) Any person who commits an offence under this section is on conviction, liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding ten years, or to both."

Justification: Substandard, falsified and falsely labelled health products occasion serious public health challenges.

CLAUSE 48
THAT, Clause 48 of the Bill be amended—

(a) by renumbering the provision as sub-clause (1); and
(b) by inserting the following new sub-clauses immediately after sub-clause (1)—

"(2) The Authority shall have power to enter and inspect manufacturing premises to confirm compliance with prescribed good manufacturing practices and issue a certificate of compliance in the prescribed format upon payment of prescribed fees.

(3) The Cabinet Secretary shall make regulations for the better carrying out of the provisions of this section.

(4) Without prejudice to the generality of subsection (3), the Authority shall make regulations on—

(a) revocation and suspension of manufacturing licences;
(b) withdrawal of revocation of manufacturing licences upon request; and
(c) transfer of manufacturing licences."

Justification: To give the Authority power enforce compliance with good manufacturing practices as recommended by WHO which will in turn encourage continuous improvement of internal quality control systems and production processes by manufacturers.

PART VII

THAT, the Bill be amended in the title of Part VII by deleting the expression "PART VII" and substituting therefor the expression "PART VI".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 51
THAT, the Bill be amended by inserting the following new clauses immediately after clause 51—

Information that is required to be displayed on the pack.

51A. A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;
(b) the net weight;
(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;
(d) the name and address of manufacturer of the therapeutic cosmetic;
(e) a warning statement; and
(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

Justification: To enhance transparency on the ingredients used in therapeutic cosmetics in line with the Good Manufacturing Practices

Manufacturing of cosmetics.

51B. (1) The Cabinet Secretary shall make regulations for the effective implementation of this section.

(2) The regulations made under subsection (1) may

(a) require manufacturers of cosmetics to register with the Authority; and

(b) impose restrictions, requirements or other conditions on manufacturers of cosmetics, if such restrictions, requirements or conditions are necessary to protect public health.

Justification: To enhance transparency on the ingredients used in therapeutic cosmetics in line with the Good Manufacturing Practices

CLAUSE 52

THAT, Clause 52 of the Bill be amended by deleting the words "have a therapeutic effect or value" and substituting therefor the words "treat, diagnose or prevent disease, or affect the structure or functions of the body".

Justification: Using the term "therapeutic cosmetic" already indicates that the cosmetic has therapeutic effect hence there is no need to restate the same.

CLAUSE 54

THAT, Clause 54 of the Bill be amended by

(a) deleting sub-clause (3) and substituting therefor the following new sub-clause (3) —

"(3) Any person who manufactures, sells, supplies, imports or exports a therapeutic cosmetic which contains a prohibited ingredient commits an offence and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both."

Justification: To provide for a penalty for the offence of manufacturing or selling therapeutic cosmetics that contain prohibited ingredients.

(b) inserting the following new sub-clause immediately after sub-clause (3)—

"(4) The Authority shall make regulations exempting from any labelling requirement of this Part, therapeutic cosmetics which are, in accordance with the practice of the trade, to be processed, labelled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Part upon removal from such processing, labelling or repacking establishment."

Justification: To allow for the making of regulations on use of prohibited ingredients in relation to therapeutic cosmetics.

PART VIII

THAT, the Bill be amended in the title of Part VIII by deleting the expression "PART VIII" and substituting therefor the expression "PART VII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 55

THAT, Clause 55 of the Bill be amended in sub-clause (1) by inserting the words ", in-vitro diagnostics medical devices register" immediately after the words "human medical devices register".

Justification: To make provision for in-vitro diagnostics.

CLAUSE 56

THAT, Clause 56 of the Bill be amended in sub-clause (1) by inserting the words "falsified, falsely-labelled or counterfeited" immediately after the word "substandard" appearing in paragraph (c).

Justification: To incorporate internationally accepted terminology.

CLAUSE 58

THAT, Clause 58 of the Bill be amended—

(a) in sub-clause (2) by inserting the words "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" immediately after the word "Authority";

Justification: This will enable the country to comply with WHO standards on manufacturing.

(b) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act, documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

(4) An importer, distributor or dealer shall establish and implement documented procedures for the maintenance of importation or distribution records and shall maintain an importation or distribution record of each medical device to be submitted to the Authority."

Justification: To allow the Authority to consult and receive advice from the Kenya Nuclear Regulatory Authority that exercises regulatory control over nuclear and radioactive materials and facilities under section 6(c)(i) of the Nuclear Regulatory Act, No. 29 of 2019. To require importers, distributors or dealers to keep records of medical devices submitted to the Authority.

CLAUSE 59

THAT, Clause 59 of the Bill be amended in sub-clause (1) by inserting the words "unregistered establishments for medical devices and" immediately after the word "under".

Justification: To provide for the registration of establishments for medical devices by the Authority.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 59

Registration of medical devices establishment.

59A. (1) An application for registration of a medical devices establishment shall be submitted to the Authority in the prescribed format and shall be accompanied by the prescribed fees.

(2) An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority of such system.

(3) Where the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Director-General shall issue a registration certificate for the medical devices establishment in the prescribed format.

(4) A medical devices establishment registration certificate under this section shall be valid for a period of one year, renewable annually upon application in accordance with the prescribed conditions.

(5) The registration certificate for manufacturers shall be valid for five years following a successful reinspection.

(6) The Authority may refuse to issue a medical devices establishment registration certificate where

(a) an applicant has made a false or misleading statement in the application;

(b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

(c) an applicant has failed to meet the prescribed conditions for medical devices establishment registration.

(7) Where the Authority does not issue a medical devices establishment registration certificate under subsection (6), the Authority shall

(a) notify the applicant in writing of the reasons for refusing the registration of the establishment; and

(b) give the applicant an opportunity to respond to the Authority and provide relevant documentation or evidence in support of the application.

(8) After the issuance of a medical devices establishment registration certificate, where there is a change to any of the information submitted at the time of application, the holder of the registration certificate

shall submit the new information to the Authority within ten working days of the change.

Justification: To make provision for the registration of establishments for medical devices.

NEW PART

THAT, the Bill be amended by inserting the following new Part immediately after the new clause 59A—

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance. **59B.** (1) The Authority shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system.

(2) The Centre established under subsection (1) shall receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority.

(3) The Authority shall conduct both passive surveillance and active surveillance of health products and technologies.

(4) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements.

(5) All entities responsible for placing a health product or technology in the market shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies.

(6) The entities referred to in subsection (5) shall submit safety information to the Authority in the prescribed manner.

(7) The consumers, general public and health care professionals shall report adverse reactions and adverse events to the Authority in the prescribed manner.

Justification: To anchor the role of the Authority in the regulation of pharmacovigilance in the country.

PART XI

THAT, the Bill be amended in the title of Part XI by deleting the expression "PART XI" and substituting therefor the expression "PART IX".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 60

THAT the Bill be amended by deleting Clause 60 and substituting therefor the following new clause 60

Establishment of the National Quality Control Laboratory.

60. (1) There is established the National Quality Control Laboratory of the Authority which shall be used as a facility for

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;
(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;
(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;
(d) field testing of regulated products using screening techniques;
(e) providing technical support to local manufacturers and building their capacity in matters pertaining to quality control of regulated products through on site and off site training and laboratory assessments;
(f) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;
(g) conducting research and training and providing high quality analytics and expert knowledge in the areas of medicinal products and active pharmaceutical ingredients; and
(h) developing and administering a data bank on quality assurance on behalf of the Authority.

(2) The National Quality Control Laboratory shall be the quality control laboratory of health products and technologies for the Authority.

(3) The Board of the Authority shall appoint a Director, National Quality Control Laboratory who shall be responsible to the Authority for the day to day management of the National Quality Control Laboratory.

(4) The Director National Quality Control Laboratory shall hold office on such terms and conditions of service as may be specified in the instrument of appointment by the Board of the Authority.

(5) The Director National Quality Control Laboratory shall be a registered pharmacist and shall possess a Master's degree in a science related field from a recognized university.

(6) The Director of the National Quality Control Laboratory shall—

(a) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;

(b) ensure timely quality control testing of all samples in conformity with national and international standards;

(c) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;

(d) collaborate with other laboratories, regulatory and law enforcement agencies, manufacturers of pharmaceutical and other health products to ensure quality in health products and technologies;

(e) handle appeals on test results;

(f) where the laboratory lacks capacity, subcontract laboratory testing services;

(g) advice the Authority on matters of testing and quality control over health products and technologies; and

(h) perform any other duties assigned by the Authority from time to time.

(7) The funds to be used for the management of the Laboratory shall consist of all moneys received or recovered under this Part and a portion of the moneys appropriated by Parliament to the Authority.

(8) Subject to subsection (7), monies generated by the Laboratory in the course of the performance of its functions under this section shall be solely expended on the Laboratory.

Justification: The NQCL, headed by a Director appointed by the Authority, to become a regulatory laboratory of the Authority as recommended by the WHO so that the country can achieve Maturity Level 3. To ringfence monies for the Laboratory such that monies generated by the Laboratory shall be solely expended on the Laboratory and the Authority ought to give a portion of the monies appropriated to it by Parliament to the Laboratory.

CLAUSE 61

THAT, Clause 61 of the Bill be amended in sub-clause (1) by deleting the words "Director-General" and substituting therefor the words "Director of the National Quality Control Laboratory".

Justification: For compliance with WHO guidelines which requires that a certificate of analysis should be issued by a person capable of ensuring the authenticity of the test samples.

PART XII

THAT, the Bill be amended in the title of Part XII by deleting the expression "PART XII" and substituting therefor the expression "PART X".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 63

THAT, Clause 63 of the Bill be amended

(a) in sub-clause (1) by deleting the words "medicine, drug, appliance or article" wherever they appear and substituting therefor the words "health product or technology"; and

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (2) by inserting the words "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (d).

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on diseases listed in the Sixth Schedule.

CLAUSE 64

THAT, Clause 64 of the Bill be amended by deleting the words "a medicine, drug, appliance or article" wherever it appears and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 65

THAT, Clause 65 of the Bill be amended

(a) in paragraph (a) by

(i) deleting the words "or similar article"; and

(ii) deleting the word "extravagant,".

Justification: To ensure objectivity.

(b) in paragraph (b) by deleting the word "an article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 66

THAT, Clause 66 of the Bill be amended

(a) in sub-clause (1)—

(i) by deleting the words "drug, appliance or article" wherever they appear in paragraph (a) and substituting therefor the words "health product or technology"; and

(ii) by deleting the words "drug, appliance or article" appearing in paragraph (b) and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (3) by—

(i) renumbering the provision as clause (2); and

(ii) by inserting the words ", enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (ii).

Justification: To include enrolled pharmaceutical technologists as part of persons who are covered under the provided defence in relation to offences as regards prohibition of advertisements on abortion and false or misleading advertisements.

CLAUSE 67

THAT Clause 67 of the Bill be amended—

(a) by deleting the word "articles" appearing in the marginal note and substituting therefor the words "health products and technologies";

(b) by deleting sub-clause (1) and substituting the following new sub-clause (1)–

"(1) Subject to this Act, a person shall not sell by retail a health product or technology consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the health product or technology or on a label affixed thereto, or if the health product or technology is sold or supplied in more than one container, on the inner container or on a label affixed thereto—

(a) the appropriate designation of the substance so recommended or of each of the active constituents, or of each of the ingredients from which it has been compounded; and

(b) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients; provided that this subsection shall not apply to a health product or technology made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person."

(c) in sub-clause (2) by deleting the word "article" wherever it appears in the definition of "appropriate quantitative particulars" and substituting therefor the words "health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(d) in sub-clause (3) by—

(i) deleting the word "an article" appearing in sub-clause (3) and substituting therefor the words "a health product or technology";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(ii) deleting the words "two hundred thousand" appearing in paragraph (a) and substituting therefor the words "one million";

(iii) deleting the words "three hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

Justification: To make the fines payable commensurate to the offences relating to labeling of health products and technologies containing medicine.

CLAUSE 68

THAT, the Bill be amended by deleting Clause 68.

Justification: It is preferable to make provision for valid exemptions through regulations as opposed to providing defences for offences relating to labeling of medicines.

CLAUSE 69

THAT, Clause 69 of the Bill be amended by

(a) deleting the word "article" and substituting therefor the words "health product or technology"; and

(b) deleting the word "articles" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIII

THAT, the Bill be amended in the title to Part XIII by deleting the expression "PART XIII" and substituting therefor the expression "PART XI".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 71

THAT, Clause 71 of the Bill be amended

(a) in the marginal note by deleting the words "medicines or medical devices" and substituting therefor the words "health products and technologies"; and

(b) in sub-clause (1) by deleting the words "or homoeopathic medicine, preparation or medical device" and substituting therefor the words "health products and technologies".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 72

THAT, Clause 72 of the Bill be amended

(a) in the marginal note by deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies";

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by inserting the words "including a health product and technology for emergency use" immediately after the word "technology"; and

Justification: To make provision for supply of health products and technologies during emergency situations.

(c) in sub-clause (3) by deleting the words "medicine or medical device product" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 73

THAT, Clause 73 of the Bill be amended—

(a) in the marginal note by deleting the word "goods" and substituting therefor the words "health products and technologies".

(b) in sub-clause (1) by deleting the words "drug, article" wherever they appear and substituting therefor the words "health product or technology";

(c) in sub-clause (2) by deleting the words "drug or article" wherever they appear and substituting therefor the words "health product or technology";

(d) in sub-clause (3) by deleting the words "drug or article" and substituting therefor the words "health product or technology"; and

(e) in sub-clause (4) by deleting the words "drug or article" and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 78

THAT, Clause 78 of the Bill be amended in sub-clause (1) by inserting the words "or enrolled pharmaceutical technologist" immediately after the words "registered pharmacist" appearing in paragraph (b).

Justification: To provide for the application of penal sanctions to enrolled pharmaceutical technologists as regards body corporates.

CLAUSE 79

THAT, the Bill be amended by deleting Clause 79 and substituting the following new clause 79—

Inspection and verification of health products and technologies at the ports of entry.

79. (1) A person who imports a health product or technology shall notify the inspectors of the Authority at the ports of entry to conduct pre-clearance inspection and verification.

(2) Any person who imports a health product or technology and causes it to be released to the market without authorization under subsection (1) shall be guilty of an offence.

(3) Any person who commits an offence under this section is upon conviction, liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

Justification: Clause 79 be deleted as the function of inspection of animals intended for slaughter is outside the regulatory purview of the Authority.

The new clause on inspection and verification of health products and technologies at the ports of entry enables the Authority to enforce compliance with the prescribed standards of quality, safety and efficacy of health products and technologies before release at the

ports of entry so as to prevent concealment, misdeclaration, diversion and cross border smuggling of health products and technologies.

CLAUSE 80

THAT, Clause 80 of the Bill be amended

(a) by deleting the words "article" and "articles" wherever they appear and substituting therefor the words "health product or technology" and "health products and technologies" respectively in sub-clause (6), (7), (8), (9), (10), (11) and (12).

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) in sub-clause (1) by—

(i) deleting the word "article" wherever it appears and substituting therefor the words "health product or technology"; and

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(ii) inserting the words "or any other vessel" immediately after the word "vehicle" appearing in paragraph (b).

Justification: To expand the scope to include all other means of conveying health products and technologies.

CLAUSE 81

THAT, the Bill be amended by deleting Clause 81.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

CLAUSE 82

THAT, the Bill be amended by deleting Clause 82.

Justification: Regulation is a function of National Government under the Fourth Schedule to the Constitution.

CLAUSE 83

THAT, the Bill be amended by deleting Clause 83.

Justification: The clause infringes on the exercise of the functions of the Authority contrary to the recommendation of the World Health Organization.

CLAUSE 85

THAT, Clause 85 of the Bill be amended by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology".

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

CLAUSE 86

THAT, Clause 86 of the Bill be amended in sub-clause (1) by deleting paragraph (b) and substituting therefor the following new paragraph (b)—

"(b) in the case of a subsequent offence, to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both".

Justification: To make enhance the general penalty for offences committed in relation to this Bill and to make the fines payable commensurate to the imprisonment terms.

CLAUSE 87

THAT, Clause 87 of the Bill be amended in sub-clause (1) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology" in paragraph (c)

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

PART XIV

THAT, the Bill be amended in the title of Part XIV by deleting the expression "PART XIV" and substituting therefor the expression "PART XII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 88

THAT, Clause 88 of the Bill be amended by deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) such monies as may be appropriated by the National Assembly for the purposes of the Authority".

Justification: For proper drafting and consistency in the wording used in the Statute Book.

CLAUSE 91

THAT, Clause 91 of the Bill be amended by—deleting the words "Kenya National Audit Office" wherever they appear and substituting therefor the words "Auditor-General".

Justification: For proper reference to the Auditor-General as designated under Article 229 of the Constitution and which is the successor of the Kenya National Audit Office.

PART XV

THAT, the Bill be amended in the title of Part XV by deleting the expression "PART XV" and substituting therefor the expression "PART XIII".

Justification: To correct a minor error in numbering of the parts of the Bill.

CLAUSE 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—

(i) deleting the word "drugs," in paragraph (a)(i);

(ii) deleting the words "any drug" in paragraph (a)(ii);

(iii) deleting the word "product" and substituting therefor the word "products" in paragraph (d);

(iv) deleting the word "drugs" wherever it appears and substituting therefor the words "health products or technologies" in paragraph (h);
(v) deleting the word "article" and substituting therefor the words "health product or technology" in paragraph (k);
(vi) deleting the word "articles" and substituting therefor the words "health products and technologies" in paragraph (m);
(vii) deleting the words "drugs, medical devices" and substituting therefor the words "health products and technologies" in paragraph (o);
(viii) deleting the word "medicines" and substituting therefor the words "health products and technologies" in paragraph (v);
(ix) deleting paragraph (x) and substituting therefor the following new paragraph (x)—

"(x) governing administration of clinical trials of health products and technologies;"

(x) deleting the words "medicine, medical device" and substituting therefor the words "health product or technology" in paragraph (aa);
(xi) deleting the words "medicines or medical devices" and substituting therefor the words "health products or technologies" in paragraph (bb);
(xii) deleting paragraph (dd) and substituting therefor the following new paragraph (dd)

"(dd) the compounding of health products and technologies and the dispensing of health products and technologies"

Justification: To harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(xiii) inserting the words ", an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in paragraph (bb);

Justification: For inclusion of pharmaceutical technologists who are currently involved in the dispensing of medicines and medical devices pursuant to the Pharmacy and Poisons Act, Cap. 244 and their scope of training.

(xiv) deleting paragraph (ii);

Justification: The general provision on the making of regulations is set out in sub-clause (1).

(xv) inserting the following new paragraphs immediately after paragraph (ii)
"(jj) on pharmacovigilance and post market surveillance;
(kk) official regulatory lot release of vaccines and other biological products imported and manufactured in Kenya;
(ll)pricing of health products and technologies;
(mm) good practices in the regulation of medical products;
(nn) inspections, licensure and certification of the manufacture of medical products by health facilities;

(oo) inspections, licensure and certification of manufacture of medical products and other regulated products by facilities not directly regulated by the Authority including steel industries, sugar industries;
(pp) inspection and recognition of pharmaceutical quality control laboratories;
(qq) to regulate licit use of narcotic and psychotropic substances; and
(rr) to regulate parallel importation of medicines;"

(b) by renumbering sub-clause (2) as sub-clause (3).

Justification: To provide for the making of regulations on licit use of narcotic and psychotropic substances, parallel importation of medicines, safety monitoring, pharmacovigilance and post market surveillance.

CLAUSE 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the word "Board" and substituting therefor the word "Boards";

(ii) deleting paragraph (d) and substituting therefor the following new paragraph (d)—

"(d) all members and staff of the former Boards shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Boards."

(b) by deleting the sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) In this section, "the former Boards" means the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory established under the Pharmacy and Poisons Act, Cap. 244."

Justification: To provide for the transition of both the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory.

(c) in sub-clause (3) by deleting the word "twelve" appearing in the opening sentence and substituting therefor the words "twenty-four".

Justification: To provide sufficient time which will facilitate the conduct of extensive stakeholder participation on the regulation of pharmacy practice regulation.

CLAUSE 97

THAT, Clause 97 of the Bill be amended by inserting the words "with reference to section 96 (3)" immediately after the words "that Schedule" in sub-clause (1).

Justification: To prevent a lacuna in respect of the regulation of the pharmaceutical practice.

SECOND SCHEDULE

THAT, the Bill be amended by deleting the Second Schedule.

Justification: The Chairperson, Board Members and Director General of the Authority are not State Officers and hence do not need to subscribe to an oath.

THIRD SCHEDULE

THAT, the Bill be amended by deleting the Third Schedule.

Justification: The matters of the tenure of office, allowances, protection from liability and disclosure of interest by Board members are already provided for in the main Bill. The issue of approval of the Board members by the Parliament has been proposed for deletion as the Authority's Board members are not State Officers.

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended by deleting paragraph (1), (2), (3), (4) and (5) and substituting therefor the following new paragraphs—

1. Biologics Committee.
2. Pharmacovigilance Committee.
3. Complementary, Alternative or Herbal Medicines Committee.
4. Radiopharmaceuticals Committee.
5. Cosmetics and Borderline Products Committee.
6. Clinical Trial Scientific Technical Advisory Committee.
7. Health Technology Assessment Committee.
8. Nutraceuticals and Dietary Supplements Committee.
9. Digital Health and Technologies Committee.
10. Medical Devices and Health Technologies Committee.
11. Veterinary Medicines Committee.

Justification: The scientific advisory committees amended to take into account all aspects of health products and technologies and to delete the Scientific Advisory Committees on food which is outside the scope of the Bill as amended.

SEVENTH SCHEDULE

THAT, the Seventh Schedule of the Bill be amended by

(a) deleting the word "Board" in the paragraph on Cap. 244

(b) deleting the phrase "(s. 116) and substituting the phrase ("s.97").

Justification: For proper cross referencing of the Pharmacy and Poisons Act, Cap. 244 and clause 97 on repeals.

(c) deleting the paragraph on Cap. 254.

Justification: Food is outside the purview of the Bill.

MIN. NO. NADC-H/2023/492: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 4.30 p.m.

Sign.....Date 2/11/2023

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

MINUTES OF HUNDRED AND TWENTHY SEVENTH (127TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON WEDNESDAY 1ST NOVEMBER, 2023 AT 2.00 P.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P -**Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha	- Principal Clerk Assistant II
2.	Mr. Hassan A. Arale	- Clerk Assistant I
3.	Ms. Christine Odhiambo	- Senior Legal Counsel
4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant At Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

MIN. NO. NA/DC-H/2023/486: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 2.30 p.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/487: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. MARTIN OWINO PETERS, MP.

Hon. Martin Owino Peters, MP submitted as that Clause 72 of the Bill be amended in sub clause (1) by deleting the word "person" appearing immediately after the words "The Authority may authorize a" and substituting therefor the words "registered pharmacist".

MIN. NO. NA/DC-H/2023/488: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. DR. JAMES NYIKAL, MP.

CLAUSE 2

THAT, Clause 2 of the Bill be amended by inserting the following new definitions in the proper alphabetic sequence

No. 21 of 2017.

"Director-General for Health" has the meaning assigned to it under the Health Act;

"wholesaler dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

Justification: To distinguish the Director-General for Health with the Director-General of the Authority and for consistency with the amendment proposed below to clause 81 of the Bill. To define a wholesaler dealer as the term is used in the Bill under clause 39 of the Bill

CLAUSE 12

THAT, Clause 12 of the Bill be amended by deleting paragraph (t).

Justification: The provision relates to an administrative function as regards human resource management and development and need not be in the Bill.

CLAUSE 21

THAT, Clause 21 of the Bill be amended

(a) by deleting sub-clause (4);and

(b) in sub-clause (9) by deleting the words "Cabinet Secretary, with respect to its activities and the Cabinet Secretary shall lay a copy of each report before Parliament" and substituting therefor the following words "Board of the Authority which shall submit a copy of the report to the Cabinet Secretary who shall transmit the report to Parliament".

Justification: Sub-clause (4) provides for the co-option of members into the scientific advisory committees. This is unnecessary as the appointing authority needs to appoint the relevant skills to the Committee in the first instance.

Amendment of sub-clause (9) to require that the scientific advisory committees shall submit its report to the Board of the Authority which shall submit the same to the Cabinet Secretary who must transmit it to Parliament. The Committee report had not provided for the transmittal of the reports of the scientific advisory committees to Parliament.

CLAUSE 22

THAT, Clause 22 of the Bill be amended in sub-clause (3) by deleting the words "sub-section (1)" and substituting therefor the words "The provisions of subsection(1)(a)".

Justification: Sub-clause (3) should not only apply where a medicine is not registered by the Authority and not in instances where a medicines is adulterated, substandard or fails to comply with the specifications in law.

CLAUSE 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (4) and substituting therefor the following new sub-clause (4)—

"(4) Where the Authority finds that an application for registration of a medicine or medical device does not satisfy the requirements provided in subsection (3), it shall notify the applicant in writing of the reasons why that medicine or medical device should not be registered and invite the applicant to make comments on its finding within a period of one month from the date of the notification."

Justification: For proper drafting of the sub-clause (4) as the provision is currently not clear.

CLAUSE 31

THAT, the Bill be amended by deleting clause 31.

Justification: To remove the aspect of transfer of certificate of registration of health products and technologies.

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "upon consultation and concurrence with the person who prescribed the medicine," immediately after the word "shall";
(b) by deleting sub-clause (2);
(c) by renumbering sub-clause (3) as sub-clause (2); and
(d) by deleting sub-clause (4).

Justification: To require that a prescriber of a medicine is consulted before medicine is substitution with a generic medicine. With the amendment to sub-clause (1), sub-clause (2) and (4) are unnecessary as the factors will be discussed by the Prescriber and the Pharmacist at the point of consultation.

CLAUSE 38

THAT, Clause 38 of the Bill be amended by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not

exceeding one million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 1,000,000.

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances".

Justification: To insert a missing word which will make the sub-clause much clearer.

CLAUSE 42

THAT, Clause 42 of the Bill be amended in sub-clause (3) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three years" and substituting therefor the words "five hundred thousand shillings or to imprisonment for a term not exceeding one year".

Justification: To enhance the fine for the offence of failure to record the sale or supply of scheduled substances in a Schedules Substances Book as is required in clause 42 from Kshs. 100,000 to Kshs. 500,000. To reduce the jail term from three years to one year as 3 years is too punitive.

CLAUSE 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "five hundred thousand".

Justification: To enhance the penalty for the offence of failure to label a container of scheduled substances in the manner set out in clause 44 from Kshs. 200,000 to Kshs. 500,000

CLAUSE 79

THAT, the Bill be amended by deleting Clause 79.

Justification: The regulation of meat is outside the ambit of the regulation of the Authority.

CLAUSE 81

THAT, Clause 81 of the Bill be amended by deleting the words "Director of Medical Services" and substituting therefor the words "Director-General for Health".

Justification: The Health Act, No. 21 of 2017 makes provision for the office of the Director-General for Health which replaced the office of the Director of Medical Services.

CLAUSE 83

THAT, Clause 83 of the Bill be amended by deleting the words "Cabinet Secretary" wherever they appear and substituting therefor the words "the Authority".

Justification: The function of regulation of HPTs is a preserve of the Authority and the power provided in clause 83 is utilized administratively in the performance of this function. The Cabinet secretary responsible for matters of health is only responsible for policy.

CLAUSE 90

THAT, Clause 90 of the Bill be amended in sub-clause (2) by deleting the words "think fit" appearing in paragraph (f) and substituting therefor the words "deem appropriate".

Justification: For proper drafting.

CLAUSE 92

THAT, Clause 92 of the Bill be amended in sub-clause (2) by inserting the words "with the approval of the Cabinet Secretary" immediately after the word "determine".

Justification: For checks and balances in the investment of the funds of the Authority which will ensure prudent use of the funds by the Authority.

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);

Justification: Amendment of paragraph (1) is necessary for consistency with sub-paragraph (1) which establishes the National Food Safety Committee.

(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;
(g)the Director-General for Health or a representative designated in writing;"

Justification: For inclusion of KMA in the Human Medicines Committee as prescribers of medicines are crucial in ensuring patient safety.

For inclusion of the Director-General for Health in view of his technical expertise on matters of health generally.

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

Justification: The words "in consultation with the Cabinet Secretary responsible for health," are superfluous as it is already indicated that the Chairperson of the Medical Devices Committee will be appointed by the Cabinet Secretary.

MIN. NO. NADC-II/2023/489: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 4.30 p.m.

Sign.....Date.....

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

MINUTES OF HUNDRED AND TWENTHY SIXTH (126TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON WEDNESDAY 1ST NOVEMBER, 2023 AT 9.00 A.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P -**Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha	- Principal Clerk Assistant II
2.	Mr. Hassan A. Arale	- Clerk Assistant I
3.	Ms. Christine Odhiambo	- Senior Legal Counsel
4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant At Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

IN ATTENDANCE- HON. MEMBERS WITH PROPOSED AMENDMENTS

1. Hon. Dr. Otiende Omollo, MP-
2. Hon. Millie Odhiambo, MP - attended through Visual and sent submission by email.

MIN. NO. NA/DC-H/2023/486: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 9.30 a.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/487: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. DR. OTIENDE OMOLLO, MP.

The Hon. Dr. Otiende Omollo, MP attended through Visual and presented the following amendments to the Committee as per the order paper of 25th October, 2023 at 2:30 pm.

Under Clause 2
That, the Clause 2 of the Bill be amended by deleting the definition of "pharmacy" and substituting therefor the following new definition-
"pharmacy has the meaning assigned to it under the Pharmacy and poisons Act.

Clause 8
That, Clause 8 be amended in sub-clause (2) by deleting paragraph (j) and substituting therefor the following new paragraph-
"one person, not being a governor, who is a registered pharmacist of good standing, nominated by the Council of Governors"

Clause 39
That, clause 39 of the Bill be amended in the marginal note by deleting the words "Wholesale Dealers Licence" and substituting therefor the word "Local Technical Representative Licence"
The Honorable member also said clause 25 and 35 needs to be relooked.

MIN. NO. NA/DC-H/2023/488: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. MILLIE ODHIAMBO, MP.

The Hon. Millie Odhiambo, MP was invited to the winnowing process of the Kenya Drug Authority Bill, 2022 through a letter ref. NA/DIDC/DC-H/2023/ (099) dated 27th October, 2023 for a meeting on 31st October and 1st November, 2023 and attended the meeting through Visual on 1st November and presented the following proposed amendments to the Committee which she sent through email earlier as follows for consideration since she had travelled out of the Country;

PART I- PRELIMINARY: Add the definition of "alternative medicine" **"alternative medicine"** means alternative medicine as defined under the Health Act.

Definition of "drug"

(a) Add the words "herbal medicine" after the words "any medicine" and before the words "medicinal preparation, medicinal substance, therapeutic substance prepared, sold or represented for use in-"
(b) Add the word "herbal medicine"" after the words "any medicine" and before the words "medicinal preparation"

(b) (ii) delete the word "if" appearing after the words "restoring, correcting or modifying functioning" and after the words "organs in humans or animals" and replace with the word "of".

Definition of "falsified medicines" Put a semi colon (;) after the words "... of active or other ingredients" and before the words "or falsely labelled medicine"

Definition of health products and technologies Delete and replace with **"health products"** means chemical substances, therapeutic cosmetics, herbal medicines, medicines, scheduled substances and related products and substances.

"health technologies" means medical devices including radiation-emitting devices and related products.

Definition of herbal medicine or products Delete and replace with **"herbal medicine"** means *the use of plants to treat disease and enhance general health and wellbeing.*

"herbal product" means a plant derived material or preparations with claimed therapeutic or other human or veterinary health benefits, which contain either raw or processed ingredients from one or more plants, or material of inorganic or animal origin;

Definition of "insanitary condition" Add the words "herbal medicine" after the words "as might contaminate a drug or a therapeutic cosmetic" and before the words "with dirt or filth"

Definition of "Label" Add the words "herbal medicine" after the words "accompanying any drug" and before the words "therapeutic cosmetic"

NB: There appears to be something missing in this definition and I cannot tell what it is. The original drafter can assist.

Definition of "manufacture"

Delete the word "product or" appearing after the words "means any process carried out in the course of making" and add the words "or product" after the words "medicinal substance" and add the word "extracting" after the words "and includes" and before the words "packaging, blending, mixing"

Definition of "medicinal substance" Add the words "herbal medicine" after the words "medicine" and before the word "product"

Definition of "registered midwife" Delete the words "by law to practice the profession of midwife in Kenya" and replace with the words "to practice as such under the Nurses and Midwives' Act"

Definition of "registered pharmacist"

Delete the words "by the body for the time being responsible for registration of pharmacists" and replace with the words "under the Pharmacy and Poisons Act":

Definition of "substandard medicine"

Add the words "under this Act or any other written law" after the words "means medicines which do not meet defined standards and specifications" and before the words "and includes products that have been contaminated"

Definition of "therapeutic cosmetic"

Delete the words "or altering complexion" appearing after the words "sold or represented for use in cleaning, improving" and before the words "skin, hair, eyes or teeth"

Clause 6 (4) (a): Delete the word "engineering" appearing after the word "in either pharmacy, medicine", and before the words "or equivalent fields";

Clause 7 (a) and (b) - Delete sub clause (a) and (b) and then replace with the following:

(a) Is a State officer

Renumber the subsections consequently.

(e) delete subsection "e" and replace with the words "is a public officer"

(f) delete the words "Act", regulation under this" appearing at the end of the sentence and replace with "regulations under this Act"

Clause 8 (3)- Delete (e) appearing between "h" and "i"

(a) **Clause 8 (6)** Delete sub clauses (a) and (b) and replace with (a) Is a State officer

Clause 8 (7)

Add the word "youth representation" after the words "regard shall be had of the need for" and before the word "regional" and add the word "and ethnic" after the word "regional" and before the words "balance and the realization"

Clause 10 (1) (f) Delete the words "permission of the" and replace with "notifying the"

Clause 12 (o)- Add the words "chemicals, medicine" after the words "promote rational use of

Clause 12 (a) - Delete the word "ensure" and replace with the word "set"

Clause 12 (b) - Delete the word "that" appearing after the word "ensure" and before the words 'compliance with existing legislation" and replace with the words "that there is" and further delete the words "is being promoted and controlled"

Clause 12 (g) - Delete the word "being" after the word "products and technologies are" and before the words "assessed accordingly

Clause 13 (F)- Delete the words "co-opt in such committees" and replace with the words "hire as consultants"

Clause 17 (2) - Add the words "youth inclusion" after the words "The principles of" and after the words "ethnic, regional and gender"

Clause 21 (1) - Delete the words "Cabinet Secretary" appearing after the word "The" and before the word "may establish scientific" and further delete the word "Cabinet Secretary" appearing before the word "under this Act" and replace with the word "Authority".

Clause 21 (3) - Delete the word "Cabinet Secretary" and replace with "Board"

Clause 21 (4) - Delete the word "Cabinet Secretary" and replace with the "Board"

Clause 21 (9) - Delete the word "Cabinet Secretary" appearing before the words "with respect to its activities" and replace with the word "Board"; further delete the words "and the Cabinet Secretary shall lay a copy of each report before Parliament.

NEW Sub-clause 21 (10)- The Board shall prepare and submit annually a report of its activities including that of any subcommittees to the Cabinet Secretary and the Cabinet Secretary shall submit the said report to parliament.

Clause 22 (2) (b)- Delete the words "five years" and replace with "three years".

Clause 22 (3) - Delete entire clause

Clause 24 (3) - Add sub clause (c) as follows:_(c) is herbal medicine

Clause 24 (4) (a) - Delete the words "one hundred" and replace with "five hundred"

Clause 24 (b) - Delete the words "two hundred thousand" and replace with "one million shillings" and further delete the words "five years" and replace with "three years"

Clause 27 -_Add a new Clause 27 (1) as follows:

27 (1) "The Authority may issue product licences as provided under this Act

Renumber current 27 to 27 (2)

Clause 28 (1) - Add the words "and herbal medicines" before the word "register" and after the word "There is established a medicines"

Clause 28 (2) - Add the words "herbal medicine" after the words "content of the medicines" and before the word "register"

Clause 29 (1) - Add a new Clause 29 (1) as follows then renumber the subsequent subsections

29 (1) Any pharmacist may apply for the registration of a medicine, herbal medicine or medical device as provided for under this Act.

Clause 29 (1) - Add the word "herbal medicine" in sub clause 29 (1) in the Bill after the words "Every application for the registration of a medicine" and before the words "or medical device"

Clause 29 (3) (a) - Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

Clause 29 (3) (b) - Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

Clause 29 (3) (c) - Add the words "or herbal medicine" after the word "that medicine" and before the word "is in the public domain"

Clause 29 (4) - Add the words "herbal medicine" after the words "of a medicine" and before the words "it shall cause the applicant"

Clause 29 (4) (b) - Add the words "comment" after the words "with the applicant's" and after the words "on the Authority's reasons for not being so satisfied"

Clause 29 (6) - Add the words "herbal medicine" after the word "medicine" and before the words "the registrar shall register"; and further after the word "medicine" and before the words "as are

required by this Act"; and further after the words "in the prescribed form in respect of that medicine"

Clause 29 (7) - Add the words "and herbal medicine" after the words "Every medicine" and before the words "shall be registered"

Clause 29 (8)- Add the words "and herbal medicine" after the words "allocate to every medicine" and before the words "registered under this Act"; and further after the words "name of such medicine" and before the words "and which shall be stated in the certificate"; and further after the words "issued in respect of that such medicine"

Clause 29 (9) - Add the words "and herbal medicine" after the words "registration of medicine" and before the words "already registered"; and further add the words "under this Act or any other written law" after the words "already registered" and before the words "shall be valid for a period of"

Clause 29 (12) Add the words "and herbal medicine" after the words "in respect of a medicine" and before the words "referred to in subsection (4)"

New Sub clause 29 (12) (a), (b) and (c)_Provide for a new sub clause 29 (12) and renumber the current 29 (12) to 29 (13) and others consequently. Provide for the sub clause 29 (12) as follows:

(a) "The Authority may reject any application if the applicant fails to meet the standards as required by this Act or any other written law"
(b) A person dissatisfied with the decision of the Registrar may appeal to the Board within the period specified under subsection 14
(c) Where a person is dissatisfied with the decision of the Board, the applicant may appeal to the High Court within thirty days of the decision being communicated to him or her.

Clause 13 -_Add the words "of appeal" after the words "expiry of the appropriate period"; and further delete the words "referred to in sixty days"

Clause 30 (1)

Add the words "or herbal medicine" after the words "on application by the holder" and before the words "a certificate of registration"; and further after the words "register with respect to that medicine"

Clause 30 (3) (b)

Add the words "or herbal medicine" after the words "in respect of the medicine" and before the words "after receiving the existing certificate of registration"; and further after the words "register with respect to that medicine"; and further after the words "in respect of that medicine" and before the words "for cancellation"

A New Sub clause 30 (3) - Provide a new sub clause 30 (3) and renumber the current (3) as (4) and provide for the new (3) as follows: (3) The applicant shall provide reasons for the proposed amendments

Clause 31 (1) Add the words "or herbal medicine" after the words "registration of a medicine"

Clause 32 (1) Add the words "herbal medicine" after the words "registration of a medicine" and before the words "" or medical device"

Clause 32 (1) (a) Add the words "herbal medicine" after the words "to which particular medicine" and before the words "" or medical device"

Clause 32 (1) (b) Add the words "herbal medicine" after the words "particular medicine" and before the words "" or medical device"

Clause 32 (1) (c) Add the words "herbal medicine" after the words "particular medicine" and before the words "" or medical device"

Clause 32 (2) Add the words "herbal medicine" after the words "any medicine" and before the words "" or medical device"; and further after the words "in respect of that medicine" and before the words "or medical device"

Clause 32 (4) Add the words "herbal medicine" after the words "registration of that medicine" and before the words "" or medical device"

Clause 32 (4) (b) Add the words "herbal medicine" after the words "that the registration of the medicine" and before the words "or medical device"

Clause 32 (5) Add the words "herbal medicine" after the words "in respect of a medicine" and before the words "" or medical device"; and further after the words "of the registration of that medicine" and before the words "or medical device".

Clause 33 (1) and (2)

(1) Add the words "herbal medicine" after the words "registration of a medicine" and before the words "" or medical device"

(2) Add the words "herbal medicine" after the words "registration of a medicine"

New Sub clause 33 (3) Provide for a new sub clause 3 and renumber current sub clause (3) to (4). Provide for the new sub clause (3) as follows:

(3) In the case of cancellation of registration of a herbal medicine the Registrar shall in such case specify-

(a) The name under which the herbal medicine is registered

(b) The active components of the herbal medicine

(c) The name of the applicant

(d) The name of the person who has propriety rights over the herbal medicine

(e) The registration number allocated to the herbal medicine;

(f) The conditions if any, subject to which that medicine is registered

Clause 35 (1) Delete the word "shall" appearing after the words "A pharmacist" and before the words "dispense and interchangeable" and replace with the word "may"

New Clause 35 (4) (d) Add a new sub-clause (4) (d) as follows:

34 (4) (d) unless the purchaser or patient is first informed of the same and agrees to the change.

Clause 36 (1) Delete the words "on a commercial scale"

Clause 38 (2) Delete "one hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment"

Clause 40 (4) Delete the words "whose decision thereon shall be final" appearing at the end of the sentence.

Clause 40 (7) Delete the words "two hundred thousand" appearing after the words "to a fine not exceeding" and replace with "one million"; and delete the words "two years" appearing after the words "imprisonment for a term not exceeding" and replace with "three years".

Clause 41(1) (d) Add the words "enrolled pharmaceutical technologist and registered pharmacist" after the word "practitioner"

Clause 42 (2) (a)

Delete the words "provided that where a person represents that he urgently requires a Schedule Substances for the purpose of his trade, business or profession and satisfies the seller that by reason of some emergency he is unable before delivery to furnish the order in writing, the seller may forthwith deliver the Scheduled Substances to the purchaser who will within twenty-four hours of the sale furnish the seller with the written order"

Clause 42 (3) Delete the words "one hundred thousand" appearing after the words "to a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

Clause 43 (3) Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 44 (3) Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 45 Delete the words "five hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

Clause 46 (1) Delete the word "This" appearing at the beginning of the sentence and replace with the words "The electronic supply of medicine"

Clause 59 (3) Add the word "who" between the words "A person" and the words "sells or supplies"

Clause 60 (1) (c) Add the words "medicinal herbs" after the words "manufactured and imported medicine" and after the words "or medicinal substances"

Clause 63 (1) Add the words "medical herbs" after the words "referring to a medicine" and before the words "drug, appliance or article"; and further before the words "to imply that the medicine" and before the words "drug, appliance or article".

Clause 67 (3) (a) Delete the words "two hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to an imprisonment" and replace with the words "one million".

Clause 67 (3) (b)_Delete the words "three hundred thousand" appearing after the words "a fine of at least" and before the words "shillings or to an imprisonment" and replace with the words "two million".

Clause 68 (1) Add the words "or herbal medicine" after the words "recommended a medicine" and before the words "to prove".

Clause 71_Add the words "herbal medicine" after the words "homoeopathic medicine preparation" and before the words "or medical device"

Clause 72 (3)_Add the words "herbal medicine" after the words "quantity of a particular medicine" and after the words "or medical device"

Clause 79_Delete Clause 79

Clause 86_Delete the words "seven hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

Clause 88 (v) Add the words "herbal medicine" at the end of the sentence.

Clause 88 (aa) Add the words "herbal medicine" after the words "a specified medicine" and before the words "medical device"

CLAUSE 88 (bb) Add the words "herbal medicine" after the words "dispense medicine" and before the words "medical device"

Clause 88 (dd)_Add the words "herbal medicine" after the words "compounding of medicine" and before the words "medical device"

FOURTH SCHEDULE Section (1) (1) replace Cabinet Secretary with "the Board"

Section (4) (2) (1) Add the words "herbal medicine" after the words "human medicinal products" and before the words "giving advice"

TITLE - Change the Title to the **KENYA DRUG AND HEALTH TECHNOLOGIES BILL.**

MIN. NO. NA/DC-H/2023/488: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. PETER KALUMA, MP.

The Hon. Peter Kaluma, MP was invited to the winnowing process of the Kenya Drug Authority Bill, 2022 through a letter ref. NA/DDC/DC-H/2023/ (099) dated 27th October, 2023 for a meeting on 31st October and 1st November, 2023 but sent the following written proposed amendments to the Committee for consideration since he had travelled out of the Country;

General views:

1. We exclude anything to do with the practice of veterinary medicine from the Bill as this is dealt with under a law whose repeal has not been proposed here;
2. The manufacture of drugs be left to graduate Pharmacists;
3. Sale and dispensing of drugs once prescribed by a qualified medical practitioner or Dentist be allowed not only to pharmacists but also to holders of diploma in pharmaceutical technology, pharmacy or equivalent qualifications;
4. Proposed repeal of some sections of the Narcotic Drugs and Psychotropic Substances Act be avoided. The Act is dealing with a different category of drugs the possession, use or consumption of which is punished differently.
5. Measures be taken to ensure good provisions of the laws proposed to be repealed are incorporated into Bill. These include Part II of the Pharmacy and Poisons Act.
6. This is serious law. while it seeks to repeal two existing laws, the Memorandum states that it's purposed to comply with some WHO requirements. It would be good to involve the Ministry of Health and key stakeholders in the harmonization process. This would secure that the government position is presented, understood and carried forth into the proposed law and the requirements of WHO specified and met.
7. Amendments proposed by the Committee infringe S.O 133 as they derogate from the substratum of the various clauses of the Bill they seek to alter. It would be better the whole Bill be withdrawn and a new Bill be presented by the Government.

Specific Amendment Proposals:

1. **Clause 2**
   Veterinary medicine - delete

   "enrolled pharmaceutical technologist" - refers to definition in law being repealed. Pick definition from the law and insert it here. "means a pharmaceutical technologist whose name appears on the Roll of pharmaceutical technologists

   "herbal medicine or product" - insert full stop (.) after "plants" in*second last line and delete all words following.

2. **Insert:**
   "traditional medicines or products" means a plant or animal derived material or preparations with claimed therapeutic or other human benefits, which contain either raw or processed ingredients from one or more plants or animals, or material of inorganic origin."

3. Clause 3(2) - delete.
4. Clause 6(3) substitute "four" with "three"
5. Clause 6(4) (a) - insert full stop after "engineering" and delete the words following "or equivalent fields".

6. Clause 6(4)(d) insert "established for regulation of pharmacy, medicine or engineering profession."
7. Delete clause 6(6) - it conflicts with the lawful mandate of the Board in Clause 8(1).
8. Delete Clause 6(8)
9. Delete Clause 6(9)
10. Delete Clause 7 (a) and (b)
11. Delete "is" in 7(d) and substitute "has been"
12. 8(2)(a)(i) insert, "medical practitioner or medical engineer" after the word "pharmacist"
13. Amend 8(2)(a)(ii) by inserting medical or medical engineering" after "pharmaceutical"
14. Delete 8(2)(f)8(2)(j) - delete "County" before "Governor"
15. Delete 8(3)
16. Delete 8(6)(a) and (b)
17. Substitute "is" with "has been" in clause 8(6)(e)
18. Clause 8(7) delete all words after "Board" and insert ", regard shall be had to the need for ethnic and regional balance and the need to ensure that persons of same biological sex shall not comprise more than two thirds of the members of the Board."
19. Delete Clause 9
20. Delete 10(2).
21. Clause 12 (f) substitute "events" with "effects"
22. 13(a) substitute "association" with "collaboration
23. 13(c) - delete "any" and substitute "lawful".
24. Delete Clause 21 and the Fourth schedule. Establishment of Committees already provided for inn Clause 13(e). The Clause contradicts Clause 12(i) and (j) which vest the duty to advise CS in the Authority and Clause 34.
25. Insert new 22(4) subsection (1) shall not apply to traditional medicines or products"
26. Clause 31 - insert full stop after "person" and delete all words following.
27. Delete 32(5)
28. Clause 38(1)(b) insert semi colon (;) after "substances" and delete the words following thereafter.
29. Clause 13(c) delete "for mining, agricultural or horticultural purposes"
30. 13(e)*delete "by a qualified medical practitioner, dentist, or veterinary surgeon or by a hospital, or dispensary or similar institution"
31. 39(4) amend by inserting "is a qualified pharmacist, medical practitioner or medical engineering practitioner or holder of diploma in pharmacy, pharmaceutical technology"
32. Clause 41(1)(b) insert "or pharmaceutical technologist or dispensing chemist" after "pharmacist"
33. Clause 41 (1)(d) delete "or veterinary".
34. Clause 41(1)(f) - insert full stop (.) immediately after the word "behalf" and delete all words appearing thereafter as they are repetitions of earlier provisions.
35. Clause 41(2)(a) - delete "²or veterinary surgeon"
36. Clause 43 (1) - delete veterinary surgeon"
37. Clause 46 (1) substitute "This" with "Electronic sale of medicines"
38. Delete Clause 79
39. Clause 81 - Delete "or the Director of Veterinary Services, in relation to any matter appearing to affect the general interests of agriculture in Kenya,"
40. Clause 95 (aa) delete "or veterinary surgeon "Subject the regulations to approval by Parliament.
41. Second Schedule – Delete

42. Fourth Schedule - Delete.
43. Seventh Schedule - Delete Narcotic Drugs and Psychotropic Substances Act and its provisions.

NB: Ensure all good provisions of the Acts proposed to be repealed are carried into the new law by way of substitutive provisions. These include sections 6,7,8,9 of PPA.

MIN. NO. NADC-H/2023/489: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 12.30 p.m.

Sign.....Date 2/11/2023

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

MINUTES OF HUNDRED AND TWENTHY FIFTH (125TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON TUESDAY 31ST OCTOBER, 2023 AT 2.00 P.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P -**Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha	- Principal Clerk Assistant II
2.	Mr. Hassan A. Arale	- Clerk Assistant I
3.	Ms. Christine Odhiambo	- Senior Legal Counsel
4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant At Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

IN ATTENDANCE- HON. MEMBERS WITH PROPOSED AMENDMENTS

1. Hon. Anthony Oluoch, MP
2. Hon. Irene Mayaka, MP

MIN. NO. NA/DC-H/2023/483: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 9.30 a.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/484: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) BY HON. IRENE MAYAKA, MP.

The Hon. Irene Mayaka, MP presented the following amendments to the Committee; -

Under Clause 37

That clause 37 of the Bill be amended –

(a) By inserting the following new sub-clause immediately after sub-clause (2) "(3) The Cabinet Secretary shall publish the list prepared under subsection (1) in the Gazette.

(4) the list published under subsection (3) shall include narcotic substances, prescription only medications, over the Counter medicines, hazardous and prohibited substances".

(b) By renumbering sub-clause (5); and

(c) By renumbering sub-clause (4) as sub-clause (6);

MIN. NO. NADC-H/2023/485: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 4.30 p.m.

Sign.....Date.....2/11/2023

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

MINUTES OF HUNDRED AND TWENTHY FOURTH (124TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN HILTON GARDEN INN ON TUESDAY 31ST OCTOBER, 2023 AT 9.00 A.M

PRESENT

1. The Hon. Dr. Pukose Robert, M.P – **Chairperson**
2. The Hon. Ntwiga Patrick Munene, M.P -**Vice-Chairperson- Chairing**
3. The Hon. Dr. Nyikal James Wambura, M.P.
4. The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, M.P
5. The Hon. Mary Maingi, MP
6. The Hon. Oron Joshua Odongo, M.P.
7. The Hon. Prof. Jaldesa Guyo Waqo, M.P
8. The Hon. Wanyonyi Martin Pepela, M.P
9. The Hon. Owino Martin Peters, M.P
10. The Hon. Mathenge Duncan Maina, M.P
11. The Hon. Kibagendi Antony, M.P
12. The Hon. Lenguris Pauline, M.P

ABSENT WITH APOLOGY

1. The Hon. Titus Khamala, M.P
2. The Hon. Muge Cynthia Jepkosgei, M.P
3. The Hon. Kipngor Reuben Kiborek, M.P

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4.	Ms. Emma Essendi	- Senior Legal Counsel
5.	Mr. Salat Adan	- Principal Serjeant At Arms
6.	Ms. Rahab Chipkilim	- Audio Officer III
7.	Ms. Victoria Wanjiku	- Intern

IN ATTENDANCE- HON. MEMBERS WITH PROPOSED AMENDMENTS

1. Hon. Anthony Oluoch, MP
2. Hon. Irene Mayaka, MP

MIN. NO. NA/DC-H/2023/480: PRELIMINARIES/INTRODUCTION

The meeting was called to order at 9.30 a.m. with a word of prayer by the Vice- Chairman Hon. Patrick Ntwiga Munene, M.P and introductions were then done.

MIN. NO. NA/DC-H/2023/481: CONSIDERATION OF THE PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022) HON. ANTHONY OLUOCH, MP.

The Hon. Anthony Oluoch, MP presented the following amendments to the Committee; -

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title

"AN ACT of Parliament to establish the Kenya Health Products and Technologies Authority to ensure safety, quality and efficacy or performance of drugs, poisons, therapeutic and biological products, therapeutic cosmetics, herbal medicines and products, chemical substances, medical devices, veterinary products and other health technologies; to provide for the harmonization and administration of the laws relating to the regulation of, drugs, poisons, therapeutic products, therapeutic cosmetics, chemical products, veterinary products and medical devices and the control and safe handling of poisons; to safeguard the security of the supply chains for, therapeutic products, cosmetics and veterinary products; to provide for measures to optimize the use of therapeutic products in health care in Kenya and for connected purposes."

Clause 2

THAT, the Clause 2 of the Bill be amended—

(a) in the definition of the term "advertisement" by deleting the words "herbal medicines and products";

(b) in the definition of the term "article" by

(i) deleting the words "herbal medicine" appearing in paragraph (a); and

(ii) deleting the words "herbal medicine" appearing in paragraph (b);

(c) in the definition of "authorized seller of scheduled substances" by inserting the words "and enrolled as a pharmaceutical technologist or registered as a pharmacist" immediately after the word "Act";

(d) in the definition of the term "health products and technologies" by deleting the words "herbal medicines and products";

(e) by deleting the definition of the term "herbal medicine or product" and substituting therefor the following new definition—

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations and excludes herbs, herbal materials, herbal preparations, finished herbal products sold or dispensed on a small scale by traditional health practitioners;"

(f) in the definition of the term "medicine" by inserting the words "other than herbal medicines or products" immediately after the words "or mixture of substances".

(g) in the definition of "pharmacy" by inserting the words "licensed and" immediately after the words "carried out by" appearing in paragraph (a);

(h) deleting the definition of "chemical substance" and substituting therefor the following new definition—

"chemical substance" means any substance or mixture of substances prepared, sold or represented for use as a germicide, antiseptic, disinfectant, pesticide, insecticide, rodenticide, vermicide, detergent or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;

(i) deleting the definition of "therapeutic cosmetic" and substituting therefor the following new definition—

"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, to target and repair skin issues, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;".

Clause 3

THAT, Clause 3 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraph (c); and

(b) by inserting the following new sub-clause immediately after sub-clause (2)—

(3) This Act shall not apply to the regulation of herbal medicines or products.

Clause 6

THAT, Clause 6 of the Bill be amended in sub-clause (4) by deleting the word "ten" in appearing in paragraph (c) and substituting therefor the word "fifteen".

Clause 8

THAT, Clause 8 of the Bill be amended in sub-clause (7) by inserting the words ", fair representation of persons with disabilities" immediately after the words "regional balance."

Clause 12

THAT, Clause 12 of the Bill be amended in paragraph (o) by deleting the words "and herbal drugs;"

Clause 23

THAT, Clause 23 of the Bill be amended in sub-clause (2) by

(a) deleting the words "one million" appearing in paragraph (a) and substituting therefor the words "two million"; and

(b) deleting the words "two million" appearing in paragraph (b) and substituting therefor the words "five million".

Clause 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (9).

Clause 35

THAT, Clause 35 of the Bill be amended in sub- clause (2) by inserting the word "registered" immediately after the words "may prohibit a".

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36.

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the words "or pharmaceutical technologists" immediately after the words "a Registered Pharmacist".

Clause 41

THAT, Clause 41 of the Bill be amended in sub-clause (1) by inserting the words "or pharmaceutical technologists" immediately after the words "a pharmacist" appearing in paragraph (b)".

Clause 42

THAT, Clause 42 of the Bill be amended by

(a) deleting sub-clause (1) and substituting therefor the following new sub-clause (1)
"(1) An authorized seller shall enter a record of such particulars of the scheduled substance before delivery of the scheduled substance under this Act."

(b) inserting the following new sub-clause (2) immediately after the new sub-clause (1)

"(2) A record under subsection (1) shall be in the format prescribed by the Authority and shall indicate

(a) the date of the sale;
(b) the name and address of the purchaser;
(c) the quantity of the scheduled substances sold; and
(d) the purpose for which it is stated by the purchaser to be required."

(c) renumbering sub-clause (2) as sub-clause (3); and

(d) renumbering sub-clause (3) as sub-clause (4).

Clause 51

THAT, the Bill be amended in clause 51 by inserting the words "and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both" immediately after the word "offence".

Clause 54

THAT, the Bill be amended by deleting clause 54.

Clause 63

THAT, Clause 63 of the Bill be amended by deleting sub-clause (3).

MIN. NO. NADC-H/2023/482: ADJOURNMENT

There being no any other business, the Chairperson, adjourned the meeting at exactly 12.30 p.m.

Sign.....Date.....2/11/2023.....

HON. PATRICK NTWIGA MUNENE, M.P.

VICE- CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

ANNEXURE 2- REPORT ADOPTION SCHEDULE

THE NATIONAL ASSEMBLY
13TH PARLIAMENT - SECOND SESSION – 2023
DIRECTORATE OF DEPARTMENTAL COMMITTEES
DEPARTMENTAL COMMITTEE ON HEALTH,
ADOPTION LIST FOR THE REPORT ON THE WINNOWING PROCESS OF THE KENYA DRUG AUTHORITY BILL, 2022 (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

DATE: 2/11/2023

VENUE: HILTON GARDEN INN

NO.	NAME	SIGNATURE
1.	The Hon. Dr. Pukose Robert, M.P.- **Chairperson**	
2.	The Hon. Ntwiga Patrick Munene, M.P.-**Vice-Chairperson**	
3.	The Hon. Maingi Mary, M.P.	
4.	The Hon. Muge Cynthia Jepkosgei, M.P	
5.	The Hon. Kipngor Reuben Kiborek, M.P.	
6.	The Hon. Wanyonyi Martin Pepela, M.P	
7.	The Hon. Mathenge Duncan Maina, M.P.	
8.	The Hon. Lenguris Pauline, M.P.	
9.	The Hon. Oron Joshua Odongo, M.P.	
10.	The Hon. Dr. James Nyikal Wambura, M.P.	
11.	The Hon. Kibagendi Antoney, M.P.	
12.	The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS M.P.	
13.	The Hon. Prof. Jaldesa Guyo Waqo, M.P.	
14.	The Hon. Titus Khamala, M.P	
15	The Hon. Owino Martin Peters, M.P.	

ANNEXURE 3- SPEAKER'S COMMUNICATION

3. Other Honourable Members, including the Deputy Speaker, Hon. Gladys Boss, MP and the Chairperson of the Departmental Committee on Health, Hon. (Dr.) Robert Pukose, MP, weighed in on the matter and gave their input and clarification on the nature of the proposed amendments.

4. **Honourable Members,** having considered the issues raised by the Member for Homa Bay Town Constituency in relation to the assurances by the Chairperson of the Departmental Committee on Health and other Members, I was inclined to permit the consideration of the Bill in the Committee of the Whole House. In so doing, I was hopeful that the Committee would conscientiously consider and decide each of the proposed amendments, including those that I approved after publication of the Order Paper.

5. I also guided the House that should need for certain proposed amendments to undergo winnowing arise, while in the Committee of the House, the Chairperson of the Committee would be at liberty to stay the relevant Clause to allow further consideration. For the record, Committee of the Whole House on the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022) commenced yesterday and progressed up to Clause 22.

6. As you are aware, **Honourable Members,** the resumption of the Committee of the Whole House during today's morning Sitting was interrupted due to lack of Quorum. The same business is scheduled to resume in this Sitting as listed under Order Number 11 of today's Order

REPUBLIC OF KENYA

THIRTEENTH PARLIAMENT - (SECOND SESSION)
THE NATIONAL ASSEMBLY
COMMUNICATION FROM THE CHAIR

(No. 78 of 2023)

REFERRAL OF A BILL TO A WINNOWING PROCESS UNDER STANDING ORDER 131– THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

Honourable Members,

1. You may recall that, during the Afternoon Siting of the House yesterday, Tuesday 24th October 2023, the Member for Homa Bay Town Constituency, the Hon. Peter Kaluma, MP, rose on a Point of Order pursuant to the provisions of Standing Order 131. The Hon. Kaluma sought the indulgence of the Chair to stay the consideration of the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022) in Committee of the Whole House.

2. The Member for Homa Bay Town Constituency relied on the argument that proposed amendments in respect to the Bill were nearly on all the Clauses. He averred that it was an established established practice of the House pursuant to Sanding Order 131 that, where so many amendments are proposed on a Bill, the Speaker refers the amendments to the relevant Committee to for harmonization. A process popularly known as *winnowing.* He further implied that where the multiplicity of amendments appeared to re-write the Bill, the Speaker would order such Bill to be re-published.

Paper. Before proceeding to the said Order, I wish to inform the House that several Members have approached me and canvassed their concerns on the Bill and the proposed amendments.

7. Without delving into the details of the Members' concerns, the bottom-line was for the Speaker to stay further consideration of the Bill to allow winnowing of the proposed amendments. Notably, the Members' concerns resonate with the Point of Order that the Member for Homa Bay Town Constituency raised yesterday.

8. In this regard**, Honourable Members,** I am inclined to defer further consideration of the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022) in the Committee of the Whole House.

9. To this end, I direct that the proposed amendments to the Bill be subjected to a winnowing process before the Departmental Committee on Health. All Members with amendments, including all other Members desirous of proposing amendments to the Bill are required to appear before the Committee to prosecute their proposals.

10. For fairness **Honourable Members**, I advise the Chairperson of the Departmental Committee on Health in whose name the Bill is published to consider recusing himself during the winnowing process and allow the Vice Chairperson or another Member of the Committee to steer the process.

11. For clarity, Committee of the whole House had concluded consideration of Clauses 3 to 22. In the event contestations arise with regard to those Clauses, the House will be at liberty to recommit the clauses in accordance with Standing Order 136A. The Bill will be resumed later on

a day to be determined by the House Business Committee upon reporting of the results of the winnowing process by the Committee.

12. The House is accordingly guided.

I thank you!

THE RT. HON. (DR.) MOSES F.M. WETANG'ULA, EGH, MP
SPEAKER OF THE NATIONAL ASSEMBLY

Wednesday, October 25, 2023

ANNEXURE 4- LETTERS INVITING MEMBERS TO THE MEETING TO SUBMIT PROPOSED AMENDMENTS OF THE BILL TO THE COMMITTEE

THE NATIONAL ASSEMBLY
OFFICE OF THE CLERK

P. O. Box 41842-00100
Nairobi, Kenya
Main Parliament Buildings

Telephone: +254202848000 ext. 3300
Email: cna@parliament.go.ke
www.parliament.go.ke/the-national-assembly

When replying please quote

Ref. NA/DDC/DC-H/2023/ (099) **27th October, 2023**

Hon. Dr. Robert Pukose, MP
Parliament Buildings,
NAIROBI

Hon. Peter Kaluma, MP
Parliament Buildings,
NAIROBI

Hon. T. J. Kajwang, MP
Parliament Buildings,
NAIROBI

Hon. Dr. James Nyikal, MP
Parliament Buildings,
NAIROBI

Hon. Dr. Otiende Amolo, MP
Parliament Buildings,
NAIROBI

Hon. Irene Mayaka, MP
Parliament Buildings,
NAIROBI

Hon. Anthony Oluoch, MP
Parliament Buildings,
NAIROBI

Hon. Millie Odhiambo, MP
Parliament Buildings,
NAIROBI

Hon. Martin Peters Owino, MP
Parliament Buildings,
NAIROBI

Dear Hon Pokose

REF: MEETING ON HARMONIZATION OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022

The Departmental Committee on Health is established under Standing Order 216 (1) and is mandated to, inter-lia, *"study and review all legislation referred to it"*.

The Committee is in receipt of proposed amendments to the Kenya Drugs Authority Bill, 2022 for harmonization before consideration at Committee of the Whole House. The amendments were submitted in accordance with the provisions of Standing Order 131, which states '*the Speaker may direct any Member proposing an amendment to the Bill to appear before the relevant Departmental Committee dealing with the subject matter of the Bill to present his or her proposed amendments'*.

In light of the foregoing, the Committee has scheduled to meet you on **Tuesday, 31st October, 2023** and **Wednesday 1st November, 2023 at 10.00 am** as per the attached schedule to present your proposed amendments in accordance with Standing Order 131. The meeting venue will be communicated in due course.

Our Liaison Officers on this subject are; **Mr. Hassan A. Arale** who may be contacted on Tel. No. **0721480578** or email address hassan.arale@gmail.com and **Ms. Gladys Kiprotich**, Tel. No. **0718721253** or email address gladys.kiprotich@gmail.com

Yours

JEREMIAH NDOMBI, MBS
For:- CLERK OF THE NATIONAL ASSEMBLY

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Hon. Martin Peters Owino, MP
Parliament Buildings,
NAIROBI

Dear Hon Kaluma

REF: MEETING ON HARMONIZATION OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022

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Yours

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Hon. Millie Odhiambo, MP
Parliament Buildings,
NAIROBI

Hon. Martin Peters Owino, MP
Parliament Buildings,
NAIROBI

Dear Hon Kajwang

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Yours

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Hon. Millie Odhiambo, MP
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Hon. Martin Peters Owino, MP
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Dear Hon Nyikal

REF: MEETING ON HARMONIZATION OF PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022

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In light of the foregoing, the Committee has scheduled to meet you on **Tuesday, 31st October, 2023** and **Wednesday 1st November, 2023 at 10.00 am** as per the attached schedule to present your proposed amendments in accordance with Standing Order 131. The meeting venue will be communicated in due course.

Our Liaison Officers on this subject are; **Mr. Hassan A. Arale** who may be contacted on Tel. No. 0721480578 or email address hassan.arale@gmail.com and **Ms. Gladys Kiprotich**, Tel. No. 0718721253 or email address gladys.kiprotich@gmail.com

Yours

JEREMIAH NDOMBI, MBS
For:- CLERK OF THE NATIONAL ASSEMBLY

THE NATIONAL ASSEMBLY
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Dear Hon. Dr. Amolo

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Dear Hon. Mayaka

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Dear Hon Oloo

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Dear Hon Odhiambo

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For:- CLERK OF THE NATIONAL ASSEMBLY

ANNEXURE 5: SUBMISSION BY MEMBERS

Compliant State Corporations, *laid on the Table of the House on Wednesday, 23rd August 2023.*

25*. **MOTION – PROCEEDINGS OF THE SECOND ORDINARY SESSION OF THE SIXTH PAN-AFRICAN PARLIAMENT (PAP)**
(Member of the Pan-African Parliament)

THAT, this House **notes** the Report of the Record of Proceedings of the Second Ordinary Session of the Sixth Pan-African Parliament (PAP) held in Midrand, South Africa, from 15th May to 2nd June 2023, *laid on the Table of the House on Thursday, 24th August 2023.*

26*. **MOTION – PROCEEDINGS OF THE 2023 UNITED NATIONS HIGH LEVEL POLITICAL FORUM ON SUSTAINABLE DEVELOPMENT**
(The Vice Chairperson, Parliamentary Caucus on Sustainable Development Goals (SDGs) and Business)

THAT, this House **notes** the Report of the Parliamentary Caucus on Sustainable Development Goals (SDGs) and Business on the Proceedings of the 2023 United Nations High Level Political Forum on Sustainable Development (HLPF 2023) held in New York, United States of America (USA) from 10th to 21st July 2023, *laid on the Table of the House on Thursday, 24th August 2023.*

27*. **THE NATIONAL GOVERNMENT CONSTITUENCIES DEVELOPMENT FUND (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 13 OF 2023)**
(The Leader of the Majority Party and the Leader of the Minority Party)

Second Reading

28*. **THE CONFLICT OF INTEREST BILL (NATIONAL ASSEMBLY BILL NO. 12 OF 2023)**
(The Leader of the Majority Party)

Second Reading

Denotes Orders of the Day

...../*Notices**

NOTICES

I. THE INSURANCE (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 18 OF 2023)

Notice is given that the Chairperson of the Departmental Committee on Finance and National Planning intends to move the following amendment to the Insurance (Amendment) Bill, 2023 at the Committee Stage—

CLAUSE 3

THAT, clause 3 of the Bill be amended in the proposed new section 67H (1) by deleting the word "shareholder," appearing at the beginning of the subclause.

II. THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

1) Notice is given that the Chairperson of the Departmental Committee on Health intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

> "AN ACT of Parliament to establish a comprehensive legal framework for the regulation of Health Products and Technologies; to safeguard public health through development of a regulatory system to ensure safety, quality, efficacy, effectiveness and performance of health products; to establish the Kenya Health Products and Technologies Authority and for connected purposes".

CLAUSE 1

THAT, Clause 1 of the Bill be amended by—

(a) deleting the phrase "Kenya Drugs Authority Act, 2022" and substituting therefor the phrase "Kenya Health Products and Technologies Regulatory Authority Act, 2022";

(b) deleting the words "and commencement" in the marginal note.

CLAUSE 2

THAT, Clause 2 of the Bill be amended—

(a) in the definition of "article" by–

(i) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (a); and

(ii) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" appearing in paragraph (b);

(b) in the definition of "Authority" by deleting the words "Kenya Drugs Authority" and substituting therefor the words, "Kenya Health Products and Technologies Regulatory Authority";

(c) in the definition of "chemical substance" by deleting the words "or detergent";

(d) in the definition of "drug" by deleting the word "if" appearing in paragraph (b)(ii) and substituting therefor the word "of";

(e) by deleting the definition of "enrolled pharmaceutical technologist";

(f) in the definition of "health products and technologies" by inserting the words, "dietary supplement" immediately after the words, "therapeutic cosmetics";

(g) by deleting the definition of "herbal medicine or product";

(h) by deleting the definition of "medical device";

(i) by deleting the definition of "medicinal substance";

(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";

(k) by deleting the definition of "pharmacy";

(l) by deleting the definition of "pharmaceutical technologist";

(m) by deleting the definition of "registered midwife";

(n) in the definition of "scheduled substance" by deleting the words "in the relevant schedule under this Act" and substituting therefor the words "in the list published by the Cabinet Secretary under section 37 of this Act";

(o) by deleting the definition of "therapeutic cosmetic"; and

(p) by inserting the following new definitions in their proper alphabetic sequence—

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"adverse event" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment;

"biologicals" means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies and includes products derived from human blood and plasma;

"Board" means the Board of the Authority established under section 8;

"Centre" means the National Pharmacovigilance Centre established under section 59B;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dietary supplement" means a product taken by mouth that is added to the diet to help meet daily requirements of essential nutrients, and which usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

"enrolled pharmaceutical technologist" means a person enrolled as such by the body for the time being responsible for the enrolment of pharmaceutical technologists;"

"falsified medical product" means a product that is deliberately or fraudulently misrepresented in relation to its identity, composition or source;

"Field Safety Corrective Action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, and includes—

(a) the return of a medical device to the product owner or its representative;

(b) device modification which may include—

(i) retrofit in accordance with the product owner's modification or design change;
(ii) permanent or temporary changes to the labelling or instructions for use;
(iii) software upgrades including those carried out by remote access;
(iv) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;
(v) device exchange;
(vi) device destruction; or
(vii) advice given by product owner regarding the use of the device.

"health product" includes a medicine, medical product, medicinal substance, vaccine, diagnostic, medical device, blood or blood product, traditional and alternative medicine, therapeutic feed and nutritional formulation, cosmetic and related products;

"health technology" means the application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives;

"herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations;

"in-vitro diagnostics medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector and who holds a minimum of a diploma in pharmacy;

"lot" or "sub-lot" means a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous; and in the case of continuous manufacture, the lot corresponds to a defined fraction of the production characterized by its intended homogeneity;

"lot release" means the process of the evaluation of an individual lot of a licensed biological product by the Authority before giving approval for its release onto the market;

"marketing authorization" means the certificate of registration issued by the competent health product regulatory authority in the country of origin for the purpose of marketing or free distribution of a health product after evaluation for safety, efficacy and quality;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;

(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"passive surveillance" means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importation" means importation into Kenya, by a licensed importer of a health product other than the marketing authorization holder or his or her technical representative, of the following health products which require marketing authorization in Kenya—

(a) patented health products under section 58(2) of the Industrial Property Act, 2001;
(b) non-patented health products; or
(c) branded generic health products;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;

"scheduling" means, in relation to a substance, the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;

"substandard medical product" means a registered medical product that fails to meet either its quality standards or specifications, or both;

"therapeutic cosmetic" means a cosmetic which—

(a) offers an additional benefit to a person over an ordinary cosmetic; or

(b) contains a bioactive product formulated from an animal ingredient that may have visible and measurable short or long-term effects on a person,

and may include a product that may be absorbed through the skin or a mucous membrane;

"unregistered medical product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;

"vessel" means a truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;

CLAUSE 3

THAT, Clause 3 of the Bill be amended by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(l) This Act applies to the regulation of—

(a) medicines, medical products and technologies;
(b) medical devices including radiation emitting products;
(c) radiopharmaceuticals;
(d) complementary, alternative or herbal medicines;
(e) cosmetics and Borderline Products;
(f) in-vitro diagnostics medical devices;
(g) therapeutic feeds;
(h) clinical trials;
(i) nutraceuticals and dietary supplements;
(j) digital health and technologies;
(k) scheduled substances;
(l) chemical substances; and
(m) biological products for use in humans and the starting materials used in their manufacture."

CLAUSE 4

THAT, Clause 4 of the Bill be amended in sub-clause (1) by deleting the words "Kenya Drugs Authority" and substituting therefor the words "Kenya Health Products and Technologies Regulatory Authority".

CLAUSE 5

THAT, Clause 5 of the Bill be amended by deleting the words, "but the Authority may establish branches anywhere in Kenya" and substituting therefor the words "or in such other place as the board of the Authority may, by resolution, determine".

CLAUSE 6

THAT, Clause 6 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) There shall be a Director-General who shall be the chief executive officer of the Authority."

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) The Director-General shall be appointed by the Board, through a transparent and competitive process, on such terms as may be specified in the instrument of appointment."

(c) in sub-clause (3) by deleting the word "four" and substituting therefor the word "three".

(d) by deleting sub-clause (4) and substituting the following new sub-clause (4)—

"(4) A person shall be qualified for appointment as a Director-General if such person—

(a) holds a bachelor's degree in pharmacy from a university recognized in Kenya;
(b) holds a masters' degree in pharmacy, medicine or any relevant field from a university recognized in Kenya;
(c) has at least ten years' experience in pharmacy or its equivalent;
(d) has served in a senior management position for at least five years;
(e) is a member of a professional body; and
(f) meets the requirements of Chapter six of the Constitution."; and

(e) by deleting sub-clause (5).

CLAUSE 7

THAT, Clause 7 of the Bill be amended in paragraph (f) by deleting the words "Act. regulation under this" and substituting therefor the words "regulation under this Act.".

CLAUSE 8

THAT, Clause 8 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "Kenya Drugs" and substituting therefor the words "Kenya Health Products and Technologies Regulatory';

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–

"(2) The Board shall comprise—

(a) a non-executive Chairperson appointed by the President and who shall—

(i) be a registered pharmacist of good standing with a degree in pharmacy; and

(ii) have at least ten years' experience in the pharmaceutical sector, five of which shall be at senior management level;

(b) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing;

(c) the Principal Secretary the Ministry for the time being responsible for finance or a representative designated in writing;

(d) the Director-General for Health or a representative designated in writing;

(e) one person nominated by the Pharmaceutical Society of Kenya;

(f) one person nominated by the Kenya Pharmaceutical Association;

(g) one person nominated by the Kenya Medical Association;

(h) one person, not being a Governor, with knowledge and experience in health products and technologies nominated by the Council of County Governors to represent the interests of counties;

(i) one person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and

(j) the Director-General of the Authority who shall be the secretary and an *ex officio* member of the Board."; and

(c) by deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

"(3) The Cabinet Secretary shall appoint the members of the Board under subsection (e), (f), (g), (h) and (i) by notice in the *Gazette*."

CLAUSE 9

THAT, the Bill be amended by deleting Clause 9.

CLAUSE 10

THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "section 12" appearing in paragraph (c) and substituting therefor the words "section 11".

CLAUSE 12

THAT, Clause 12 of the Bill be amended by—

(a) inserting the following paragraphs immediately after paragraph (e)—

"(ea) regulate the disposal of health products and technologies;
(eb) monitor the market for the presence of unregistered and illegal health products and technologies;
(ec) conduct analytical tests of health products and technologies";

(b) deleting paragraph (f) and substituting therefor the following new paragraph (f)—

"(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act through analysis of reports on adverse reactions and events, including any other health product and technology use related issues and take appropriate regulatory actions when necessary";

(c) deleting paragraph (g) and substituting therefor the following new paragraph (g)—

"(g) regulate clinical trials and ensure that clinical trial protocols of health products and technologies are being assessed according to the prescribed ethical and professional criteria and defined standards including mandatory bioequivalence studies";

(d) inserting the following new paragraphs immediately after paragraph (g)—

"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials, emergency use and compassionate use;
(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements";

(e) deleting paragraph (n) and substituting therefor the following new paragraph (n)—

"(n) appoint inspectors and order inspection of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act";

(f) inserting the following new paragraphs after paragraph (o)—

"(oa) conduct national regulatory authority lot release, official authority batch release of specified biologicals to ensure the quality, safety and efficacy of biological products through a regulatory release system in compliance with established approaches, policies, guidelines, procedures and in line with World Health Organization and internationally recognized guidelines;
(ob) carry out and promote research related to medicines and health products";

(g) inserting the following paragraphs after paragraph (q)—

"(qa) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;
(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;
(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;
(qd) maintain a register of all authorized health products and technologies manually or electronically;
(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;
(qf) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

CLAUSE 13

THAT, Clause 13 of the Bill be amended by—

(a) deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate for the furtherance of the purpose of the Act;"

(b) inserting the following new paragraphs immediately after paragraph (a)—

"(aa) adopt and implement any such internationally recognized good regulatory practices;

(ab) determine and implement effective and efficient reliance mechanisms;

(ac) issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;

(ad) levy, collect and utilize fees for services rendered;

(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; (af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

CLAUSE 21

THAT, Clause 21 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) The Board may establish such scientific advisory committees of the Authority, as may be necessary for the effective performance of the functions of the Authority".

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9) —

"(9) An advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary".

PART IV

THAT, Part IV of the Bill be amended by deleting the title and substituting therefor the following new title–

PART III—HEALTH PRODUCTS AND TECHNOLOGIES

CLAUSE 22

THAT, Clause 22 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";

(b) in sub-clause (1) by—

(i) deleting the words "sell any medicine" appearing in the opening sentence and substituting therefor the words "sell, manufacture, supply, distribute or dispense any health product or technology";

(ii) deleting paragraph (d) and substituting therefore the following new paragraph (d)—

"(d) is falsified,";

(c) in sub-clause (3) by—

(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) deleting the words "pharmaceutical product" appearing in paragraph (b) and substituting therefor the words, "health product or technology".

CLAUSE 23

THAT, Clause 23 of the Bill be amended in sub-clause (1) by—

(a) deleting the word "medicines" appearing in paragraph (a) and substituting therefor the words, "health products or technologies";
(b) deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words, "health products or technologies"; and
(c) deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words, "health products or technologies".

CLAUSE 24

THAT, Clause 24 of the Bill be amended—

(a) in the marginal note by deleting the word "medicines" and substituting therefor the words "health products and technologies";
(b) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(c) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)–

"(2) If a standard has not been prescribed for a health product or technology but a standard for the health product or technology is contained in any of the publications specified in the Fifth Schedule, any person who manufactures, labels, packages, sells or advertises any other substance or article in such a manner that is likely to be mistaken for the health product or technology having met any of the standards contained in any of the publications specified in the Fifth Schedule, commits an offence.";

(d) in sub-clause (3)–

(i) by deleting the word "medicine" wherever it appears in the opening sentence and substituting therefor the words "health product or technology"; and

(ii) by deleting the word "drug" appearing in paragraph (b) and substituting therefor the words "health product or technology";

(e) in sub-clause (4)—

(i) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three months" appearing in paragraph (a) and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years"; and

(ii) by deleting the words "two hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

CLAUSE 25

THAT, the Bill be amended by deleting Clause 25.

CLAUSE 26

THAT, Clause 26 of the Bill be amended by—

(a) deleting the word "medicine" appearing in the marginal note and substituting therefor the words "health product or technology"; and

(b) deleting the word "medicine" and substituting therefor the words "health product or technology".

CLAUSE 27

THAT, Clause 27 of the Bill be amended—

(a) by deleting the words "medicinal products" appearing in paragraph (a) and substituting therefor the words "health products or technologies";

(b) by deleting the words "medicinal products" appearing in paragraph (b) and substituting therefor the words "health products or technologies"; and

(c) by deleting paragraph (c) and substituting the following new paragraph (c)—
"(c) the quality of the health products or technologies of each such description, according to the specification and the method or proposed method of manufacture of the health products or technologies and the provisions proposed for securing that the health products or technologies as sold or supplied will be of that quality; and"

NEW CLAUSES 27A, 27B, 27C & 27D

THAT, the Bill be amended by inserting the following new clauses immediately after clause 27–

Application for product licence.

27A. (1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Authority for the registration of the health product or health technology in the prescribed form.

(2) An applicant under subsection (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Authority in the declaration page of the application form; and

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—

(a) a proposed label for use on the health product or technology;

(b) a copy of the manufacturing licence of the health product or technology, where applicable;

(c) a copy of the good manufacturing practice certificate from the Authority and the regulatory authority of the country where the health product or technology is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognized by the Authority, where applicable;

(e) a copy of the marketing authorization or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product or technology;

(h) proof of ownership of the site for the manufacture of the health product or technology, where applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body—

(i) a copy of the certificate of registration;
(ii) the professional information relating to the health product or technology; and
(iii) the conditions of the registration of the health product or technology;

(k) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;
(ii) a valid wholesale dealer's licence issued in accordance with this Act;
(iii) a valid licence to sell poisons issued in accordance with this Act; or
(iv) a valid manufacturing licence issued in accordance with this Act; and
(v) proof of payment of the application fees as prescribed by the Authority.

(4) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation

Processing of application for registration of health product or technology.

27B. (1) The Authority shall consider the application made under section 27A, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in the prescribed form.

(2) The Authority may, while considering the application, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;
(b) the labelling of the health product or technology;
(c) the statement of the representations to be made for the promotion of the health product or technology regarding—
(i) the claim to be made for the health product or technology;
(ii) the route of administering the health product or technology;
(iii) the dosage of the health product or technology;
(iv) the storage conditions of the health product or technology;
(v) the contra-indications, the side effects and precautions, if any of the health product or technology; and
(vi) the package size of the health product or technology.

(3) When evaluating an application, the Authority may—

(a) subject a sample of the health product or technology to an evaluation by an analyst; and

(b) consider the evaluation report of the analyst that has evaluated the health product or technology.

(4) Where the Authority is not satisfied as to the quality, safety efficacy, performance or economic value of the health product or technology, it may, after providing an opportunity to the applicant to be heard, reject the application and inform the applicant the reasons for rejection in writing.

Registration during emergency.

27C. (1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to life or health, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subsection (1) shall apply to the Authority in the prescribed form.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(4) An application under subsection (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(5) When determining an application under this section, the Authority shall consider the facts established from the valid

marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for health products and technologies, if available.

(6) The person to whom the certificate of registration is issued under this section, shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) A provisional certificate of registration issued under subsection (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked.

(8) Any variation to the agreement appointing the local representative to the application made under subsection (2) shall be notified to the Authority within seven days of the variation.

Authorization of unregistered health product or technology.

27D. (1) The Authority may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product or technology that is not registered.

(2) A health product or technology distributed pursuant to authorization granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) A person who intends to obtain the authorization under subsection (1), for purposes other than a clinical trial, shall apply to the Authority in the prescribed form.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(5) The application made under subsection (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;

(b) written consent of the applicant, where applicable;

(c) details of registration or pending registration of the health product or technology with any other

regulatory authority, where applicable;

(d) evidence of compliance by the manufacturer of the health product or technology with good manufacturing practice standards as determined by the Authority;

(e) reasons why a registered health product or technology cannot be used;

(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(g) proof that the applicant holds—

(i) a valid practicing licence issued by the body responsible for the profession of pharmacy;

(ii) a valid wholesale dealer's licence issued in accordance with this Act;

(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or

(iv) a valid manufacturing licence issued in accordance with this Act; and

(v) proof of payment of the application fees as prescribed by the Authority.

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—

(a) progress reports after every six months from the date of issuance of the authorization;

(b) any adverse event report, where an adverse event occurred; and

(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or

(d) withdraw the authorization to treat the patient.

(8) The Authority may, by notice in writing withdraw the

authorization issued under subsection (1) if the any of purposes or the manner specified in subsection (2) is contravened.

(9) A health product or technology authorized under this section shall be labelled in accordance with this Act.

(10) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

(11) The requirements in this section shall apply to applications for donations of health products and technologies.

CLAUSE 28

THAT, Clause 28 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines register" and substituting therefor the words "health products and technologies register";
(b) in sub-clause (1) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register"; and
(c) in sub-clause (2) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register".

CLAUSE 29

THAT, Clause 29 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines and medical devices" and substituting therefor the words "health products and technologies";
(b) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) Every application for registration of a health product or technology shall be submitted to the Registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant health product or technology and by the prescribed registration fee."

(c) in sub-clause (3)–
(i) by deleting the word "medicine" appearing in paragraph (a) and substituting therefor the words "health product or technology";
(ii) by deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words "health product or technology";
(iii) by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology";

(d) in sub-clause (4) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

(e) by deleting sub-clause (6) and substituting therefor the following new sub-clause (6)—

"(6) Where the Authority has approved the registration of any health product or technology if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, the Registrar shall register that health product or technology and shall enter in the register such particulars in regard to the health product or technology as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that health product or technology."

(f) in sub-clause (7) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(g) in sub-clause (8) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(h) in sub-clause (9) by deleting the word "medicines" and substituting therefor the words "health products and technologies";

(i) in sub-clause (10) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(j) in sub-clause (11) by deleting the word "medicine" and substituting therefor the words "health product or technology";

(k) in sub-clause (12) by deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology";

(l) in sub-clause (14) by deleting paragraph (a) and substituting therefor the following new paragraph (a) —

"(a)Kenya Essential Medicines List, Kenya Essential Diagnostics list and Kenya Essential Medical Supplies list' means the list of essential medicines, diagnostics and medical supplies included in the latest editions of the official publications relating to guidelines for standard treatment which is compiled by the state department responsible for Health;"

NEW CLAUSES 29A & 29B

THAT, the Bill be amended by inserting the following new clauses immediately after clause 29–

Authorization of health products and technologies.

29A. (1) A person shall not import any health product or technology unless—

(a) the imported health product or technology has been authorized through issuance of an import permit or a written authorization by the Authority; and

(b) the imported health product or technology is inspected and verified by an inspector of the Authority at the ports of entry prior to its release.

(2) No batch or lot of any registered product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in cases of biological therapeutics.

(3) Each applicable test conducted by the manufacturer under subsection (2) shall be made on each batch or lot after completion of all processes of manufacture and such test may affect compliance with the standard applicable to the product.

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

(5) Every batch or lot of a registered biological therapeutic imported into Kenya or manufactured in Kenya shall be evaluated and, on being satisfied of conformity with prescribed standards and payment of prescribed fees, the Director-General shall approve its release into the market and issue a certificate of official batch or lot release in the prescribed format.

(6) The Authority may recognize and accept official lot release certificates issued by other national regulatory authorities of other countries for a specific batch or lots of biological therapeutic manufactured within the territories of those national regulatory authorities, in issuance of a certificate under this section.

(7) A person who contravenes this section commits an offence and shall on conviction be liable—

(a) in the case of a first offence, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both; or

(b) in the case of a subsequent offence, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.

Parallel importation of health products and technologies.

29B. (1) A person shall not engage in the parallel importation of a health product or technology into Kenya unless—

(a) the person is incorporated as a limited liability company under the Companies Act;

(b) the person has been granted a certificate of parallel importation;

(c) the person is licensed to parallel import the health product or technology;

(d) the health product or technology has a valid registration in Kenya under this Act; and

(e) the health product or technology has a valid market authorization in the country of origin.

(2) A person who wishes to undertake parallel importation of a health product or technology shall apply to the Board for a certificate of parallel importation in the prescribed manner.

(3) The Board shall establish and maintain a system that ensures that a registered parallel imported health product or technology can be traced from its sourcing, manufacturing, packaging, storage, transport to its delivery to the health facility, institution or private practice where the health product or technology is intended to be used.

(4) A person who—

(a) is the holder of a certificate of parallel importation or licensee and fails to comply with any requirement or obligation in this Act;

(b) contravenes any prohibition prescribed by the Authority; or

(c) fails to comply with any requirement imposed on that person by the Board pursuant to this Act,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

CLAUSE 30

THAT, Clause 30 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology"; and

(b) in sub-clause (3), by deleting the word "medicine" wherever it appears in paragraph (b) and substituting therefor the words "health product or technology".

CLAUSE 31

THAT, Clause 31 of the Bill be amended—

(a) in sub-clause (1) by deleting the word "medicine" and substituting therefor the words "health product or technology"; and
(b) in sub-clause (3), by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology".

CLAUSE 32

THAT, Clause 32 of the Bill be amended—

(a) by deleting sub-clause (1) and substituting therefor the following new sub-clause (1)–

"(1) The Authority shall cancel the registration of a health product or technology if—

(a) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(b) a particular health product or technology does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular health product or technology available to the public."

(b) in sub-clause (2) by deleting the words "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology",
(c) in sub-clause (4)–
(i) by deleting the words "medicine or medical device" appearing in the opening sentence and substituting therefor the words "health product or technology"; and
(ii) by deleting the words "medicine or medical device" appearing in paragraph (b) and substituting therefor the words "health product or technology"; and
(d) by deleting the words "medicine or medical device" wherever it appears in sub-clause (5) and substituting therefor the words "health product or technology".

CLAUSE 33

THAT, Clause 33 of the Bill be amended in sub-clause (1) by deleting the words "medicine or medical device" and substituting therefor the words "health product or technology".

CLAUSE 34

THAT, Clause 34 of the Bill be amended—

(a) by deleting the words "medicines" and "medicine" wherever it appears and substituting therefor the words "health product or technology"; and
(b) in the marginal note by deleting the words "medicines" and substituting therefor the words "health products and technologies".

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";
(b) in sub-clause (1) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(c) in sub-clause (2) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(d) in sub-clause (3) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist"; and
(e) in sub-clause (4) by inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist".

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 36—

Clinical trials.

36A. (1) A health product or technology shall not be used for clinical trial unless an approval is granted by the Authority with the approval of the relevant ethics body.

(2) A person who intends to commence a clinical trial on a health product or technology shall make an application to the Authority in the prescribed form and the application shall be accompanied by the study protocol in the prescribed format and the prescribed fee.

(3) The study protocol submitted under subsection (2) shall include a post-trial access program to ensure access of investigational medicinal substances by participants in the trial before grant of marketing authorization by the Authority.

(4) The Authority shall prescribe guidelines for evaluation of applications made under subsection (2) to be implemented for accelerated evaluations during emergency situations, epidemics and outbreaks.

(5) A person granted an approval under this section shall put in place a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated and the safety and well-being of the participants of the study.

(6) The Authority shall carry out inspection of the clinical trials and monitor compliance of the clinical trials with the prescribed requirements.

(7) Any amendments to clinical trials protocols shall be submitted to the Authority for approval before implementation.

PART V

THAT, the Bill be amended in the title to Part V by deleting the expression "PART V" and substituting therefor the expression "PART IV".

CLAUSE 37

THAT, Clause 37 of the Bill be amended—

(a) in sub-clause (2) by deleting the words "and dealers in mining, agricultural or horticultural accessories" appearing in paragraph (a);
(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)—
"(3) The Cabinet Secretary shall publish the list of scheduled substances prepared under subsection (1) in the *Gazette.*"

(c) by renumbering sub-clause (3) as sub-clause (4);
(d) by deleting sub-clause (4) and substituting therefor the following new sub-clauses —

"(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.
(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsection (1), (2) and (3)."

CLAUSE 38

THAT, Clause 38 of the Bill be amended—
(a) in sub-clause (1) by—

(i) deleting the words "the Limitations prescribed by this sub-section" and substituting therefor the words "the following limitations";
(ii) deleting paragraph (c)

(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding two million shillings or to imprisonment for a term not exceeding three years; or to both."

CLAUSE 39

THAT, Clause 39 of the Bill be amended by deleting sub-clause (5) and substituting therefor the following new sub-clause (5)—

"(5) A licence issued under this section shall be valid for a period of one year, renewable annually".

CLAUSE 40

THAT, the Bill be amended by deleting clause 40.

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraphs (c) and (e);
(b) in sub-clause (2) by deleting paragraph (b) and (c); and
(c) by deleting sub-clause (3).

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "paragraph (b) of Section 53(2)" appearing in paragraph (a) and substituting therefor the words "section 41(2)(b)"; and
(b) in sub-clause (3) by deleting the words "three years" and substituting therefor the words "one year"

CLAUSE 43

THAT, Clause 43 of the Bill be amended in sub-clause (1)—

(a) by deleting the opening sentence and substituting therefor the following new opening sentence—

"(1) A qualified healthcare professional may supply or dispense a Scheduled Substance with therapeutic value for the purpose of medical, dental or veterinary treatment, as the case may be, subject to the following provisions—"

(b) in paragraph (b) by—

(i) inserting the word "and" immediately after the word "supplied" appearing in sub-paragraph (iii); and

(ii) deleting the word "and" appearing in sub-paragraph (iv);

(c) by deleting paragraph (c).

CLAUSE 45

THAT, the Bill be amended by deleting Clause 45 and substituting therefor the following new clause 45—

Automatic machines.

45. (1) An authorized seller may use an automatic machine to dispense over-the-counter scheduled substances.

(2) The Authority shall develop regulations on the—

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

CLAUSE 46

THAT, the Bill be amended by deleting Clause 46 and substituting therefor the following new clause 46—

Electronic sale of health products and technologies.

46. (1) The Authority shall prescribe guidelines to provide for the electronic supply and dispensing of scheduled substances including through e-pharmacy, telemedicine, medication therapy management and online pharmacy.

(2) The regulations made under subsection (1) shall provide for—

(a) licensure of e-pharmacies;

(b) safety of patients;

(c) verification of the identity and traceability of patients;

(d) verification of the identity and traceability of prescribers; and

(e) integrity, legitimacy and authenticity of prescriptions including avoidance of multiple use of the same prescription.

(3) The electronic supply and dispensing of scheduled substances shall be permitted provided that the supply of such health products and technologies conforms with all requirements

for the particular health product or technology in terms of its scheduling status and any other requirements as may be specified in regulations in relation to such supply or dispensing.

(4) In the case of a prescription-only medicine, the required prescription shall have been obtained as a result of at least one physical interaction between an authorised practitioner and the patient within a period of at least six months.

(5) Any person who contravenes this section shall be guilty of an offence, and shall on conviction, be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding one year, or to both.

NEW CLAUSE

THAT, the Bill be amended by inserting the following new clause immediately after clause 46—

Dietary supplements.

46A. (1) A dietary supplement shall—

(a) not contain scheduled substances; and
(b) have a stated or implied therapeutic purpose.

(2) Where a dietary supplement contains folic acid, the maximum daily dose for the dietary supplement shall be as per the guidelines prescribed by the Board of the Authority.

PART VI

THAT, the Bill be amended in the title of Part VI by deleting the expression "PART VI—MANUFACTURE OF MEDICINAL SUBSTANCES" and substituting therefor the expression "PART IV—MANUFACTURE OF HEALTH PRODUCTS".

CLAUSE 47

THAT, Clause 47 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicinal substance" and substituting therefor the words "health product";
(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A manufacturing licence issued under this section shall be valid for a period of one year, renewable annually."

(c) in sub-clause (3) by deleting the words "medicinal substance" and substituting therefor the words "health product;

(d) in sub-clause (4) by deleting the words "medicinal substance" and substituting therefor the words "health product";

(e) by inserting the following sub-clauses immediately after sub-clause (5)—

"(6) The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product regulated under this Act.

(7) The personnel qualified to conduct lot release of vaccines and batch release of health products shall submit their qualifications to the Authority.

(8) Any person who commits an offence under this section is on conviction, liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding ten years, or to both."

CLAUSE 48

THAT, Clause 48 of the Bill be amended—

(a) by renumbering the provision as sub-clause (1); and
(b) by inserting the following new sub-clauses immediately after sub-clause (1)—

"(2) The Authority shall have power to enter and inspect manufacturing premises to confirm compliance with prescribed good manufacturing practices and issue a certificate of compliance in the prescribed format upon payment of prescribed fees.

(3) The Cabinet Secretary shall make regulations for the better carrying out of the provisions of this section.

(4) Without prejudice to the generality of subsection (3), the Authority shall make regulations on—

(a) revocation and suspension of manufacturing licences;
(b) withdrawal of revocation of manufacturing licences upon request; and
(c) transfer of manufacturing licences."

PART VII

THAT, the Bill be amended in the title of Part VII by deleting the expression "PART VII" and substituting therefor the expression "PART VI".

NEW CLAUSES 51A & 51B

THAT, the Bill be amended by inserting the following new clauses immediately after clause 51—

Information that is required to be displayed on the pack.

51A. A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;
(b) the net weight;
(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;
(d) the name and address of manufacturer of the therapeutic cosmetic;
(e) a warning statement; and
(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

Manufacturing of cosmetics.

51B. (1) The Cabinet Secretary shall make regulations for the effective implementation of this section.

(2) The regulations made under subsection (1) may—
(a) require manufacturers of cosmetics to register with the Authority; and
(b) impose restrictions, requirements or other conditions on manufacturers of cosmetics, if such restrictions, requirements or conditions are necessary to protect public health.

CLAUSE 52

THAT, Clause 52 of the Bill be amended by deleting the words "have a therapeutic effect or value" and substituting therefor the words "treat, diagnose or prevent disease, or affect the structure or functions of the body".

CLAUSE 54

THAT, Clause 54 of the Bill be amended by—

(a) deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

"(3) Any person who manufactures, sells, supplies, imports or exports a therapeutic cosmetic which contains a prohibited ingredient commits an offence and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both."

(b) inserting the following new sub-clause immediately after sub-clause (3)—

"(4) The Authority shall make regulations exempting from any labelling requirement of this Part, therapeutic cosmetics which are, in accordance with the practice of the trade, to be processed, labelled, or repacked in substantial quantities at establishments other than those where originally processed or

packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Part upon removal from such processing, labelling or repacking establishment."

PART VIII

THAT, the Bill be amended in the title of Part VIII by deleting the expression "PART VIII" and substituting therefor the expression "PART VII".

CLAUSE 55

THAT, Clause 55 of the Bill be amended in sub-clause (1) by inserting the words ", in-vitro diagnostics medical devices register" immediately after the words "human medical devices register".

CLAUSE 56

THAT, Clause 56 of the Bill be amended in sub-clause (1) by inserting the words "falsified, falsely-labelled or counterfeited" immediately after the word "substandard" appearing in paragraph (c).

CLAUSE 58

THAT, Clause 58 of the Bill be amended—

(a) in sub-clause (2) by inserting the words "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" immediately after the word "Authority";
(b) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act, documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

(4) An importer, distributor or dealer shall establish and implement documented procedures for the maintenance of importation or distribution records and shall maintain an importation or distribution record of each medical device to be submitted to the Authority."

CLAUSE 59

THAT, Clause 59 of the Bill be amended in sub-clause (1) by inserting the words "unregistered establishments for medical devices and" immediately after the word "under".

NEW CLAUSE 59A

THAT, the Bill be amended by inserting the following new clause immediately after clause 59—

Registration of medical devices establishment.

59A. (1) An application for registration of a medical devices establishment shall be submitted to the Authority in the prescribed format and shall be accompanied by the prescribed fees.

(2) An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority of such system.

(3) Where the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Director-General shall issue a registration certificate for the medical devices establishment in the prescribed format.

(4) A medical devices establishment registration certificate under this section shall be valid for a period of one year, renewable annually upon application in accordance with the prescribed conditions.

(5) The registration certificate for manufacturers shall be valid for five years following a successful reinspection.

(6) The Authority may refuse to issue a medical devices establishment registration certificate where—

(a) an applicant has made a false or misleading statement in the application;

(b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

(c) an applicant has failed to meet the prescribed conditions for medical devices establishment registration.

(7) Where the Authority does not issue a medical devices establishment registration certificate under subsection (6), the Authority shall—

(a) notify the applicant in writing of the reasons for refusing the registration of the establishment; and

(b) give the applicant an opportunity to respond to the Authority and provide relevant documentation or evidence in support of the application.

(8) After the issuance of a medical devices establishment

registration certificate, where there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Authority within ten working days of the change.

NEW PART

THAT, the Bill be amended by inserting the following new Part immediately after the new clause 59A—

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

59B. (1) The Authority shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system.

(2) The Centre established under subsection (1) shall receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority.

(3) The Authority shall conduct both passive surveillance and active surveillance of health products and technologies.

(4) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with good pharmacovigilance practices and the prescribed requirements.

(5) All entities responsible for placing a health product or technology in the market shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies.

(6) The entities referred to in subsection (5) shall submit safety information to the Authority in the prescribed manner.

(7) The consumers, general public and health care professionals shall report adverse reactions and adverse events to the Authority in the prescribed manner.

PART XI

THAT, the Bill be amended in the title of Part XI by deleting the expression "PART XI" and substituting therefor the expression "PART IX".

CLAUSE 60

THAT the Bill be amended by deleting Clause 60 and substituting therefor the following new clause 60—

Establishment of the National Quality Control Laboratory.

60. (1) There is established the National Quality Control Laboratory of the Authority which shall be used as a facility for—

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;

(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;

(d) field testing of regulated products using screening techniques;

(e) providing technical support to local manufacturers and building their capacity in matters pertaining to quality control of regulated products through on site and off site training and laboratory assessments;

(f) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;

(g) conducting research and training and providing high quality analytics and expert knowledge in the areas of medicinal products and active pharmaceutical ingredients; and

(h) developing and administering a data bank on quality assurance on behalf of the Authority.

(2) The National Quality Control Laboratory shall be the quality control laboratory of health products and technologies for the Authority.

(3) The Board of the Authority shall appoint a Director, National Quality Control Laboratory who shall be responsible to the Authority for the day to day management of the National Quality Control Laboratory.

(4) The Director National Quality Control Laboratory shall hold office on such terms and conditions of service as may be specified in the instrument of appointment by the Board of the Authority.

(5) The Director National Quality Control Laboratory shall be a registered pharmacist and shall possess a Master's degree in a science related field from a recognized university.

(6) The Director of the National Quality Control Laboratory shall—

(a) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;
(b) ensure timely quality control testing of all samples in conformity with national and international standards;
(c) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;
(d) collaborate with other laboratories, regulatory and law enforcement agencies, manufacturers of pharmaceutical and other health products to ensure quality in health products and technologies;
(e) handle appeals on test results;
(f) where the laboratory lacks capacity, subcontract laboratory testing services;
(g) advice the Authority on matters of testing and quality control over health products and technologies; and
(h) perform any other duties assigned by the Authority from time to time.

(7) The funds to be used for the management of the Laboratory shall consist of all moneys received or recovered under this Part and a portion of the moneys appropriated by Parliament to the Authority.

(8) Subject to subsection (7), monies generated by the Laboratory in the course of the performance of its functions under this section shall be solely expended on the Laboratory.

CLAUSE 61

THAT, Clause 61 of the Bill be amended in sub-clause (1) by deleting the words "Director-General" and substituting therefor the words "Director of the National Quality Control Laboratory".

PART XII

THAT, the Bill be amended in the title of Part XII by deleting the expression "PART XII" and substituting therefor the expression "PART X".

CLAUSE 63

THAT, Clause 63 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicine, drug, appliance or article" wherever they appear and substituting therefor the words "health product or technology"; and
(b) in sub-clause (2) by inserting the words "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (d).

CLAUSE 64

THAT, Clause 64 of the Bill be amended by deleting the words "a medicine, drug, appliance or article" wherever it appears and substituting therefor the words "health product or technology".

CLAUSE 65

THAT, Clause 65 of the Bill be amended—

(a) in paragraph (a) by—
  (i) deleting the words " or similar article"; and
  (ii) deleting the word "extravagant,".
(b) in paragraph (b) by deleting the word " an article" and substituting therefor the words "health product or technology".

CLAUSE 66

THAT, Clause 66 of the Bill be amended—

(a) in sub-clause (1)—
  (i) by deleting the words "drug, appliance or article" wherever they appear in paragraph (a) and substituting therefor the words "health product or technology"; and
  (ii) by deleting the words "drug, appliance or article" appearing in paragraph (b) and substituting therefor the words "health product or technology";

(b) in sub-clause (3) by—
  (i) renumbering the provision as clause (2); and
  (ii) by inserting the words ", enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (ii).

CLAUSE 67

THAT, Clause 67 of the Bill be amended—

(a) by deleting the word "articles" appearing in the marginal note and substituting therefor the words "health products and technologies";
(b) by deleting sub-clause (1) and substituting the following new sub-clause (1)–

"(1) Subject to this Act, a person shall not sell by retail a health product or technology consisting of or comprising a substance recommended as a medicine unless there is written so as to be clearly legible on the health product or technology or on a label affixed thereto, or if the health product or technology is sold or supplied in more than one container, on the inner container or on a label affixed thereto—

(a) the appropriate designation of the substance so recommended or of each of the active constituents, or of each of the ingredients from which it has been compounded; and
(b) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients; provided that this subsection shall not apply to a health product or technology made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person."

(c) in sub-clause (2) by deleting the word "article" wherever it appears in the definition of "appropriate quantitative particulars" and substituting therefor the words "health product or technology";
(d) in sub-clause (3) by—
(i) deleting the word " an article" appearing in sub-clause (3) and substituting therefor the words " a health product or technology";
(ii) deleting the words "two hundred thousand" appearing in paragraph (a) and substituting therefor the words "one million";
(iii) deleting the words "three hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

CLAUSE 68

THAT, the Bill be amended by deleting Clause 68.

CLAUSE 69

THAT, Clause 69 of the Bill be amended by—
(a) deleting the word "article" and substituting therefor the words "health product or technology"; and
(b) deleting the word "articles" and substituting therefor the words "health products and technologies".

PART XIII

THAT, the Bill be amended in the title to Part XIII by deleting the expression "PART XIII" and substituting therefor the expression "PART XI".

CLAUSE 71

THAT, Clause 71 of the Bill be amended—

(a) in the marginal note by deleting the words "medicines or medical devices" and substituting therefor the words "health products and technologies"; and

(b) in sub-clause (1) by deleting the words "or homoeopathic medicine, preparation or medical device" and substituting therefor the words "health products and technologies".

CLAUSE 72

THAT, Clause 72 of the Bill be amended—

(a) in the marginal note by deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies";

(b) in sub-clause (1) by inserting the words "including a health product and technology for emergency use" immediately after the word "technology"; and

(c) in sub-clause (3) by deleting the words "medicine or medical device product" and substituting therefor the words "health product or technology".

CLAUSE 73

THAT, Clause 73 of the Bill be amended—

(a) in the marginal note by deleting the word "goods" and substituting therefor the words "health products and technologies".

(b) in sub-clause (1) by deleting the words "drug, article" wherever they appear and substituting therefor the words "health product or technology";

(c) in sub-clause (2) by deleting the words "drug or article" wherever they appear and substituting therefor the words "health product or technology";

(d) in sub-clause (3) by deleting the words "drug or article" and substituting therefor the words "health product or technology"; and

(e) in sub-clause (4) by deleting the words "drug or article" and substituting therefor the words "health product or technology".

CLAUSE 78

THAT, Clause 78 of the Bill be amended in sub-clause (1) by inserting the words "or enrolled pharmaceutical technologist" immediately after the words "registered pharmacist" appearing in paragraph (b).

CLAUSE 79

THAT, the Bill be amended by deleting Clause 79 and substituting the following new clause 79—

Inspection and verification of health products and technologies at the ports of entry.

79. (1) A person who imports a health product or technology shall notify the inspectors of the Authority at the ports of entry to conduct pre-clearance inspection and verification.

(2) Any person who imports a health product or technology and causes it to be released to the market without authorization under subsection (1) shall be guilty of an offence.

(3) Any person who commits an offence under this section is upon conviction, liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both.

CLAUSE 80

THAT, Clause 80 of the Bill be amended—

(a) by deleting the words "article" and "articles" wherever they appear and substituting therefor the words "health product or technology" and "health products and technologies" respectively in sub-clause (6), (7), (8), (9), (10), (11) and (12).

(b) in sub-clause (1) by—

(i) deleting the word "article" wherever it appears and substituting therefor the words "health product or technology"; and

(ii) inserting the words "or any other vessel" immediately after the word "vehicle" appearing in paragraph (b).

CLAUSE 81

THAT, the Bill be amended by deleting Clause 81.

CLAUSE 82

THAT, the Bill be amended by deleting Clause 82.

CLAUSE 83

THAT, the Bill be amended by deleting Clause 83.

CLAUSE 85

THAT, Clause 85 of the Bill be amended by deleting the word "article" wherever it appears and and substituting therefor the words "health product or technology".

CLAUSE 86

THAT, Clause 86 of the Bill be amended in sub-clause (1) by deleting paragraph (b) and substituting therefor the following new paragraph (b)—

"(b) in the case of a subsequent offence, to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both".

CLAUSE 87

THAT, Clause 87 of the Bill be amended in sub-clause (1) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology" in paragraph (c)

PART XIV

THAT, the Bill be amended in the title of Part XIV by deleting the expression "PART XIV" and substituting therefor the expression "PART XII".

CLAUSE 88

THAT, Clause 88 of the Bill be amended by deleting paragraph (a) and substituting therefor the following new paragraph (a)—

"(a) such monies as may be appropriated by the National Assembly for the purposes of the Authority".

CLAUSE 91

THAT, Clause 91 of the Bill be amended by—deleting the words "Kenya National Audit Office" wherever they appear and substituting therefor the words "Auditor-General".

PART XV

THAT, the Bill be amended in the title of Part XV by deleting the expression "PART XV" and substituting therefor the expression "PART XIII".

CLAUSE 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—
  (i) deleting the word "drugs," in paragraph (a)(i);
  (ii) deleting the words "any drug" in paragraph (a)(ii);
  (iii) deleting the word "product" and substituting therefor the word "products" in paragraph (d);

(iv)deleting the word "drugs" wherever it appears and substituting therefor the words "health products or technologies" in paragraph (h);

(v) deleting the word "article" and substituting therefor the words "health product or technology" in paragraph (k);

(vi)deleting the word "articles" and substituting therefor the words "health products and technologies" in paragraph (m);

(vii) deleting the words "drugs, medical devices" and substituting therefor the words "health products and technologies" in paragraph (o);

(viii) deleting the word "medicines" and substituting therefor the words "health products and technologies" in paragraph (v);

(ix)deleting paragraph (x) and substituting therefor the following new paragraph (x)—

"(x) governing administration of clinical trials of health products and technologies;"

(x) deleting the words "medicine, medical device" and substituting therefor the words "health product or technology" in paragraph (aa);

(xi)deleting the words "medicines or medical devices" and substituting therefor the words "health products or technologies" in paragraph (bb);

(xii) deleting paragraph (dd) and substituting therefor the following new paragraph (dd)—

"(dd) the compounding of health products and technologies and the dispensing of health products and technologies"

(xiii) inserting the words ",an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in paragraph (bb);

(xiv) deleting paragraph (ii);

(xv) inserting the following new paragraphs immediately after paragraph (ii)—

"(jj) on pharmacovigilance and post market surveillance;

(kk) official regulatory lot release of vaccines and other biological products imported and manufactured in Kenya;

(ll)pricing of health products and technologies;

(mm) good practices in the regulation of medical products;

(nn) inspections, licensure and certification of the manufacture of medical products by health facilities;

(oo) inspections, licensure and certification of manufacture of medical products and other regulated products by facilities not directly regulated by the Authority including steel industries, sugar industries;

(pp) inspection and recognition of pharmaceutical quality control laboratories;

(qq) to regulate licit use of narcotic and psychotropic substances; and

(rr) to regulate parallel importation of medicines;"

(b) by renumbering sub-clause (2) as sub-clause (3).

CLAUSE 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the word "Board" and substituting therefor the word "Boards";

(ii) deleting paragraph (d) and substituting therefor the following new paragraph (d)—

"(d) all members and staff of the former Boards shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Boards."

(b) by deleting the sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) In this section, "the former Boards" means the Pharmacy and Poisons Board and the Board of Management of the National Quality Control Laboratory established under the Pharmacy and Poisons Act, Cap. 244."

(c) in sub-clause (3) by deleting the word "twelve" appearing in the opening sentence and substituting therefor the words "twenty four".

CLAUSE 97

THAT, Clause 97 of the Bill be amended by inserting the words "with reference to section 96 (3)" immediately after the words "that Schedule" in sub-clause (1).

SECOND SCHEDULE

THAT, the Bill be amended by deleting the Second Schedule.

THIRD SCHEDULE

THAT, the Bill be amended by deleting the Third Schedule.

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended by deleting paragraph (1), (2), (3), (4) and (5) and substituting therefor the following new paragraphs—

1. Biologics Committee.
2. Pharmacovigilance Committee.
3. Complementary, Alternative or Herbal Medicines Committee.
4. Radiopharmaceuticals Committee.

5. Cosmetics and Borderline Products Committee.
6. Clinical Trial Scientific Technical Advisory Committee.
7. Health Technology Assessment Committee.
8. Nutraceuticals and Dietary Supplements Committee.
9. Digital Health and Technologies Committee.
10. Medical Devices and Health Technologies Committee.
11. Veterinary Medicines Committee.

SEVENTH SCHEDULE

THAT, the Seventh Schedule of the Bill be amended by—

(a) deleting the word "Board" in the paragraph on Cap. 244
(b) deleting the phrase "(s. 116) and substituting the phrase ("s.97").
(c) deleting the paragraph on Cap. 254.

2) Notice is given that the Member for Mathare (Hon. Anthony Oluoch) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

"AN ACT of Parliament to establish the Kenya Health Products and Technologies Authority to ensure safety, quality and efficacy or performance of drugs, poisons, therapeutic and biological products, therapeutic cosmetics, herbal medicines and products, chemical substances, medical devices, veterinary products and other health technologies; to provide for the harmonization and administration of the laws relating to the regulation of, drugs, poisons, therapeutic products, therapeutic cosmetics, chemical products, veterinary products and medical devices and the control and safe handling of poisons; to safeguard the security of the supply chains for, therapeutic products, cosmetics and veterinary products; to provide for measures to optimize the use of therapeutic products in health care in Kenya and for connected purposes."

CLAUSE 2

THAT, the Clause 2 of the Bill be amended—

(a) in the definition of "authorized seller of scheduled substances" by inserting the words "and enrolled as a pharmaceutical technologist or registered as a pharmacist" immediately after the word "Act";
(b) in the definition of "pharmacy" by inserting the words "licensed and" immediately after the words "carried out by" appearing in paragraph (a);
(c) deleting the definition of "chemical substance" and substituting therefor the following new definition—

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);

(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;

(g)the Director-General for Health or a representative designated in writing;"

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

4) **Notice is given that the Nominated Member (Hon. Irene Mayaka) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 37

THAT, Clause 37 of the Bill be amended —

(a) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Cabinet Secretary shall publish the list prepared under subsection (1) in the *Gazette.*

(4)The list published under subsection (3) shall include narcotic substances, prescription-only medications, pharmacist-only medications, pharmacy-only medications, over-the-counter medicines, hazardous substances and prohibited substances".

(b) by renumbering sub-clause (3) as sub-clause (5); and

(c) by renumbering sub-clause (4) as sub-clause (6);

5) **Notice is given that the Member for Ndhiwa (Hon. Martin Peters Owino) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 72

THAT, clause 72 of the Bill be amended in subclause (1) by deleting the word "person" appearing immediately after the words "The Authority may authorise a" and substituting therefor the words "registered pharmacist".

6) **Notice is given that the Member for Homa Bay Town (Hon. George Kaluma) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 3

THAT, the Bill be amended by deleting clause 3.

DIRECTOR
RECEIVED
25 OCT 2023
Directorate of Departmental Committees

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SNA
24/10/23

REPUBLIC OF KENYA
PARLIAMENT

Hon. George Peter Kaluma, MP.
Homa Bay Town Constituency
Assistant Speaker
Member: Administration & Internal Affairs Committee

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HBTC/PARL024/10/2023

24th October, 2023

The Speaker
National Assembly of Kenya
Parliament Building
NAIROBI

Hassan Arale
to facilitate
25/10/23

DD cttees
24/10/23

Dear Sir,

RE: REQUEST TO REFER THE KENYA DRUGS AUTHORITY BILL TO THE RELEVANT DEPARTMENTAL COMMITTEE PURSUANT TO S.O NUMBER 131 OF THE NATIONAL ASSEMBLY STANDING ORDERS

The above matter refers.

The above Bill is listed in the order paper for consideration by the House at the Committee of the whole today afternoon.

Pursuant to Standing Order Number 131, I request that you consider directing the several amendments brought, to be presented to the relevant departmental committee for in-depth consideration and harmonization for the following reasons:

1. The amendments are more than 10 and are very substantive;
2. The Bill seeks the repeal 2 existing laws and to repeal 3 substantive sections of the Narcotics Drugs and Psychotropic Substances Act; there is need for critical consideration of the effect of the proposed repeals against the provisions of the Bill.
3. The Health Committee has proposed several amendments to the Bill which in my view amount to complete overhaul of the Bill. Several Members including myself, desired to bring similar amendments as the departmental committee on Health and only stopped on information that the amendments were already proposed by the Health Committee.

Thank you.

Yours faithfully,

Hon. George Peter Kaluma, MP.
HOMA BAY TOWN CONSTITUENCY
GPK/gpk

NATIONAL ASSEMBLY
RECEIVED
24 OCT 2023
SPEAKER'S OFFICE
P. O. Box 41842, NAIROBI.

NATIONAL ASSEMBLY
RECEIVED
24 OCT 2023
CLERK'S OFFICE
P. O Box 41842, NAIROBI

Notice of the sitting for harmonization reached me after I had traveled out of the country on official engagements. I'll be back on 4th November.

General views:

1. We exclude anything to do with the practice of veterinary medicine from the Bill as this is dealt with under a law whose repeal has not been proposed here;
2. The manufacture of drugs be left to graduate Pharmacists;
3. Sale and dispensing of drugs once prescribed by a qualified medical practitioner or Dentist be allowed not only to pharmacists but also to holders of diploma in pharmaceutical technology, pharmacy or equivalent qualifications;
4. Proposed repeal of some sections of the Narcotic Drugs and Psychotropic Substances Act be avoided. The Act is dealing with a different category of drugs the possession, use or consumption of which is punished differently.
5. Measures be taken to ensure good provisions of the laws proposed to be repealed are incorporated into Bill. These include Part II of the Pharmacy and Poisons Act.
6. This is serious law. while it seeks to repeal two existing laws, the Memorandum states that it's purposed to comply with some WHO requirements. It would be good to involve the Ministry of Health and key stakeholders in the harmonization process. This would secure that the government position is presented, understood and carried forth into the proposed law and the requirements of WHO specified and met.
7. Amendments proposed by the Committee infringe S.O 133 as they derogate from the substratum of the various clauses of the Bill they seek to alter. It would be better the whole Bill be withdrawn and a new Bill be presented by the Government.

Specific Amendment Proposals:

1. **Clause 2**
   Veterinary medicine - delete
   "enrolled pharmaceutical technologist" - refers to definition in law being repealed. Pick definition from the law and insert it here. "means a pharmaceutical technologist whose name appears on the Roll of pharmaceutical technologists
   "herbal medicine or product" - insert fullstop (.) after "plants" in*second last line and delete all words following.
2. **Insert:**
   "traditional medicines or products" means a plant or animal derived material or preparations with claimed therapeutic or other human benefits, which contain either raw or processed ingredients from one or more plants or animals, or material of inorganic origin."

3. **Clause 3(2) - delete.**
4. **Clause 6(3) substitute "four" with "three"**
5. **Clause 6(4) (a) -** insert fullstop after "engineering" and delete the words following "or equivalent fields".
6. **Clause 6(4)(d) insert** "established for regulation of pharmacy, medicine or engineering profession."

7. **Delete clause 6(6)** - it conflicts with the lawful mandate of the Board in Clause 8(1).
8. **Delete Clause 6(8)**
9. **Delete Clause 6(9)**
10. **Delete Clause 7 (a) and (b)**
11. **Delete "is" in 7(d)** and substitute "has been"
12. **8(2)(a)(i) insert,** "medical practitioner or medical engineer" after the word "pharmacist"
13. **Amend 8(2)(a)(ii)** by inserting medical or medical engineering" after "pharmaceutical"
14. **Delete 8(2)(f)**8(2)(j) - delete "County" before "Governor"
15. **Delete 8(3)**
16. **Delete 8(6)(a) and (b)**
17. **Substitute "is" with "has been" in clause 8(6)(e)**
18. **Clause 8(7) delete all words** after "Board" and insert ", regard shall be had to the need for ethnic and regional balance and the need to ensure that persons of same biological sex shall not comprise more than two thirds of the members of the Board."
19. **Delete Clause 9**
20. **Delete 10(2).**
21. **Clause 12 (f)** substitute "events" with "effects"
22. **13(a) substitute** "association" with "collaboration
23. **13(c) - delete** "any" and substitute "lawful".
24. **Delete Clause 21** and the Fourth schedule. Establishment of Committees already provided for inn Clause 13(e). The Clause contradicts Clause 12(i) and (j) which vest the duty to advise CS in the Authority and Clause 34.
25. **Insert new 22(4) subsection (1)** shall not apply to traditional medicines or products"
26. **Clause 31 -** insert fullstop after "person" and delete all words following.
27. **Delete 32(5)**
28. **Clause 38(1)(b)** insert semi colon (;) after "substances" and delete the words following thereafter.
29. **Clause 13(c)** delete "for mining, agricultural or horticultural purposes"
30. **13(e)*delete** "by a qualified medical practitioner, dentist, or veterinary surgeon or by a hospital, or dispensary or similar institution"
31. **39(4)** amend by inserting "is a qualified pharmacist, medical practitioner or medical engineering practitioner or holder of diploma in pharmacy, pharmaceutical technology"
32. **Clause 41(1)(b)** insert "or pharmaceutical technologist or dispensing chemist" after "pharmacist"
33. **Clause 41 (1)(d) delete "or veterinary".**
34. **Clause 41(1)(f)** - insert fullstop (.) immediately after the word "behalf" and delete all words appearing thereafter as they are repetitions of earlier provisions.
35. **Clause 41(2)(a)** - delete "²or veterinary surgeon"
36. **Clause 43 (1)** - delete veterinary surgeon"
37. **Clause 46 (1)** substitute "This" with "Electronic sale of medicines"
38. **Delete Clause 79**
39. **Clause 81 -** Delete "or the Director of Veterinary Services, in relation to any matter appearing to affect the general interests of agriculture in Kenya,"

40. **Clause 95 (aa) delete "or veterinary surgeon** "Subject the regulations to approval by Parliament.
41. **Second Schedule – Delete**
42. **Fourth Schedule - Delete.**
43. **Seventh Schedule** - Delete Narcotic Drugs and Psychotropic Substances Act and its provisions.

NB: Ensure all good provisions of the Acts proposed to be repealed are carried into the new law by way of substitutive provisions. These include sections 6,7,8,9 of PPA.

19th October, 2023

The Clerk of the National Assembly

Parliament Buildings

NAIROBI

RE: THE KENYA DRUGS AUTHORITY BILL, 2022– COMMITTEE STAGE AMENDMENTS

NOTICE is given that the Member for Seme Constituency, Hon. (Dr.) Nyikal James Wambura, MP intends to move the following amendments to the Kenya Drugs Authority Bill, 2022, (National Assembly Bill No.54 of 2022) at the Committee Stage—

CLAUSE 2

THAT, Clause 2 of the Bill be amended by inserting the following new definitions in the proper alphabetic sequence—

No. 21 of 2017.

"Director-General for Health" has the meaning assigned to it under the Health Act;

"wholesaler dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

Justification: To distinguish the Director-General for Health with the Director-General of the Authority and for consistency with the amendment proposed below to clause 81 of the Bill. To define a wholesaler dealer as the term is used in the Bill under clause 39 of the Bill

CLAUSE 12

THAT, Clause 12 of the Bill be amended by deleting paragraph (t).

Justification: The provision relates to an administrative function as regards human resource management and development and need not be in the Bill.

CLAUSE 21

THAT, Clause 21 of the Bill be amended—

(a) by deleting sub-clause (4);and

(b) in sub-clause (9) by deleting the words "Cabinet Secretary, with respect to its activities and the Cabinet Secretary shall lay a copy of each report before Parliament" and substituting therefor the following words "Board of the Authority which shall submit a copy of the report to the Cabinet Secretary who shall transmit the report to Parliament".

Justification: Sub-clause (4) provides for the co-option of members into the scientific advisory committees. This is unnecessary as the appointing authority needs to appoint the relevant skills to the Committee in the first instance.

Amendment of sub-clause (9) to require that the scientific advisory committees shall submit its report to the Board of the Authority which shall submit the same to the Cabinet Secretary who must transmit it to Parliament. The Committee report had not provided for the transmittal of the reports of the scientific advisory committees to Parliament .

CLAUSE 22

THAT, Clause 22 of the Bill be amended in sub-clause (3) by deleting the words "sub-section (1)" and substituting therefor the words "The provisions of subsection(1)(a)".

Justification: Sub-clause (3) should not only apply where a medicine is not registered by the Authority and not in instances where a medicines is adulterated, substandard or fails to comply with the specifications in law.

CLAUSE 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (4) and substituting therefor the following new sub-clause (4)—

"(4) Where the Authority finds that an application for registration of a medicine or medical device does not satisfy the requirements provided in subsection (3), it shall notify the applicant in writing of the reasons why that medicine or medical device should not be registered and invite the applicant to make comments on its finding within a period of one month from the date of the notification."

Justification: For proper drafting of the sub-clause (4) as the provision is currently not clear.

CLAUSE 31

THAT, the Bill be amended by deleting clause 31.

Justification: To remove the aspect of transfer of certificate of registration of health products and technologies.

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "upon consultation and concurrence with the person who prescribed the medicine," immediately after the word "shall";
(b) by deleting sub-clause (2);
(c) by renumbering sub-clause (3) as sub-clause (2); and
(d) by deleting sub-clause (4).

Justification: To require that a prescriber of a medicine is consulted before medicine is substitution with a generic medicine. With the amendment to sub-clause (1), sub-clause (2) and (4) are unnecessary as the factors will be discussed by the Prescriber and the Pharmacist at the point of consultation.

CLAUSE 38

THAT, Clause 38 of the Bill be amended by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

"(2) A person who is in possession of a scheduled substance otherwise than in accordance with the provisions of this section commits an offence and shall on conviction, be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding three years; or to both."

Justification: To enhance the penalty for the offence of possession of a scheduled substance contrary to the provisions of the Bill from Kshs. 100,000 to Kshs. 1,000,000.

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances".

Justification: To insert a missing word which will make the sub-clause much clearer.

CLAUSE 42

THAT, Clause 42 of the Bill be amended in sub-clause (3) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three years" and substituting therefor the words "five hundred thousand shillings or to imprisonment for a term not exceeding one year".

Justification: To enhance the fine for the offence of failure to record the sale or suplly of scheduled substances in a Schedules Substances Book as is required in clause 42 from Kshs. 100,000 to Kshs. 500,000. To reduce the jail term from three years to one year as 3 years is too punitive.

CLAUSE 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "five hundred thousand".

Justification: To enhance the penalty for the offence of failure to label a container of scheduled substances in the manner set out in clause 44 from Kshs. 200,000 to Kshs. 500,000

CLAUSE 79

THAT, the Bill be amended by deleting Clause 79.

Justification: The regulation of meat is outside the ambit of the regulation of the Authority.

CLAUSE 81

THAT, Clause 81 of the Bill be amended by deleting the words "Director of Medical Services" and substituting therefor the words "Director-General for Health".

Justification: The Health Act, No. 21 of 2017 makes provision for the office of the Director-General for Health which replaced the office of the Director of Medical Services.

CLAUSE 83

THAT, Clause 83 of the Bill be amended by deleting the words "Cabinet Secretary" wherever they appear and substituting therefor the words "the Authority".

Justification: The function of regulation of HPTs is a preserve of the Authority and the power provided in clause 83 is utilized administratively in the performance of this function. The Cabinet secretary responsible for matters of health is only responsible for policy.

CLAUSE 90

THAT, Clause 90 of the Bill be amended in sub-clause (2) by deleting the words "think fit" appearing in paragraph (f) and substituting therefor the words "deem appropriate".

Justification: For proper drafting.

CLAUSE 92

THAT, Clause 92 of the Bill be amended in sub-clause (2) by inserting the words "with the approval of the Cabinet Secretary" immediately after the word "determine".

Justification: For checks and balances in the investment of the funds of the Authority which will ensure prudent use of the funds by the Authority.

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);

Justification: Amendment of paragraph (1) is necessary for consistency with sub-paragraph (1) which establishes the National Food Safety Committee.

(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;
(g)the Director-General for Health or a representative designated in writing;"

Justification: For inclusion of KMA in the Human Medicines Committee as prescribers of medicines are crucial in ensuring patient safety.

For inclusion of the Director-General for Health in view of his technical expertise on matters of health generally.

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

Justification: The words "in consultation with the Cabinet Secretary responsible for health," are superfluous as it is already indicated that the Chairperson of the Medical Devices Committee will be appointed by the Cabinet Secretary.

Signed ———————————————— Date ————————————

HON. (DR.) NYIKAL JAMES WAMBURA, MP

7) **Notice is given that the Member for Rarieda (Hon. (Dr.) Otiende Amollo) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 2

THAT, the Clause 2 of the Bill be amended by deleting the definition of "pharmacy" and substituting therefor the following new definition—

Cap. 244. "pharmacy" has the meaning assigned to it under the Pharmacy and Poisons Act.

CLAUSE 8

THAT, the Clause 8 of the Bill be amended in sub-clause (2) by deleting paragraph (j) and substituting therefor the following new paragraph—

"(j)one person, not being a Governor, who is a registered pharmacist of good standing, nominated by the Council of Governors";

CLAUSE 39

THAT, the Clause 39 of the Bill be amended in the marginal note by deleting the words "Wholesale Dealer's Licence" and substituting therefor the word "Local Technical Representative Licence ".

...../Notices(Cont'd)*

23rd October, 2023

The Clerk,
National Assembly,
Parliament Buildings,
P.O Box 41842- 00100
NAIROBI.

RE: COMMITTEE STAGE AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022 – HON. ANTHONY OLUOCH, MP

NOTICE is given that the member of Parliament for Mathare Constituency, Hon. Anthony Oluoch, MP, intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 (National Assembly Bills No. 54) at the Committee Stage—

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and substituting therefor the following new Long Title—

"AN ACT of Parliament to establish the Kenya Health Products and Technologies Authority to ensure safety, quality and efficacy or performance of drugs, poisons, therapeutic and biological products, therapeutic cosmetics, herbal medicines and products, chemical substances, medical devices, veterinary products and other health technologies; to provide for the harmonization and administration of the laws relating to the regulation of, drugs, poisons, therapeutic products, therapeutic cosmetics, chemical products, veterinary products and medical devices and the control and safe handling of poisons; to safeguard the security of the supply chains for, therapeutic products, cosmetics and veterinary products; to provide for measures to optimize the use of therapeutic products in health care in Kenya and for connected purposes."

CLAUSE 2

THAT, the Clause 2 of the Bill be amended—

(a) in the definition of the term "advertisement" by deleting the words "herbal medicines and products";

(b) in the definition of the term "article" by—

(i) deleting the words "herbal medicine" appearing in paragraph (a); and

(ii) deleting the words "herbal medicine" appearing in paragraph (b);

(c) in the definition of "authorized seller of scheduled substances" by inserting the words "and enrolled as a pharmaceutical technologist or registered as a pharmacist" immediately after the word "Act";

(d) in the definition of the term "health products and technologies" by deleting the words "herbal medicines and products";

(e) by deleting the definition of the term "herbal medicine or product" and substituting therefor the following new definition—

> "herbal medicine or product" means a plant derived material or preparations with claimed therapeutic or other health benefits, which contain either raw or processed ingredients from one or more plants or material of inorganic or animal origin and includes herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations and excludes herbs, herbal materials, herbal preparations, finished herbal products sold or dispensed on a small scale by traditional health practitioners;"

(f) in the definition of the term "medicine" by inserting the words "other than herbal medicines or products" immediately after the words "or mixture of substances".

(g) in the definition of "pharmacy" by inserting the words "licensed and" immediately after the words "carried out by" appearing in paragraph (a);

(h) deleting the definition of "chemical substance" and substituting therefor the following new definition—
"chemical substance" means any substance or mixture of substances prepared, sold or represented for use as a germicide, antiseptic, disinfectant, pesticide, insecticide, rodenticide, vermicide, detergent or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;

(i) deleting the definition of "therapeutic cosmetic" and substituting therefor the following new definition—
"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, to target and repair skin issues, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;".

CLAUSE 3

THAT, Clause 3 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraph (c); and

(b) by inserting the following new sub-clause immediately after sub-clause (2)—

(3) This Act shall not apply to the regulation of herbal medicines or products.

CLAUSE 6

THAT, Clause 6 of the Bill be amended in sub-clause (4) by deleting the word "ten" in appearing in paragraph (c) and substituting therefor the word "fifteen".

CLAUSE 8

THAT, Clause 8 of the Bill be amended in sub-clause (7) by inserting the words ",fair representation of persons with disabilities" immediately after the words "regional balance."

CLAUSE 12

THAT, Clause 12 of the Bill be amended in paragraph (o) by deleting the words "and herbal drugs;"

CLAUSE 23

THAT, Clause 23 of the Bill be amended in sub-clause (2) by —

(a) deleting the words "one million" appearing in paragraph (a) and substituting therefor the words "two million"; and
(b) deleting the words "two million" appearing in paragraph (b) and substituting therefor the words "five million".

CLAUSE 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (9).

CLAUSE 35

THAT, Clause 35 of the Bill be amended in sub- clause (2) by inserting the word "registered" immediately after the words "may prohibit a".

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36.

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the words "or pharmaceutical technologists" immediately after the words "a Registered Pharmacist".

CLAUSE 41

THAT, Clause 41 of the Bill be amended in sub-clause (1) by inserting the words "or pharmaceutical technologists" immediately after the words "a pharmacist" appearing in paragraph (b)".

CLAUSE 42

THAT, Clause 42 of the Bill be amended by—

(a) deleting sub-clause (1) and substituting therefor the following new sub-clause (1)—

"(1) An authorized seller shall enter a record of such particulars of the scheduled substance before delivery of the scheduled substance under this Act."

(b) inserting the following new sub-clause (2) immediately after the new sub-clause (1)—

"(2) A record under subsection (1) shall be in the format prescribed by the Authority and shall indicate —

(a) the date of the sale;
(b) the name and address of the purchaser;
(c) the quantity of the scheduled substances sold; and
(d) the purpose for which it is stated by the purchaser to be required."

(c) renumbering sub-clause (2) as sub-clause (3); and

(d) renumbering sub-clause (3) as sub-clause (4).

CLAUSE 51

THAT, the Bill be amended in clause 51 by inserting the words "and, on conviction, shall be liable to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding two years, or to both" immediately after the word "offence".

CLAUSE 54

THAT, the Bill be amended by deleting clause 54.

CLAUSE 63

THAT, Clause 63 of the Bill be amended by deleting sub-clause (3).

Signed ———————————————— Date ————————————

HON. ANTHONY OLUOCH, MP

REPUBLIC OF KENYA
PARLIAMENT

Hon. Millie Odhiambo Mabona, MP.

Suba North Constituency

Parliament Buildings
Tel: +254 20 2221291 Mobile: +254 786 947 783
P.O. Box 41842 - 00100 Nairobi, Kenya
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The Speaker,

24th October 2023

The Kenya National Assembly

P.O. Box 41482-00100

NAIROBI

Dear Sir

RE: PROPOSED AMENDMENTS TO THE KENYA DRUGS AUTHORITY BILL, 2022, (NATIONAL ASSEMBLY BILLS NO. 54)

TAKE NOTICE THAT HON MILLIE ODHIAMBO MABONA, MP SUBA NORTH intends to bring amendments to the Kenya Drugs Authority Bill, 2022, (National Assembly Bill No. 54) as follows:

PART I- PRELIMINARY :

Add the definition of "alternative medicine"

"alternative medicine" means alternative medicine as defined under the Health Act.

Definition of "drug"

(a) Add the words "herbal medicine" after the words "any medicine" and before the words "medicinal preparation, medicinal substance, therapeutic substance prepared, sold or represented for use in-"

(b) Add the word "herbal medicine"" after the words "any medicine" and before the words " medicinal preparation"

(b) (ii) delete the word "if" appearing after the words "restoring, correcting or modifying functioning" and after the words "organs in humans or animals" and replace with the word "of".

Definition of "falsified medicines"

Put a semi colon (;) after the words "... of active or other ingredients" and before the words " or falsely labelled medicine"

Definition of health products and technologies

Delete and replace with

"health products" means chemical substances, therapeutic cosmetics, herbal medicines, medicines, scheduled substances and related products and substances.

"health technologies" means medical devices including radiation-emitting devices and related products.

Definition of herbal medicine or products

Delete and replace with

"herbal medicine" means the use of plants to treat disease and enhance general health and wellbeing.

"herbal product" means a plant derived material or preparations with claimed therapeutic or other human or veterinary health benefits, which contain either raw or processed ingredients from one or more plants, or material of inorganic or animal origin;

Definition of "insanitary condition"

Add the words "herbal medicine" after the words "as might contaminate a drug or a therapeutic cosmetic" and before the words "with dirt or filth"

Definition of "Label"

Add the words "herbal medicine" after the words "accompanying any drug" and before the words "therapeutic cosmetic"

NB: There appears to be something missing in this definition and I cannot tell what it is. The original drafter can assist.

Definition of "manufacture"

Delete the word "product or" appearing after the words "means any process carried out in the course of making" and add the words "or product" after the words "medicinal substance" and add the word "extracting" after the words "and includes" and before the words "packaging, blending, mixing"

Definition of "medicinal substance"

Add the words "herbal medicine" after the words "medicine" and before the word "product"

Definition of "registered midwife"

Delete the words "by law to practice the profession of midwife in Kenya" and replace with the words "to practice as such under the Nurses and Midwives' Act"

Definition of "registered pharmacist"

Delete the words "by the body for the time being responsible for registration of pharmacists" and replace with the words " under the Pharmacy and Poisons Act":

Definition of "substandard medicine"

Add the words "under this Act or any other written law" after the words "means medicines which do not meet defined standards and specifications" and before the words "and includes products thar have been contaminated"

Definition of "therapeutic cosmetic"

Delete the words "or altering complexion" appearing after the words "sold or represented for use in cleaning, improving" and before the words "skin, hair, eyes or teeth"

CLAUSE 6 (4) (a):

Delete the word "engineering" appearing after the word "in either pharmacy, medicine", and before the words "or equivalent fields";

CLAUSE 7 (a) and (b)

Delete subclause (a) and (b) and then replace with the following:

(a) Is a State officer

Renumber the subsections consequently.

(e) delete subsection "e" and replace with the words " is a public officer"

(f) delete the words "Act", regulation under this" appearing at the end of the sentence and replace with "regulations under this Act"

CLAUSE 8 (3)

Delete (e) appearing between "h" and "i"

CLAUSE 8 (6)

Delete sub clauses (a) and (b) and replace with

(a) Is a State officer

CLAUSE 8 (7)

Add the word "youth representation" after the words "regard shall be had of the need for" and before the word "regional" and add the word "and ethnic" after the word "regional" and before the words "balance and the realisation"

CLAUSE 10 (1) (f)

Delete the words " permission of the" and replace with "notifying the"

CLAUSE 12 (o)

Add the words "chemicals, medicine" after the words "promote rational use of

CLAUSE 12 (a)

Delete the word "ensure" and replace with the word "set"

CLAUSE 12 (b)

Delete the word "that" appearing after the word "ensure" and before the words 'compliance with existing legislation" and replace with the words "that there is" and further delete the words "is being promoted and controlled"

CLAUSE 12 (g)

Delete the word "being" after the word "products and technologies are" and before the words "assessed accordingly

CLAUSE 13 (f)

Delete the words "co-opt in such committees" and replace with the words "hire as consultants"

CLAUSE 17 (2)

Add the words "youth inclusion" after the words " The principles of" and after the words "ethnic, regional and gender"

CLAUSE 21 (1)

Delete the words "Cabinet Secretary" appearing after the word "The" and before the word "may establish scientific" and further delete the word "Cabinet Secretary" appearing before the word "under this Act" and replace with the word "Authority".

CLAUSE 21 (3)

Delete the word "Cabinet Secretary" and replace with "Board"

CLAUSE 21 (4)

Delete the word "Cabinet Secretary" and replace with the "Board"

CLAUSE 21 (9)

Delete the word "Cabinet Secretary" appearing before the words "with respect to its activities" and replace with the word "Board"; further delete the words "and the Cabinet Secretary shall lay a copy of each report before Parliament.

NEW Sub-clause 21 (10)

The Board shall prepare and submit annually a report of its activities including that of any subcommittees to the Cabinet Secretary and the Cabinet Secretary shall submit the said report to parliament.

CLAUSE 22 (2) (b)

Delete the words "five years" and replace with "three years".

CLAUSE 22 (3)

Delete entire clause

CLAUSE 24 (3)

Add sub clause (c) as follows:

(c) is herbal medicine

CLAUSE 24 (4) (a)

Delete the words "one hundred" and replace with "five hundred"

CLAUSE 24 (b)

Delete the words "two hundred thousand" and replace with "one million shillings" and further delete the words " five years" and replace with "three years"

CLAUSE 27

Add a new Clause 27 (1) as follows:

27 (1) "The Authority may issue product licences as provided under this Act

Renumber current 27 to 27 (2)

CLAUSE 28 (1)

Add the words "and herbal medicines" before the word "register" and after the word "There is established a medicines"

CLAUSE 28 (2)

Add the words "herbal medicine" after the words "content of the medicines" and before the word "register"

CLAUSE 29 (1)

Add a new Clause 29 (1) as follows then renumber the subsequent subsections

29 (1) Any pharmacist may apply for the registration of a medicine, herbal medicine or medical device as provided for under this Act.

CLAUSE 29 (1)

Add the word "herbal medicine" in subclause 29 (1) in the Bill after the words "Every application for the registration of a medicine" and before the words "or medical device"

CLAUSE 29 (3) (a)

Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

CLAUSE 29 (3) (b)

Add the words "or herbal medicine" after the word "the medicine" and before the word "in question"

CLAUSE 29 (3) (c)

Add the words "or herbal medicine" after the word "that medicine" and before the word "is in the public domain"

CLAUSE 29 (4)

Add the words "herbal medicine" after the words " of a medicine" and before the words "it shall cause the applicant"

CLAUSE 29 (4) (b)

Add the words "comment" after the words "with the applicant's" and after the words " on the Authority's reasons for not being so satisfied"

CLAUSE 29 (6)

Add the words "herbal medicine" after the word "medicine" and before the words " the registrar shall register"; and further after the word "medicine" and before the words "as are required by this Act"; and further after the words " in the prescribed form in respect of that medicine"

CLAUSE 29 (7)

Add the words "and herbal medicine" after the words "Every medicine" and before the words "shall be registered"

CLAUSE 29 (8)

Add the words "and herbal medicine" after the words "allocate to every medicine" and before the words "registered under this Act"; and further after the words "name of such medicine" and before the words "and which shall be stated in the certificate"; and further after the words "issued in respect of that such medicine"

CLAUSE 29 (9)

Add the words "and herbal medicine" after the words "registration of medicine" and before the words "already registered"; and further add the words "under this Act or any other written law" after the words "already registered" and before the words "shall be valid for a period of"

CLAUSE 29 (12)

Add the words "and herbal medicine" after the words "in respect of a medicine" and before the words "referred to in subsection (4)"

NEW SUBCLAUSE 29 (12) (a), (b) and (c)

Provide for a new subclause 29 (12) and renumber the current 29 (12) to 29 (13) and others consequently. Provide for the subclause 29 (12) as follows:

(a) "The Authority may reject any application if the applicant fails to meet the standards as required by this Act or any other written law"

(b) A person dissatisfied with the decision of the Registrar may appeal to the Board within the period specified under subsection 14

(c) Where a person is dissatisfied with the decision of the Board, the applicant may appeal to the High Court within thirty days of the decision being communicated to him or her.

CLAUSE 13

Add the words "of appeal" after the words "expiry of the appropriate period"; and further delete the words "referred to in sixty days"

CLAUSE 30 (1)

Add the words "or herbal medicine" after the words "on application by the holder" and before the words "a certificate of registration"; and further after the words "register with respect to that medicine"

CLAUSE 30 (3) (b)

Add the words "or herbal medicine" after the words "in respect of the medicine" and before the words "after receiving the existing certificate of registration"; and further after the words "register with respect to that medicine"; and further after the words "in respect of that medicine" and before the words "for cancellation"

A NEW SUBCLAUSE 30 (3)

Provide a new subclause 30 (3) and renumber the current (3) as (4) and provide for the new (3) as follows:

(3) The applicant shall provide reasons for the proposed amendments

CLAUSE 31 (1)

Add the words "or herbal medicine" after the words "registration of a medicine"

CLAUSE 32 (1)

Add the words "herbal medicine" after the words "registration of a medicine" and before the words ""or medical device"

CLAUSE 32 (1) (a)

Add the words "herbal medicine" after the words "to which particular medicine" and before the words ""or medical device"

CLAUSE 32 (1) (b)

Add the words "herbal medicine" after the words " particular medicine" and before the words ""or medical device"

CLAUSE 32 (1) (c)

Add the words "herbal medicine" after the words "particular medicine" and before the words ""or medical device"

CLAUSE 32 (2)

Add the words "herbal medicine" after the words "any medicine" and before the words ""or medical device"; and further after the words " in respect of that medicine" and before the words "or medical device"

CLAUSE 32 (4)

Add the words "herbal medicine" after the words "registration of that medicine" and before the words ""or medical device"

CLAUSE 32 (4) (b)

Add the words "herbal medicine" after the words "that the registration of the medicine" and before the words "or medical device"

CLAUSE 32 (5)

Add the words "herbal medicine" after the words " in respect of a medicine" and before the words ""or medical device"; and further after the words " of the registration of that medicine" and before the words " or medical device".

CLAUSE 33 (1) and (2)

(1) Add the words "herbal medicine" after the words "registration of a medicine" and before the words ""or medical device"

(2) Add the words "herbal medicine" after the words "registration of a medicine"

NEW SUBCLAUSE 33 (3)

Provide for a new subclause 3 and renumber current subclause (3) to (4). Provide for the new subclause (3) as follows:

(3) In the case of cancellation of registration of a herbal medicine the Registrar shall in such case specify-

(a) The name under which the herbal medicine is registered

(b) The active components of the herbal medicine

(c) The name of the applicant

(d) The name of the person who has propriety rights over the herbal medicine

(e) The registration number allocated to the herbal medicine;

(f) The conditions if any, subject to which that medicine is registered

CLAUSE 35 (1)

Delete the word "shall" appearing after the words "A pharmacist" and before the words "dispense and interchangeable" and replace with the word "may"

NEW CLAUSE 35 (4) (d)

Add a new sub-clause (4) (d) as follows:

34 (4) (d) unless the purchaser or patient is first informed of the same and agrees to the change.

CLAUSE 36 (1)

Delete the words "on a commercial scale"

CLAUSE 38 (2)

Delete "one hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment"

CLAUSE 40 (4)

Delete the words "whose decision thereon shall be final" appearing at the end of the sentence.

CLAUSE 40 (7)

Delete the words "two hundred thousand" appearing after the words " to a fine not exceeding" and replace with "one million"; and delete the words "two years" appearing after the words "imprisonment for a term not exceeding" and replace with "three years".

CLAUSE 41(1) (d)

Add the words "enrolled pharmaceutical technologist and registered pharmacist" after the word "practitioner"

CLAUSE 42 (2) (a)

Delete the words "provided that where a person represents that he urgently requires a Schedule Substances for the purpose of his trade, business or profession and

satisfies the seller that by reason of some emergency he is unable before delivery to furnish the order in writing, the seller may forthwith deliver the Scheduled Substances to the purchaser who will within twenty four hours of the sale furnish the seller with the written order"

CLAUSE 42 (3)

Delete the words "one hundred thousand" appearing after the words "to a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

CLAUSE 43 (3)

Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words " shillings or to imprisonment and replace with "one million".

CLAUSE 44 (3)

Delete the words "one hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

CLAUSE 45

Delete the words "five hundred thousand" appearing after the words "not exceeding" and after the words "shillings or to imprisonment and replace with "one million".

CLAUSE 46 (1)

Delete the word "This" appearing at the beginning of the sentence and replace with the words "The electronic supply of medicine"

CLAUSE 59 (3)

Add the word "who" between the words "A person" and the words "sells or supplies"

CLAUSE 60 (1) (c)

Add the words "medicinal herbs" after the words "manufactured and imported medicine" and after the words "or medicinal substances"

CLAUSE 63 (1)

Add the words "medical herbs" after the words "referring to a medicine" and before the words "drug, appliance or article"; and further before the words "to imply that the medicine" and before the words "drug, appliance or article".

CLAUSE 67 (3) (a)

Delete the words "two hundred thousand" appearing after the words " a fine not exceeding" and before the words "shillings or to an imprisonment" and replace with the words "one million".

CLAUSE 67 (3) (b)

Delete the words "three hundred thousand" appearing after the words " a fine of atr least" and before the words "shillings or to an imprisonment" and replace with the words "two million".

CLAUSE 68 (1)

Add the words "or herbal medicine" after the words "recommended a medicine" and before the words "to prove".

CLAUSE 71

Add the words "herbal medicine" after the words "homoeopathic medicine preparation" and before the words "or medical device"

CLAUSE 72 (3)

Add the words "herbal medicine" after the words "quantity of a particular medicine" and after the words "or medical device"

CLAUSE 79

Delete Clause 79

CLAUSE 86

Delete the words "seven hundred thousand" appearing after the words "a fine not exceeding" and before the words "shillings or to imprisonment" and replace with "one million"

CLAUSE 88 (v)

Add the words “herbal medicine” at the end of the sentence.

CLAUSE 88 (aa)

Add the words “herbal medicine” after the words “a specified medicine” and before the words “medical device”

CLAUSE 88 (bb)

Add the words “herbal medicine” after the words “dispense medicine” and before the words “medical device”

CLAUSE 88 (dd)

Add the words “herbal medicine” after the words “compounding of medicine” and before the words “medical device”

FOURTH SCHEDULE

Section (1) (1) replace Cabinet Secretary with “the Board”

Section (4) (2) (1)

Add the words “herbal medicine” after the words “human medicinal products” and before the words “giving advice”

TITLE

Change the Title to the **KENYA DRUG AND HEALTH TECHNOLOGIES BILL**.

Hon Millie Odhiambo-Mabona

MP Suba North

REPUBLIC OF KENYA
PARLIAMENT

Hon. CS. Irene Nyakerario Mayaka, MP.

Nominated
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23rd October, 2023

The Clerk of the National Assembly

Parliament Buildings

NAIROBI

Bill has No schedule

RE: THE KENYA DRUGS AUTHORITY BILL, 2022- COMMITTEE STAGE AMENDMENTS

NOTICE is given that the nominated Member, Hon. CS. Irene Nyakerario Mayaka, MP intends to move the following amendments to the Kenya Drugs Authority Bill, 2022, National Assembly Bill No.54 at the Committee Stage—

Clause 37

THAT, Clause 37 of the Bill be amended —

(a) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3)The Cabinet Secretary shall publish the list prepared under sub-section (1) in the *Gazette*.

(4)The list published under subsection (3) shall include narcotic substances, prescription-only medications, pharmacist-only medications, pharmacy-only medications, over-the-counter medicines, hazardous substances and prohibited substances".

(b) by renumbering sub-clause (3) as sub-clause (5), and
(c) by renumbering sub-clause (4) as sub-clause (6).

Signed ..... Date 24/10/2023

Hon. CS. Irene Nyakerario Mayaka, MP

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);

(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;

(g)the Director-General for Health or a representative designated in writing;"

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

4) **Notice is given that the Nominated Member (Hon. Irene Mayaka) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 37

THAT, Clause 37 of the Bill be amended —

(a) by inserting the following new sub-clauses immediately after sub-clause (2)—

"(3) The Cabinet Secretary shall publish the list prepared under subsection (1) in the *Gazette.*

(4)The list published under subsection (3) shall include narcotic substances, prescription-only medications, pharmacist-only medications, pharmacy-only medications, over-the-counter medicines, hazardous substances and prohibited substances".

(b) by renumbering sub-clause (3) as sub-clause (5); and

(c) by renumbering sub-clause (4) as sub-clause (6);

5) **Notice is given that the Member for Ndhiwa (Hon. Martin Peters Owino) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 72

THAT, clause 72 of the Bill be amended in subclause (1) by deleting the word "person" appearing immediately after the words "The Authority may authorise a" and substituting therefor the words "registered pharmacist".

6) **Notice is given that the Member for Homa Bay Town (Hon. George Kaluma) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—**

CLAUSE 3

THAT, the Bill be amended by deleting clause 3.