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THE NATIONAL ASSEMBLY
THIRTEENTH PARLIAMENT – SECOND SESSION – 2023

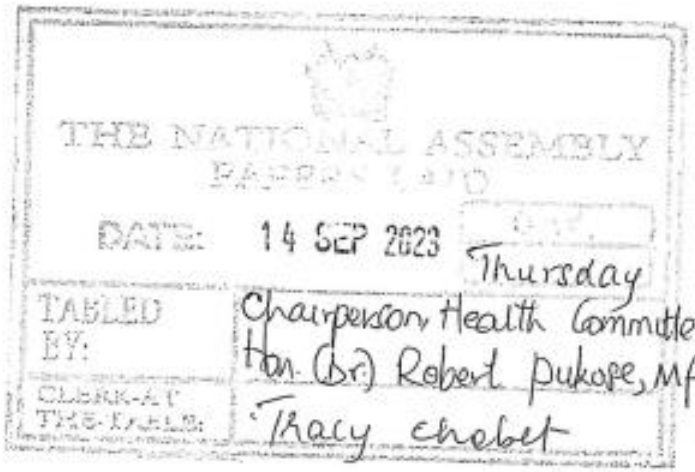
DIRECTORATE OF DEPARTMENTAL COMMITTEES
DEPARTMENTAL COMMITTEE ON HEALTH

REPORT ON:

THE KENYA DRUGS AUTHORITY BILL *(NATIONAL ASSEMBLY BILL NO. 54 OF 2022)*

CLERKS CHAMBERS
DIRECTORATE OF DEPARTMENTAL COMMITTEES
PARLIAMENT BUILDINGS
NAIROBI

SEPTEMBER, 2023



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CHAIRPERSON'S FOREWORD

This report contains proceedings of the Departmental Committee on Health on its consideration of the Kenya Drugs Authority Bill *(National Assembly Bill No. 54 of 2022)* which was published on 6th October 2022. The Bill went through First Reading on 9th November 2022 and was thereafter committed to the Departmental Committee on Health for consideration and reporting to the House pursuant to the provisions of Standing Order 127.

The Bill has ninety-seven (97) clauses. The Bill seeks to consolidate the regulation of health products and technologies in keeping with international best practices and guidance from the World Health Organization. This will promote and guarantee the quality, safety and efficacy and effectiveness of health products and technologies in the country. The Bill also establishes the Kenya Drugs Authority that is responsible for the regulation, investigation, inspection and approval of health products and technologies and related matters. Following placement of advertisements in the print media on Monday, 8th May, 2023 seeking public and stakeholder views on the Bill pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3), the Committee received memoranda from thirty-two (32) stakeholders.

The Committee also invited stakeholders vide letter REF: NA/DDC/DC-H/2023/024 dated 10th May, 2023 to submit their memoranda to the Clerk of the National Assembly on the Bill. The Committee vide letter REF: NA/DDC/DC-H/2023/039 dated 11th July, 2023 and invited the key stakeholders namely the Ministry of Health , the Office of the Attorney General, the Kenya Law Reform Commission, the Law society of Kenya, the Pharmaceutical Society of Kenya, the Pharmacy and Poisons Board, the Kenya Pharmaceutical Association,, the Kenya Medical Association, the Kenya Association of Pharmaceutical Industry and the National Quality Control Laboratory for a meeting to make their oral submissions before the Committee in a meeting held on Tuesday 18th July 2023 at 9:00 am in Committee room 2nd floor continental house and on 10th August, 2023 Committee room 12 Parliament Buildings. House. The Committee also held a retreat with some of these key stakeholders on 18th August, 2023 in English point Marina in Mombasa.

The Committee is grateful to the Offices of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings. The Committee further wishes to thank the sponsor of the Bill, Hon. Dr. Robert Pukose, MP and all stakeholders who submitted their comments on the Bill. Finally, I wish to express my appreciation to the Honourable Members of the Committee and the Committee Secretariat who made useful contributions towards the consideration of the Bill and production of this report.

On behalf of the Departmental Committee on Health and pursuant to provisions of Standing Order 199 (6), it is my pleasant privilege and honour to present to this House the Report of the Committee on its consideration of the Kenya Drugs Authority Bill (*National Assembly Bill No. 54 of 2022*). It is my pleasure to report that the Committee has considered the Kenya Drugs Authority Bill (*N.A. Bill No. 54 of 2022*) and has the honour to report back to the National Assembly with the recommendation that the Bill be **approved with amendments.**

HON. (DR.) ROBERT PUKOSE, M.P.
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

PART 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. Faith Chepkemoi
Legal Counsel II

Mr. Yakub Ahmed
Media Relations Officer II

Ms. Rahab Chepkilim
Audio Recording Officer II

Ms. Abigael Muinde
Research Officer III

Mr. Hiram Kimuhu
Fiscal Analyst III

Mr. Benson Kimanzi
Serjeant-At-Arms III

Mr. Salat Abdi Ali
Senior Serjeant-At-Arms

PART 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.

PART THREE

3.0 CONSIDERATION OF THE BILL BY THE COMMITTEE

3.1 LEGAL PROVISION ON PUBLIC PARTICIPATION

19. Article 118 (1) (b) of the Constitution of Kenya provides as follows—

> *"Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees."*

20. Standing Order 127(3) provides that—

> *"The Departmental Committee to which a Bill is committed shall facilitate public participation on the Bill through an appropriate mechanism, including—*
>
> *(a) inviting submission of memoranda;*
> *(b) holding public hearings;*
> *(c) consulting relevant stakeholders in a sector; and*
> *(d) consulting experts on technical subjects.*

21. Standing Order 127(3A) further provides that—

"The Departmental Committee shall take into account the views and recommendations of the public under paragraph (3) in its report to the House."

3.2 PUBLIC PARTICIPATION/STAKEHOLDERS CONSULTATION IN THE REVIEW OF THE BILL

3.2.1 SUBMISSIONS ON THE BILL

22. Following the call for memoranda from the public through the placement of adverts in the print media on 14th February 2023 and the Committee's engagements in meetings held on Tuesday 18th July 2023 at 9:00 am in Committee room 2nd floor continental house, on 10th August, 2023 Committee room 12 Parliament Buildings. House and at a retreat held on 18th August, 2023 at English point Marina in Mombasa, the Committee received submissions through oral presentations and written memoranda from the following stakeholders:

1) The Ministry of Health (MOH)
2) The Pharmacy and Poisons Board (PPB) vide letter dated 22nd May 2023;
3) The National Quality Control Lab (NQCL) vide memorandum dated 29th May 2023;
4) The National Gender and Equality Commission (NGEC) vide letter dated 22nd May 2023;
5) The Kenya Association of Manufacturers (KAM) vide letter dated 19th May 2023;
6) The Kenya Law Reform Commission (KLRC)
7) The Pharmaceutical Society of Kenya (PSK) vide letter dated 24th July 2023;
8) The Kenya Pharmaceutical Association (KPA) vide letter dated 22nd May 2023;
9) Agnes Kuvuna Maina, a qualified Pharmaceutical Technologist vide memorandum dated 22nd May 2023;
10) Mathew Wamuiga Gaturuku, an enrolled Pharmaceutical Technologist vide email dated 22nd May 2023;
11) Kabui John vide email of 22nd May 2023;
12) William Komen vide email of 22nd May 2023;
13) Vincent Gathukia vide email of 22nd May 2023;
14) Robert Ngetich vide email of 22nd May 2023;
15) Duncan Simwa vide email of 24th May 2023;
16) Bernard Kariuki vide email of 24th May 2023;
17) Benjamin Munyao Nthumo vide email of 22nd May 2023;
18) Dr. John Ngethe and Dr. Naoni Ngethe;
19) Dr. Alex Ogero Okaru, PhD
20) Winfred Wambui Ndirangu;
21) Daniel Kiiru Mwangi of Kimanjo Subcounty Hospital vide email of 22nd May 2023;
22) Pest Control Products Board (PCPB) vide letter dated 25th April 2023
23) The Veterinary Medicines Directorate (VMD) in the Ministry of Agriculture and Livestock Development vide memorandum submitted on 31st July 2023;
24) Agrochemicals Association of Kenya (AAK) vide letter dated 27th February 2023;
25) The Kenya National Union of Pharmaceutical Technologists (KNUPT) dated 22nd May 2023;
26) The Kenya Medical Association (KMA) vide letter dated 19th July 2023;
27) The Law Society of Kenya (LSK) vide memorandum dated 19th July 2023;
28) The Kenya Association of Pharmaceutical Industry (KAPI) vide email of 19th July 2023;

29) The Kenya Veterinary Board vide letter dated 31st July 2023;
30) The Ministry of Agriculture and Livestock Development vide letter dated 2nd August 2023; and
31) The Office of the Attorney General and Department of Justice (forwarded the memoranda by the Pest Control Products Board and the Ministry of Agriculture and Livestock Development.

3.2.2 THE MINISTRY OF HEALTH

In its memoranda, the Ministry of Health proposed the following amendments:

23. Amendment of the title of Part II by deleting the words 'The Kenya Food and Drugs Authority' and replacing with the words, *'Kenya Health Products and Technologies Regulatory Authority'*.
Justification: For consistency in the nomenclature used when referring to the Authority as the Ministry proposed the renaming of the Bill from the Kenya Drugs Authority Bill to the Kenya Health Products and Technologies Regulatory Authority Bill.

24. Deletion of the long title and substitution with the following *"A bill for an Act of Parliament to establish a comprehensive legal framework for 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".*
Justification: To highlight the main purpose of the Bill and to reflect the full scope of the Bill which includes medical devices and in vitro diagnostics. International best practice recommends a centralized or national regulatory authority for medicines.

25. Insertion of the following new definition
26. ***"Biologicals"*** *means a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma.*
Justification: The term not included in the Bill.

27. Deletion of the definition of ***"chemical substance"*** and substitution therefor with the following new definition ***"chemical" or "chemical substance"*** *means any substance or mixture of substances prepared, sold or represented for use as a germicide; antiseptic; disinfectant; pesticide; insecticide; rodenticide; vermicide; or detergent, or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;*
Justification: The proposed replacement of the Pharmacy and Poisons Act, Cap. 244 with the Bill.

28. Deletion of the definition of ***"medical substance"*** with ***"medicinal substance "*** and substitution therefor with the following new definition *"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;*

29. Deletion of the definition of ***"medical devices"*** and substitution therefor with the following new definition *"Medical Devices"* 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 a medical purpose.*

30. Deletion of the definition of ***"manufacture"*** and substitution therefor with the following new definition—

"manufacture", in relation to medicines, means *the production of medicines or any part of the process of producing medicines or bringing the products to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilizing, testing or releasing for supply of the products or of any component or ingredient of the products as part of that process; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as vehicle for administration;*

OR

"manufacture", in relation to a medical device, *means to make, fabricate, produce or process the medical device and includes:*
(i) any process carried out in the course of so making, fabricating, producing or processing the medical device; and/or (ii) the packaging and labelling of the medical device before it is supplied.

31. Deletion of the definition of **"therapeutic cosmetic"** and substitution therefor with the following new definition **"Therapeutic cosmetic"** means *-products with the ability to trigger biological actions on the dermis, a skin level beneath the stratum corneum, and have the ability to: Target and repair skin issues, prevent future damage containing ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over-the-counter.*

32. Deletion of the definition of ***"drug"*** and substitution therefor with the following new definition—
"drug" *includes any substance or mixture of substances manufactured, sold or represented for use in –*
a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings; or
b) *restoring, correcting or modifying organic functions in human beings or animals,* or c) *disinfection in premises in which food is manufactured, prepared or kept; and includes biologicals.*

33. Deletion of the definition of ***"registered pharmacist"*** and substitution therefor with the following new definition ***"Registered Pharmacist"*** means *a holder of a degree in pharmacy from a university recognised by the Authority and whose name is entered on the register;*

34. Insertion of the following new definition ***"Medicine"*** includes; -
(a) any medicine, medicinal preparation, medicinal substance, therapeutic substance or vaccine; or
(b) any substance or mixture of substances including any medicine, medicinal preparation or therapeutic substance prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in humans or animals; or restoring, correcting or modifying functioning of organs in humans or animals;
Justification: The need to define "medicine" owing to the adoption of the term "health product and technology" instead of the term "drug".

35. Insertion of the following new definition ***"scheduling"*** *means in relation to a substance, determining the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included.*
Justification: There is no clear definition for scheduling in the Bill.

36. Insertion of the following new definition ***"Wholesale dealer"*** means *a business where health products are stored, dispensed, distributed or sold in bulk to persons other than individual consumers or patients;*

OR Wholesale dealer" means *a person or company that sells goods in large quantities to retail dealers, rather than selling smaller quantities directly to consumers.*

Justification: The introduction of this definition will bring out better clarity as to who a wholesale dealer is under the Bill.

37. Insertion of the following new definition **"cosmetic"** means - *(a) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance,* and (b) *articles intended for use as a component of any such articles; except that such term shall not include soap;*
Justification: The definition provided contradicts the definition of regular cosmetic.

38. Insertion of the following new definition ***"herbs"*** means *herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations.*
Justification: To expand the scope of herbs regulated under the Bill to include herbal materials and herbal combinations.

39. Insertion of the following new definitions:

"Lot release" means *"the process of the Kenya Drug Authority evaluation of an individual lot of a licensed biological product before giving approval for its release onto the market".*

"lot/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. In continuous manufacture, the lot corresponds to a defined fraction of the production, characterized by its intended homogeneity".*

"Substandard medical products also called "out of specification", means *"registered medical products that fail to meet either their quality standards or specifications, or both".*

"Unregistered medical products" means *"the products that have not undergone evaluation and/or approval by the Kenya National Regulatory Authority (Kenya Drugs Authority) subject to permitted conditions under the Kenya Drugs Authority Act and the rules therein".*

"Falsified medical products" means *"the products that deliberately/fraudulently misrepresent their identity, composition or source";*

"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".*

"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";*

"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, to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety".*

"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";*

"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";*

"register" means *"to obtain marketing approval for a medical device from the Regulatory Authority of a Member State in order to place the medical device on the market of that Member State".*

"Putting into service" means *"the stage at which a medical device has been made available to the final user as being ready for use on the market of a Member State for its intended purpose".*

"Refurbished medical device" means *"a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it":*

"Sponsor" means *"an individual or organisation taking responsibility and liability for the initiation or implementation of a clinical investigation".*

"in vitro diagnostic (IVD) medical device" means *"any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information":*

"Health products" include *"human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products".*

"Health technologies" 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".*

"Therapeutic product" means *"a drug or medical device or any combination of drugs and medical devices, but does not include a homeopathic medicinal product or an herbal medicinal product";*

"Medication Therapy Management" means *"a range of services provided by pharmacists towards review of all medications prescribed by all prescribers providing care to the patient, and any over-the-counter and herbal products the patient may be taking to identify and address medication problems. Problems may include medications not being used correctly, duplication of medications, unnecessary medications, and the need for medication(s) for an untreated or inappropriately managed condition";*

"Dietary supplement" also called *"nutritional supplement means a product taken by mouth that is added to the diet to help meet one's daily requirements of essential nutrients, usually contains one or more dietary ingredient and include vitamins, minerals, herbs, amino acids, live microbials and enzymes".*

"accessory" means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose.

"Adverse event" means *'either a malfunction or a deterioration in the characteristics or performance of a supplied medical device or use error, which either has caused or could have caused or contributed to death, or injury to health of patients or other persons."*

"person" means *"a natural person or a legal entity including a corporation, a partnership or association duly established pursuant to the prevailing laws and regulations of Member States".*

"Local authorised representative" means *"any person in a Member State who, explicitly designated by the product owner, acts and may be addressed by authorities and bodies in a Member State instead of the product owner with regard to the latter's obligations under this Agreement, and relevant laws and regulations of the Member State"*

"custom-made medical device" means *"any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. For the purposes of this definition, a duly qualified medical practitioner is defined as a person who is duly qualified by the relevant laws and regulations of the Member State where the custom- made medical device is used. For purposes of clarity, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made medical devices".*

"Device intended for clinical investigation" means *"any device intended for use by a duly qualified medical practitioner when conducting clinical investigations as referred to in Annex 8 (Clinical Investigation), in an adequate human clinical environment. For the purposes of conducting of clinical investigation, a duly qualified medical practitioner is defined as a person who is duly qualified by the relevant laws and regulations of the Member State where the clinical investigation is carried out, and by virtue of his professional qualifications, is authorised to carry out such investigation"*

"Authorised distributor", in relation to the placing on the market of a medical device, means *'any person who has been authorised by the product owner or authorised representative to distribute the medical device in that Member State".*

"Field Safety Corrective Action (FSCA)" 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".* This may include:

(i) the return of a medical device to the product owner or its representative; (ii) device modification which may include: (a) retrofit in accordance with the product owner's modification or design change;(b) permanent or temporary changes to the labelling or instructions for use; (c) software upgrades including those carried out by remote access; (d) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. (iii) device exchange; (iv) device destruction; (v) advice given by product owner regarding the use of the device.

"Intended purpose" means *"the use for which the medical device is intended according to the specifications of its product owner as stated on any or all of the following":*

(i) the label of the medical device;
(ii) the instructions for use of the medical device;
(iii) the promotional materials in relation to the medical device.

"Physical manufacturer", in relation to a medical device, means *"any person who performs the activity of manufacture"*

"Placing on the market" means *"the making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view to distribution and/or use on the market of a Member State".*

"Product owner", in relation to a medical device, means *"any person who: (i) supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and (ii) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.*

"***examination"*** means *"Set of operations having the object of determining the value of a property".*

note: *Examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.*

"instrument": means *"Equipment or apparatus intended by the product owner to be used as IVD medical device".*

"Ivy medical device for self-testing": means *"any IVD medical device intended by the product owner for use by lay persons.*

"Lay persons: means *"any individual who does not have formal training in a relevant field or discipline".*

"Near patient testing": means *"any testing performed outside a laboratory environment by a health care professional not necessarily a laboratory professional, generally near to, or at the side of, the patient. Also known as Point-of- Care (POC)".*

"Reagent:" means *"any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as IVD medical devices".*

"self-testing:" means *"testing performed by lay persons".*

"Specimen receptacle: means *"an IVD medical device, whether vacuum- type or not, specifically intended by their product owner for the primary containment of specimens derived from the human body".*

"Transmissible agent: means *"an agent capable of being transmitted to a person, as a communicable, infectious or contagious disease".*

"Transmission means *"the conveyance of disease to a person".*

"Anti-infectives" means *"medicines that work to prevent or treat infections and include antibacterial, antivirals, antifungals and antiparasitic medications".*

"Centre" *means "the National Pharmacovigilance Centre";*

"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";*

"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';*

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

"Vessel": means *"Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey health products and technologies"*

"Good clinical practices"" *in manufacturing regulates the processes and conditions under which clinical and non-clinical research is conducted and governs how these research facilities should be maintained apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article":*

(i) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) 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; and (g) providing information for medical or diagnostic purposes by means of invitro examination of specimens derived from the human body;

(ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

"Good Laboratory practices" means *"the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations".*

Justification: To include the full scope of health products and technologies regulated under the Bill.

40. Deletion of clause 3 (1) and substitution with the following clause—

"This Act applies to regulation of health products and technologies including;

(a) Drugs;
(b) Chemical substances as defined by the Authority in the schedule;
(c) Plasma derived medicinal products and acellular blood and blood products;
(d) Biological products for use in humans;
(e) Starting materials used in the manufacture of medicines, medical products and biological products;
(f) Therapeutic cosmetics;
(g) Products containing scheduled substances and intended for use in humans;
(h) Herbal medicines and products;
(i) Medical devices;
(j) In vitro diagnostics;
(k) Medicines;
(l) Scheduled substances and all products containing scheduled substances;
(m) Therapeutic feeds; and
(n) Dietary supplements".

Justification: To include the full scope of health products and technologies regulated under the Bill.

41. Deletion of clause 4 (1) and substitution with the following: *"There is established an Authority to be known as the Kenya Health Products and Technologies Regulatory Authority".*

Justification: The Authority will regulate more than drugs and the name should reflect the same.

42. Deletion of clause 5 and substitution with the following *"the headquarters of the Authority shall be in Nairobi or in such other place as the board of the Authority may, by resolution, determine".*

Justification: The Board should have the Authority to determine the location of the Authority headquarters.

43. Deletion of clause 6 (1), (2), (3), (4), (5) and (6) and substitution with the following;

i. *There shall be a Director-General who shall be the chief executive officer of the Authority, appointed by the Board, and whose terms of reference shall be determined by the Board in the instrument of appointment or otherwise in writing from time to time.*
ii. *No person shall qualify for appointment under this section unless such person (a) Has a Bachelors' degree in Pharmacy or its equivalent from a University recognized in Kenya; (b) Hold a masters' degree in Pharmacy, Medicine, Engineering or equivalent 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; (d) Is a member of a professional body; (e) Meets the requirements of chapter six of the constitution on leadership and integrity.*
iii. *The Director-General shall, subject to the directions of the Board and*
iv. *The Director General Shall be responsible for the day-to-day management of the affairs and staff of the Authority.*

Justification: To align with good corporate governance as provided under the *'Mwongozo Code of Governance for State Corporations'* and the State Corporations Act Cap 446. which provides that the Chief Executive Officer is appointed by the Board of Directors. To further clarify the role of the Director-General in the day-to-day management of the affairs and staff of the Authority and to ensure that the Director-General has the requisite qualifications to govern the organization.

44. Deletion of clause 8 (1) and (2) and substitution with the following;

"(I) The Authority shall be managed by a Board of Directors;

(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; 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 designated representative;(c) the Principal Secretary the Ministry for the time being responsible for finance or a designated representative;(d) Head of the Directorate of Health Products and Technologies;(e) a representative from the Council of Governors not being a governor and with knowledge and experience in health products and technologies; (f) a representative nominated by the Pharmaceutical Society of Kenya; (g) a representative nominated by the Kenya Pharmaceutical Association; (h) a representative nominated by the association representing Biomedical Engineers; (i) the Director General of the Authority who shall be the secretary".

Justification: The number of board members of the Authority should be between seven and nine in compliance with *'Mwongozo Code of Governance for State Corporations'*. Given that the Authority shall be managed by a Board of Directors, a definitive name for the Board is not required. Members of the board should have the knowledge and experience required to effectively manage the Authority. To

further align with the State Corporations Act, Cap. 446 which does not provide for the position of a vice-chairperson elected by the Board.

45. Amendment of clause 12 by inserting the following new paragraphs immediately after paragraph (e)—

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

Justification: These are critical functions of the Authority.

46. Amendment of clause 12 of the Bill by deleting paragraph (f) and substituting the following new paragraph—

(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act by 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: In country safety monitoring of health products and technologies takes precedence. However, safety information from other National Regulatory Authorities may be considered through regulation and reliance mechanisms for decision making.

47. Amendment of clause 12 by deleting paragraph (g) and substituting therefor the following paragraph—

"(g) 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: Global best practice for clinical trial oversight requires entrenchment of clinical trials in law and applicable regulations. The World Health Organization (WHO) benchmarking tool further specifies the minimum legal requirements. These minimums are not captured in the Bill as currently proposed even though they are currently provided for in the Pharmacy and Poisons Act, Cap. 244.

48. Amendment of clause 12 of the Bill by inserting a new paragraph immediately after clause (g)—

"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use.

Justification: To cater for emergency situations in public health.

49. Amendment of clause 12 of the Bill by inserting a new paragraph immediately after clause (ga) *"(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with Good Pharmacovigilance Practices and the prescribed requirements".*

Justification: The Bill does not provide for the conduct of Good Pharmacovigilance Practice Inspections, which are key towards ensuring that marketing authorization holders, local technical representatives, parallel importers, distributors and outsourced persons or companies meet the prescribed requirements thereby ensuring the safety of the health products and technologies.

50. Amendment of clause 12 by deleting paragraph (n) and substituting therefor the following paragraph—

"(n) appoint inspectors and order inspection of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, retail outlets and any other premises subject to this Act."

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

51. Amendment of clause 12 by inserting a new paragraph after clause (o)

"(oa) Conduct National Regulatory Authority lot release (official authority batch release) of specified biological 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".

Justification: The regulatory function of the Authority involves lot release which is a key component in vaccine production.

52. Amendment of Clause 12 by inserting the following new paragraphs after clause (q)—

"(qa) Ensure that all health products and technologies manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy"

"(qb) *Enforce the prescribed standards of quality, safety and efficacy of all 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 either the single convention on Narcotic drugs of 1961, the convention on Psychotropic substances 1971 and the UN 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: Control over the import and export of health products and technologies import is a critical regulatory function of the Authority.

53. Amendment of clause 13 by deleting paragraph 13 (a) and substituting therefor the following paragraphs—

"(a) Collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate and in furtherance of the purpose for which the Authority is established;
"(aa) Adopt and implement any such internationally recognized good regulatory practices"
"(ab) Determine and implement effective and efficient reliance mechanism"
"(ac) Issue, suspend, withdraw/revoke any license, compliance certificate"
"(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) Formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products".

Justification: To comply with WHO requirements on regulatory functions as provided in the Global Benchmarking Tool.

54. Amendment of clause 21 (1), (3) and (4) by deleting the words ***'Cabinet Secretary'*** and substituting therefor the words, ***'the Board of the Authority'***,

55. Amendment of clause 21 (9) by deleting the words '***Cabinet Secretary'*** and substituting therefor the words ***'the Board of the Authority'*** and by deleting the word '***Parliament'*** and substituting therefor the words ***'Cabinet Secretary'***.

Justification: The Technical committees are established by Authority with the main task of guiding the Board of the Authority in effectively carrying out its mandate.

56. Amendment of PART IV by deleting the word **"medicine"** in the title of the part and replacing it with the words **"health products and technologies".**

Justification: To capture all aspects of marketing authorization for all product categories to be regulated under the Bill.

57. Under Clause 22, amendment of paragraph (c) by inserting a new paragraph immediately after (c)—

(ca) **"falsified"**

Justification: The term "falsified" is globally used and recommended by WHO.

58. Amendment of clause 22(1)(a) by deleting the word "medicine" and substituting thereof the words "health product and technology"

Justification: To harmonize terms and cover the whole scope of regulated products.

59. Amendment of clause 22 by inserting new clauses immediately after clause 22 (1)—

22 (1) "(A) Authorization of health products and technologies"

(1) A person shall not import any health product or technology unless:

(a) "The health product or technology has been authorized through issuance of an import license or any written authorizations by the authority"

(b)" The imported health products or technologies be inspected and verified by the authority's inspectors at the ports of entry before release"

(2) No batch/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/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/lot after completion of all processes of manufacture which may affect compliance with the standard applicable to the product.

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

(5) Every batch/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 Registrar shall approve its release into the market and issue a certificate of official batch/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 to issue a certificate under this section.

(7) A person who contravenes this section commits an offence.

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

60. Amendment of clause 22(3) by deleting the word **"medicine"** and substituting thereof with the word ***"health product or technology"***.

Justification: To harmonize terms and cover the whole scope of regulated products.

61. Amendment of clause 22(3)(b) by deleting the words "pharmaceutical product" and substituting thereof with the word ***"health product or technology"***.

Justification: To harmonize terms and cover the whole scope of regulated products.

62. Amendment of clause 23 (1)(a), 23 (1)(b) and 23 (1)(c) by deleting the word "medicine" and substituting thereof with the word **"health product or technology"**.

Justification: To harmonize terms and cover the whole scope of regulated products.

63. Amendment of clause 23(2)(a) by deleting the words ***"one"*** and substituting thereof with the words "two" and amendment of clause 23(2)(b) by deleting the words "two" and substituting thereof with the words "***five***".

Justification: To make the fines prohibitive and punitive due to the serious risks to public health.

64. Amendment of clause 24 (1), (2) and (3) by deleting the word "***medicine***" wherever it appears in the paragraph and substituting therefor with the words "***health product or technology***".

Justification: To harmonize terms and cover the whole scope of regulated products.

65. Amend Clause 24(4)(a) by deleting the words ***"one hundred thousand"*** and substituting thereof with the words ***"two million"*** and amend Clause 24(4)(b) by deleting the words "***two hundred thousand shillings***" and substituting thereof with the words **"five million"**.

Justification: To make the fines prohibitive and punitive due to the serious risks to public health.

66. Deletion of clause 25.

Justification: Clause 25 is more of a practice-based offense rather than a product-based offense.

67. Amendment of clause 26 by deleting the word ***"medicine"*** and substituting therefor with the words "***health product or technology***"

68. Amendment of clause 27(a) of the Bill by deleting the words ***"medicinal products"*** and replacing with the following new words ***"health products"***

69. Amendment of clause 27(b) and (c) by deleting the word ***"medicine"*** and substituting therefor with the words ***"health product or technology"***.

Justification: To harmonize terminologies in the Bill.

70. Amendment of clause 28(1) and (2) by deleting the word ***"medicine"*** and substituting therefor with the words "***health products or technologies***".

Justification: To harmonize terminologies in the Bill.

71. Amendment of clause 28 of the Bill by deleting subclause (1) and substituting therefor the following new paragraphs –

"(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.*

(1A) An application made 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; 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 has permanent residence or a company incorporated in Kenya.

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

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

(b) a copy of the manufacturing licence of the health product, 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 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;

(h) proof of ownership of the site for the manufacture of the health product, if 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 in accordance with section 9A of the Pharmacy and Poisons Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 39 of the Act;

(iii)a valid licence to deal in health products issued in accordance with the Act; or

(iv) a valid manufacturing licence issued in accordance with section 47 of the Act; and

(l) proof of payment of the prescribed application fees.

(1C) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation".

72. Amendment of clause 29(2) by deleting the words "or Essential Veterinary Medicines List".

Justification: To delete aspects touching on veterinary medicines that are out of scope of the Bill.

73. Amendment of clause 29(2) and 29(3) by deleting the word ***"medicine"*** wherever it appears in the paragraph and substituting therefor with the words ***"health product or technology".***

74. Amendment of the Bill by inserting the following new clause immediately after clause 29 (3) the following new paragraphs —

(3A) The Authority may, while considering the application made under this section, 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;

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

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

(ii) the route of administering the health product;

(iii) the dosage of the health product;

(iv) the storage conditions of the health product;

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

(vi) the package size of the health product.

(3B) When evaluating an application made under this section the Authority may—

(a) subject a sample of the health product to laboratory testing; and

(b) (b) consider the evaluation report of an institution that has evaluated the health product.

75. Amendment of clause 29(4) and 29(6) by deleting the word "medicine" wherever it appears in the paragraph and substituting therefor with the words "health product or technology"

Justification: Harmonization of terminologies.

76. Amendment of clause 29(6) by inserting the following additional words immediately after the word "medicine" "if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology."

Justification: To emphasize on the need to be satisfied about safety, efficacy, quality, performance and economic value of a health product or technology.

77. Amendment of subclause (7), (8), (9), (10), (11) and (12) of clause 29 by deleting the word "medicine" wherever it appears in the paragraph and substituting therefor with the words "health product or technology"

Justification: Harmonization of terminologies.

78. Deletion of clause 29(13).

Justification: Clause 29(13) may not be ideal as the Registrar is already required under the Bill to publish the health products registered in the *Gazette* and those whose registrations are cancelled.

79. Amendment by deleting clause 29(14(a) and substituting therefor the following new definition (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;

80. Amendment by deleting Clause 29(14(b).

81. Amendment of the Bill by inserting the following new paragraph immediately after clause 29

"29A. Registration during emergency

(1) The Authority may, where it considers it necessary to protect public or animal health or in the event of a threat to human or animal life or health, the Authority, 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 sub section (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 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 a valid practicing licence issued in accordance with section 9A of the Pharmacy and Poisons Act;

(i) a valid wholesale dealer's licence issued in accordance with section 39 of the Act;

(ii) a valid licence to deal in health products issued in accordance with the Act; or

(iii)a valid manufacturing licence issued in accordance with section 47 of the Act

(d) the fees specified in the Second Schedule.

(5) When determining an application under subsection (1), 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 medicinal products, if available.

(6) The person to whom the certificate of registration is issued under subsection (1) shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) The Authority shall issue a provisional certificate of registration under subsection,(1) if the person has

(i) a valid wholesale dealer's licence issued in accordance with section 39 of the Act;

(ii) a valid licence to deal in health products issued in accordance with the Act; or

(iii)a valid manufacturing licence issued in accordance with section 47 of the Act

(8) 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.

(9) 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.

Justification: To cater for registration of health products and technologies during public emergency situations.

82. Amendment of the Bill by inserting the following new clause immediately after clause 29—

29B. Authorization of unregistered health product or technology

(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 that is not registered.
(2) A health product 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 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 or animal pharmacological and clinical data with the health product concerned;
(b) witnessed informed written consent document, where applicable;
(c) details of registration or pending registration of the health product with any other regulatory authority, if available;
(d) evidence of compliance of the manufacturer of the health product with Good Manufacturing Practice standards as determined by the Authority;
(e) reasons why a registered health product 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;
(h) the fees specified in the Second Schedule.
(6) The Authority shall grant authorization under subsection (1) if the applicant has—

(i) a valid wholesale dealer's licence issued in accordance with section 39 of the Act;

(ii) a valid licence to deal in health products issued in accordance with the Act; or

(iii)a valid manufacturing licence issued in accordance with section 47 of the Act

(7) Where the Authority issues an authorization under this section the person to whom the authorization is issued shall submit to the Authority—
(a) progress reports after every six months from the date when the authorization was issued;

(b) any adverse event report, whenever an adverse event occurs; and

(c) a progress report within thirty days after the completion or termination of the use of the health product.

(8) The Authority may, if it is of the opinion that the safety of any patient or animal is compromised or the scientific reasons for administering the unregistered health product have changed—
(a) impose any additional conditions;
(b) request additional information;
(c) inspect the site where the unregistered health product is manufactured, stored or administered; or
(d) withdraw the authorization to treat the patient or animal.
(9) The Authority may, by notice in writing withdraw the authorization issued under subsection (1) if any of purposes or the manner specified in subsection (2) is contravened.
(10) A health product authorized under this Act shall be labelled in accordance with section 67 of the Act.
(11) An applicant shall notify the Authority of any variation to the agreement appointing the local representative within seven days of the variation.

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

Justification: To cater for authorization of health products and technologies during public emergency situations.

83. Amendment of clause 30(1) and (3) 31(1) and 31(3)(c) by deleting the word "medicine" and substituting therefor with the words "health product or technology";
84. Amendment of clause 32(1), 32(2), 32(4) and 32(5) by deleting the words "medicine or medical device" and substituting therefor with the words "health product or technology".

Justification: To ensure harmonization of terminologies.

85. Amendment of clause 33(1), 33(2) ,33(2) (a), 33(2)(b), 33(2)(e) and 33(2)(f) and clauses 34, 34(a) and 34(b) by deleting the word "medicine" and substituting therefor with the words "health product or technology".

Justification: To ensure harmonization of terms while still providing for the specific category of medical products whose requirements vary slightly.

86. Amendment of clause 35(1), 35(2) and 35(3) by deleting the word "medicine" wherever it appears in the paragraph and substituting therefor with the words "health product".

Justification: To ensure the role of the pharmacist as a prescriber is provided and for cost-effectiveness of health products.

87. Amendment of clause 35(4) by deleting the paragraph and substituting thereof the following new paragraph –

(4) A pharmacist may substitute a prescribed health product for an interchangeable multi-source medicine in consultation with the relevant prescriber.

Justification: To ensure the role of the pharmacist as a prescriber is provided and for cost-effectiveness of health products.

88. Amendment of clause 35(1) by inserting the word "pharmacist" immediately before the word "medical".

89. **Justification:** To ensure the role of the pharmacist as a prescriber is provided and for cost-effectiveness of health products.

90. Amendment of clause 36(1) by deleting the word "herbal" and substituting therefor with the words "alternative or complementary".

Justification: To cover a wider scope of alternative medicines including herbal medicines.

91. Amendment of the Bill by inserting new clause immediately after clause 36-

36AClinical trials

(1) A pharmaceutical product shall not be used for clinical trial unless an approval is granted by the Authority with the approval of the relevant ethics body.
(2) Any person who intends to commence a clinical trial on a pharmaceutical product 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 a 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 up a robust quality assurance system to ensure that the clinical trial is carried out so as to ensure the integrity of data generated, the safety and well-being of study participants.
(6) The Authority shall carry out inspections of the clinical trials so as to ensure compliance of the clinical trials with the prescribed requirements.
(7) Any protocol amendments applications shall be submitted to the Authority for approval before implementation.

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

92. *Deletion of clause 37 (2) and substitution with--*

(2) The lists to be prepared under this Section shall include

(a) Scheduled substances that will be available for general sales, in any retail outlet;

(b) Scheduled substances that will be available on the professional advice of a pharmacist, without a prescription from an authorised prescriber, and available only in licensed pharmacies;

(c) Scheduled substances that will be available only on the prescription of an authorised prescriber, and dispensed by a pharmacist or licensed dispenser;

(d) Scheduled substances that will be available only on the prescription of an authorised prescriber, and dispensed by a pharmacist or licensed dispenser, subject to the control measures prescribed in accordance with either the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988;

(e) Scheduled substances that may not be sold, except in accordance with a permit for the purposes of education, analysis or research, or for individual patient purposes.

Justification: To effectively cater for different levels of control and to align to the African Union Model law of scheduling.

93. Deletion of clause 37(4) and substitution with the following new clause to the effect that the Authority shall review the lists whenever necessary in the interest of public health and safety.

Justification: One year is too short, and may be impractical if need arises. The proposed amendment allows the Authority to act in the interest of public health and safety.

94. Introduction of new provisions as follows:

37. Requirements for scheduled substances

The Authority shall establish a uniform system of access control for products containing scheduled substances which shall take into account---

(a) restrictions on accessibility and availability to the public

(b) interest of public health and safety

(c) risks of poisoning from, misuse and abuse of scheduled substances

The following new clauses are proposed.

List of scheduled substances

(1) The Authority shall prepare and submit to the Cabinet Secretary a list of the substances which are to be treated as Scheduled Substances for the purposes of this Act.

(3) The lists to be prepared under this Section shall include-

(a) substances which, subject to this act, are not to be sold except by authorized sellers of Scheduled Substances and by licensed wholesale dealers and dealers in mining, agricultural or horticultural accessories; (b) substances which, subject to this Act, are not to be sold except by persons specially licensed to do so; and (c) any other substance declared to be a Scheduled Substance by the authority.

(3) Upon receipt of the list under sub-section (1), the Cabinet Secretary may-

(a) confirm the list

(b) amend the list by-

i) altering any reference to a substance;

ii) omitting any substance; or

iii) inserting any substance

(c) vary the list.

Review of the list

The scheduling of substances shall be undertaken at least every three years or whenever necessary in the Interest of public health and safety.

Justification: The proposal introduces a transparent process of scheduling of substances in a manner that takes into consideration restrictions on accessibility and availability to the public including public health, safety and use.

95. Clause 38(1) should be redrafted as follows:

The following persons may be in possession of Scheduled Substances, -

(a) wholesale dealer licensed under this Act;

(b) an authorized seller of Scheduled Substances registered by the Authority;

(c) a person licensed by the Authority to sell; Scheduled Substances, the personal representative of a deceased person, or the liquidator, receiver or other person appointed to deal with the property of a bankrupt or of a company which is being wound up compulsorily, or the manager of the estate of a person of unsound mind, in respect of poisons in possession of Scheduled Substances;

(d) a person, institution or department, to which a Scheduled substance has been lawfully sold under this Act;

(e) a person for whom the Scheduled Substance has been lawfully supplied or dispensed by a healthcare professional authorized under this Act; (f) the personal representative of a deceased person, or the liquidator.

Justification: To bring out the clarity of who may be in possession of scheduled substances and to prescribe limits as the current subclausedoes not prescribe any limits.

96. Redrafting of clause 39(4) and (5) as follows—

39. (4) No licence shall be issued or renewed under this section unless the person applying for or holding such licence is a registered pharmacist or an enrolled pharmaceutical technologist in control of the distribution of the Scheduled substances and is a resident in Kenya.

(5) Every licence issued under this section shall expire 365 days from the date of issue.

97. Deletion of clause 40(3).

Justification: Issuance of licence is already provided for in clause 39.

98. Redrafting of clause 40(5) as follows

(5) Every licence issued under this section shall expire 365 days from the date of issue. Justification:

Justification: The current clause is punitive for those who apply in the middle of the year.

99. Redrafting clause 41(b) as follows—

41. (1) (b) (i) a person registered as lawfully carrying on the business of a pharmacist in Kenya;

(ii) a person lawfully carrying on the business of a pharmacist or pharmaceutical technologist in Kenya subject to the prescribed schedule of substances;

Justification: To capture both cadres in pharmacy practice

100. Deletion of "veterinary surgeon and veterinary treatment" in clause 41 (1) (d).

101. Deletion of clause 41(2)(b) and (c).

102. Deletion of the National or County government or their institutions in clause 41 (1) (e).

Justification: County governments referred in clause 41 (1) (e) is not clear.

103. Redrafting clause 41(1) (f) as follows—

A licenced hospital, dispensary or similar institution or a person or institution concerned with scientific education or research where such hospital, dispensary, institution but it shall be an offense to sell Scheduled substances to any of these unless a registered pharmacist or an enrolled pharmaceutical technologist is in direct control of the Scheduled Substances at the premises from which they are sold.

104. Amendment of clause 42 (1) by deleting and substitution with the following paragraph:

(1) An authorized seller shall enter a record of such particulars of the Scheduled Substance before delivery of the Scheduled Substance under this Act. The records hall be in such a manner and format as prescribed by the Authority and shall indicate - the date of the sale, the name and address of the purchaser, quantity of the Scheduled Substances sold, and the purpose for which it is stated by the purchaser to be required.

Justification: The current clause is impractical and infringes on privacy among patients. The proposed amendment ensures the keeping of an accountable record of sold scheduled substances.

105. Deletion of clause 43 (1) and substitution with –

(1) A qualified healthcare professional may supply or dispense a Scheduled Substance with therapeutic value for the purpose of medical or dental treatment, as the case may be provided by this Act.

Justification: To restrict dispensing to authorized personnel.

106. Redrafting of 43 (1) (b) as follows–

-The person supplying or dispensing a scheduled substance shall make a record of the scheduled substances supplied within twenty-four hours in a Prescription Book.

43 (1) (c) The record under 43 (1) (b) shall be kept in such a manner and format as shall be prescribed by the Authority and shall indicate:

(i) the date on which the Scheduled Substance with therapeutic value was supplied or dispensed;

(ii) the ingredients and the quantity supplied;

(iii) the name and address of the person to whom the Scheduled Substance with therapeutic value was supplied;

(iv) the name and address of the person by whom the prescription was given.

Justification: The country is moving towards digitization of processes. There are policies and guidelines available within the Ministry of Health.

107. Deletion of "but shall not in respect of the supply be required to make an entry in the Scheduled Substances in the prescription book" in clause 43(2),

Justification: To change the prescription book to a record as the first part is sufficient.

108. Deletion of 43 (1) (c).

Justification: The content of 43 (1) (c) is covered in 43 (1) which has the expanded list of practitioners.

109. Redrafting clause 44(3) as follows–

-Any person who commits an offence under this Section is upon conviction, liable to a fine not exceeding ten million shillings, or to imprisonment for a term not exceeding three years, or to both.

Justification: The proposal makes the fine more reasonable and commensurate to the offence.

110. Deletion of clause 45 and substitution therefor with 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

(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 embrace technological advances.

111. Deletion of clause 46 and substitution therefor with the following new clause—

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

(2) The regulations in section 46 (1) shall incorporate procedures to ensure;

(i) licensure of e-pharmacies

(ii) safety of the patient

(1) This shall be permitted as long as the supply of the medicine conforms with all requirements for the particular medicine in terms of its scheduling status and any other requirements as may be specified in Regulations pertaining to this type of supply.

(2) 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 six months.

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

Justification: To make provision for the Authority to develop detailed, futuristic regulations regarding telemedicine, e-pharmacy, authenticity of prescriptions, traceability, online dispensing, and related platforms with consumer safety in mind. Electronic sale of medicines is already a global phenomenon. Many online platforms already sell medicines to consumers. The fine provided for in the bill is too lenient for the type of business and the consequences of contravening the provisions.

112. Redrafting clause 47 (2) as follows—

Each manufacturing licence shall expire 365 days after the date of issue and remains in force until it expires, is revoked or is suspended.

Justification: A license should be valid for 365 days from date of issue unless revoked or suspended earlier as the case may be.

113. Replacing the word "medicinal substance" with "health product" in clause 47(3).

Justification: To harmonize the terms used in the Bill.

114. Insertion of the following new provision–

Qualified persons in manufacturing site.

The Authority shall prescribe regulations setting out conditions for the qualifications of personnel involved in the production processes of a health product in this Act. Personnel qualified for conducting lot release of vaccines and personnel qualified for Batch release of health products shall submit to the authority qualifications for the same.

Justification: To provide for development of regulations.

115. Insertion of the following new penal provision–

Any person who commits an offense under this Section is upon conviction, liable to a fine not exceeding Kshs 100 million Kenya Shillings, or to imprisonment for a term not exceeding 10 years, or to both.

Justification: Having substandard, falsified and falsely labelled health products released to the public has potential for severe adverse public health consequences.

116. Redrafting clause 48 as follows–

(1)A person who is granted a manufacturing license under Section 47 shall comply with the Good Manufacturing Practice, as prescribed by the Authority.

(2) The Authority shall have powers to enter and inspect the 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.

Justification: To encourage continuous improvement of internal quality control systems and production processes of manufacturers in line with good manufacturing practices by WHO.

117. Insertion of the following new clause 48 (2)–

Revocation and suspension of manufacturing licenses

(1) The Authority may, by notice in writing given to the holder of a license, revoke the license, or suspend the license for a period specified in the notice, as prescribed in Regulations, if:
(a) at least one of the following persons: the holder; a person (a manager) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs; if the holder is a body corporate - a major interest holder of the body corporate;
Has been convicted of an offense against this Act;
(i) or been convicted of an offense involving fraud or dishonesty;
(ii)or breached a condition of a manufacturing license;
(iii) or been a manager, or a major interest holder, of a body corporate if the conduct resulting in that subsection applying occurred when the person was a manager or major interest holder of the body corporate in respect of which subsection i), ii) or iii applies it the conduct resulting in the subsection applying occurred when the person was a manager or major interest holder of the body corporate; or

(b) the holder requests in writing that the licence be revoked or suspended, as the case may be; or
(c) the holder ceases to carry on the business of manufacturing the products to which the licence relates; or
(d) the holder contravenes a manufacturing site authorisation in relation to the licence; or
(e) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid after they become payable; or
(f) the products are exempt as prescribed by regulations and the holder has breached a condition of the exemption in relation to those products; or
(g) the licence covers a biological that is exempt by regulations and the holder has breached a condition of the exemption in relation to the biological; or
(h) any other circumstances prescribed by the regulations for the purposes of this section exist.
(2) A reference in subsection (1)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under an applicable national law.
(3) Subsection (1)(a) does not limit subsection (1)(h).
(4) A manufacturing licence granted under this Act shall be;
(a) a licence granted under this Part; or
(b) a licence, granted under a corresponding national law relating to health products relating to manufacturing of such products.
(5) Where the Authority proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Authority shall, unless the Authority considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury by notice in writing given to the holder, inform the holder of the action that the Authority proposes to take and of the reasons for that proposed action
(7) A licence may be revoked notwithstanding that the licence is suspended.
(8) Where a licence is suspended, the Authority may, by notice in writing given to the holder of the licence, revoke the suspension.
(9) Where the Authority revokes or suspends a licence, the Authority shall cause particulars of the decision to be published in the Gazette and updated on the Authority's website as soon as is practicable after the decision is made.
Justification: To provide the conditions for withdrawal of revocation of licence on request from a manufacturer.

118. Insertion of the following new clause on ***withdrawal of revocation of manufacturing licence upon request and transfer of manufacturing license.***

Justification: The Bill should provide for a mechanism for the review of decisions made under the Bill by the Authority.

119. Restriction of clause 49 to cosmetics that contain scheduled substances by redrafting as follows-

"49 Therapeutic cosmetics containing Scheduled substances

(I) A person shall not sell any therapeutic cosmetics containing scheduled substances that-

(a) contains any substance that may cause injury to the health of the user when the therapeutic cosmetic is used-

(i) according to the directions on the label of or accompanying such therapeutic cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual thereof; or consider inclusion of a clause on adulterated cosmetics and misbranded cosmetics as follows

(1) A cosmetic shall be deemed to be adulterated-

(i) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labelling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which complies with the requirements prescribed under subsection (i);For purposes of this subsection, the Authority in consultation with the Cabinet Secretary shall prescribe labelling requirements applicable to coal tar hair dyes.

(ii) For the purposes of this subsection and subsection (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(1)A cosmetic shall be deemed to be misbranded-

(e) If its labelling is false or misleading in any particular.

(f) If in package form unless it bears a label containing –

(i)the name and place of business of the manufacturer, packer, or distributor; and

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, that under clause (ii) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Cabinet Secretary.

(a) If any word, statement, or other information required by or under authority of this Part to appear on the label or labelling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labelling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(b) If its container is so made, formed, or filled as to be misleading.

(c) If it is a colour additive, unless its packaging and labelling are in conformity with such packaging and labelling requirements, applicable to such colour additive, as may be contained in regulations issued under this Act; This subsection shall not apply to packages of colour additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

If its packaging or labelling is in violation of an applicable regulation issued pursuant this section.

Justification: Not all cosmetics contain scheduled substances. The other cosmetics are regulated through KEBS. The issues listed will not apply under good manufacturing practice (GMP).

120. Inserting the following new clause immediately after clause 51—

Information that is required to be displayed in the pack

51A. (1) A person dealing in a therapeutic cosmetic shall indicate:

(a) *the common name of therapeutic cosmetic;*
(b) *the net weight;*
(c) *all the cosmetic ingredients (except flavors and fragrances) must appear on the product label in the order of prominence;*
(d) *the name and address of manufacturer;*
(e) *a warning statement; and*
(f) *a statement that the therapeutic cosmetic is capable to cure or treat any disease or medical condition.*

Justification: For transparency with regards to the ingredients in the prescribed requirements.

121. Deletion and substitution therefor of clause 51 with following new clause–

"51 Manufacturing of cosmetics

(1) The Cabinet Secretary shall for the effective implementation of this section, develop regulations. (2) The regulations made under subsection (1), may—

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

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

Justification: For transparency with regards to the ingredients in the prescribed requirements in line with good manufacturing practice (GMP) and other guidelines.

122. Amendment of clause 52 by deleting the words ***"have a therapeutic effect or value"*** and substituting therefor the words *"to treat, diagnose or prevent disease, or affect the structure or functions of the body".*

Justification: Therapeutic may not necessarily mean treatment. The fact that the term therapeutic cosmetic is used this already means the cosmetic has therapeutic effect.

123. Inclusion of a penalty for the offence by redrafting clause 54(3) to—

Any person who manufactures, supplies, imports or exports a cosmetic that is adulterated or misbranded commits an offense and, upon conviction, shall be liable to a fine of not less than Kshs 500, 000 or to imprisonment for a term of not less than one year, or both.

124. Inclusion of the following clause–

Regulations making exemptions.

"The Cabinet Secretary shall promulgate regulations exempting from any labelling requirement of this Part 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 cover instances where such exceptions will be necessary based on the advice of the technical teams.

125. Insertion of the words "and in-vitro diagnostics medical devices register" immediately after the words "human medical devices register" in clause 55.

Justification: To provide for in-vitro diagnostics.

126. Amendment of clause 55 (1) by removing the words *"human and veterinary' immediately after th words "human medical devices register and veterinary medical devices to remain with medical devices".*

Justification: To harmonize the terms used in the Bill.

127. Inserting the following new subclauses immediately before clause 55(2) –

"A medical device to be placed on the market shall be registered with the Authority. - No person shal manufacture, import or export or distribute any medical device unless he or she is the holder of a registratio certificate -The Authority may exempt certain medical devices from the requirement for registration wher appropriate. - For a medical device to be assessed, the authority shall put in place an appropriate system fo the conformity assessment of medical devices. - Medical devices shall meet the essential principles set out i Schedule1 (Essential Principles of Safety and Performance of Medical Devices), as may be applicable, takin account of the intended purpose of the medical device concerned. - The risk-based classification of medica devices in accordance with the risk classification rules set out in schedule 2, shall be used. -In the event of dispute in the classification of a medical device, the Authority shall decide on the proper classification of th medical device concerned, whose decision shall be final".

128. Inserting the following new subclauses immediately after clause 58(1)—

"The authority will receive from the national nuclear authority, documented evidence of radiation require to enable the medical device to perform its therapeutic and diagnostic functions and the intended purpose o the device, for issuance of registration certificates of the Medical Device".

129. Inserting the following new subclauses immediately after clause 59(1) –

"An importer/ distributor/ dealer will establish and implement documented procedures for the maintenanc of importation and/or distribution records and maintain an importation and/or distribution record of eac medical device to be submitted to the Authority.- Applications for registration of medical device establishments shall be submitted to the Authority in the prescribed format and shall be accompanied by th prescribed fees - An importer/ distributor/ dealer will establish a system of notification of field safet corrective action and shall notify the Authority.

130. Insertion of the following new provisions as follows—

1. *If the Authority is satisfied that the applicant meets the prescribed requirements, the Registrar shall issu a registration certificate for the medical devices establishment in the prescribed format.*
2. *A medical devices establishment registration certificate shall expire on 31ST December each year, unless it is renewed upon application by the Applicant in accordance with the conditions set forth in the application form.*
3. *The registration certificate for manufacturers will be valid for five years following a successfu reinspection.*
4. *Refusal to issue a medical devices establishment registration certificate. The Authority may refuse to issue a medical devices establishment registration certificate if:*

a. *the applicant has made false or misleading statement(s) in the application; or*

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. *the applicant has failed to meet the conditions for medical devices establishment registration as specified in section (a) above.*

5. *In any case where the Authority does not recommend the issuing of a medical devices establishment registration certificate, the Authority shall:*
a. *notify the applicant in writing of the reasons for not recommending/refusing the registration of the establishment; and*
b. *give the applicant an opportunity to respond to the Authority and provide relevant documentation/evidence in support of the application.*

6. *Notification of change for Medical Devices Establishment.*
After the issuance of a medical devices' establishment registration certificate, if 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 10 working days of the change.

Justification: It is a requirement to submit post- market alerting system requirements to the authority. An importer, distributor or dealer will establish a system of notification of field safety corrective action and shall notify the Authority.

131. Inserting the following new Part immediately after Part IX—

"Part IXA- The National Pharmacovigilance System".
(1) The Authority shall through the National Pharmacovigilance Centre manage the national pharmacovigilance and post marketing surveillance system to 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"
(2) The Authority shall conduct both passive and active surveillance of health products and technologies.
(3) The Authority shall carry out pharmacovigilance audits and inspections in order to ensure compliance with Good Pharmacovigilance Practices and the prescribed requirements."
(4) 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. The entities in subsection (4) shall submit safety information to the Authority as prescribed'
(5) The consumers, general public, health care professionals shall report adverse reactions and events to the Authority as prescribed"

Justification: The Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules,2022 describe these roles but it is important to anchor the regulatory role of pharmacovigilance in the Bill that would then serve as guidance on development or review of existing regulations.

132. Deletion of clause 60 and substitution therefor with the following new clause—

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

a) *the examination and testing health products and technologies including vaccines and biopharmaceutical 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 such as Near Infrared Spectroscopy, Raman Spectroscopy and High-performance thin-layer chromatography 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 bn 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 regulated products; and*

g) *conduct research and training and provide high quality analytics and expert knowledge in the area of health products and active pharmaceutical ingredients.*

h) *to develop and administer a data bank on quality assurance on behalf of the Authority; collaborate with other laboratories to ensure quality in health products;*

Justification: HPTs play an essential role in ensuring the health of the Kenyan population and the attainment of UHC. At the same time, medicines are potential poisons that need to be safeguarded by qualified professional custodians in their whole life cycle from development to formulation, quality assurance, distribution, administration to the patient and ultimately, their disposal. NQCL plays a pivotal role in assuring the safety and quality and HPTs in circulation in the Country.

For the NQCL to effectively deliver on its mandate, its establishment ought to be anchored in the law with clear articles defining its governance, structure and administration. These are lacking in the KDA bill, which in effect immobilizes its existence and effective discharge of its mandate.

133. That Clause 61 (1) of the Bill be amended by deleting the words *"Director-General" appearing immediately before the words "signed by the" and insert the words Director National Quality Control Laboratory".*

Justification: A Certificate of Analysis is a document that communicates the results of a scientific test done on a product/HPT. In compliance with WHO good practices for pharmaceutical quality control laboratories, this certificate should be issued by a person who will ensure the test sample's authenticity and that it fulfils the prescribed standards set. Therefore, this role should be in the purview of Director of the Laboratory.

134. That Clause 61 is amended by inserting a new Clause 61A as follows-

61A. (1) The Authority shall appoint a Director of Laboratory Services who shall be the chief executive of the laboratory responsible to the authority for day-to-day management of the laboratory. (2) The Director Laboratory Services shall hold office on such terms and conditions of services as may be specified in the instrument of his appointment."

135. Amendment of Clause 62 by inserting the following clause—

62 (1) (a) *"A person who without permission from the Authority, manufactures, imports, distributes, supplies or dispenses promotional samples of Health Products and Technologies in a standard package other than the smallest presentation available for sale commits an offence.*

62 (1) (b) This subsection does not apply to distribution of free promotional samples of HPTs by authorized pharmaceutical representatives in a standard well-labelled package permanently marked ***"not for sale"*** *to qualified and licensed healthcare professionals.*

62 (2) (a) The Authority shall cause to be kept a register of all applications for the advertisement of any health product and technology including restricted representations; and
(b) develop uniform standards for the advertising of health products and technology;
(c) For purposes of this act, the advertisement of any health product and technology shall- (i) Have an advertisement code granted by the Authority; (ii) not make reference to an authorized practitioner or association. (iii) take into account public good and interest. (d) The Cabinet Secretary shall, make Regulations on the types of advertisements which requires an approval and the manner in which application.
(e) A person who contravenes the provisions of clause 62 commits an offense and is liable to fine not exceeding five million Kenya shillings of three (3) years of imprisonment or both.

Justification: To make provision for the handling of promotional samples of HPTs.

136. Deletion of clause63 (2) and substitution with the following;

(2) Health products and technologies may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.
(i) Notwithstanding subsection (1), the Authority in consultation with the Cabinet Secretary may ban advertising to the general public of health products and technologies.
(ii) The prohibition contained in subsection (1) shall not apply to vaccination campaigns carried out and approved by the Authority.

(iii) The direct distribution of health products and technologies to the public by the industry for promotional purposes, is prohibited.

Justification: For consistency in the document and clarity in implementation promotion of appropriate use of the medicines, to mitigate against antimicrobial resistance and to align to current best practices.
The proposed clause provides a framework for exclusion of certain persons and professionals from prohibition of advertisement.

137. Deletion of 63 (3).

Justification: This provision is misplaced as it is already covered under Part V- Scheduled Substances.

138. Deletion of clause 65 and substitution with the following:

65(a) "A person shall not take part in the publication of advertisement referring to a health product or technology or similar article in terms which in the assessment of the Authority is considered to be false or misleading and to bear little or no relation to the pharmacological properties and action of the ingredients or the component or correct use of the health product and technology"

Justification: To give more clarity on the prohibition so that the Authority's decision is not merely based on opinion by assessment.

139. Deletion of clause 66 and substitution with the following:

(1) A person commits an offence if:
- *(a) the person:*
  - *(i) publishes or broadcasts; or*
  - *(ii) causes to be published or broadcasted; in specified media, an advertisement that is required by the Regulations to be an approved advertisement; and*
- *(b) the advertisement is not an approved advertisement.*

(2) A person commits an offence if:
- *(a) the person:*
  - *(i) publishes or broadcasts; or*
  - *(ii) causes to be published or broadcast; an advertisement in specified media; and*
- *(b) the advertisement is not an approved advertisement in that it differs, in any respect, from the advertisement that was approved.*

(3) It is a defence to a prosecution under subsection (2) if:
- *(a) the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business; or*

(2) A person commits an offence if:
- *(a) the person:*
  - *(i) publishes or broadcasts; or*
  - *(ii) causes to be published or broadcast; a particular advertisement in specified media referred to in subsection (a), (c) or (d) of the definition of specified media; and*
- *(b) the advertisement:*
  - *(i) does not display its approval number; or*
  - *(ii) displays a number purporting to be its approval number but that is not its approval number; or*
  - *(iii) displays an approval number that has expired.*

(5) It is a defence to a prosecution under subsection (4) if the person prosecuted:
- *(a) is a publisher who received the advertisement to which the prosecution relates for publication in specified media referred to in subsection (a), (c) or (d) of the definition of specified media; or*
- *(b) is a broadcaster who received the advertisement to which the prosecution relates for broadcasting in visual broadcast media; in the ordinary course of business.*

(6) A person commits an offence if:
- *(a) the person:*
  - *(i) publishes or broadcasts; or*

(ii) causes to be published or broadcast; in specified media, an approved advertisement; and

(b) the person's action is in contravention of a condition to which the approval of the advertisement is subject.

(7) It is a defence to a prosecution under subsection (6) if the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business.

(8) A person who contravenes any of the provisions of sections who commits an offence under subsection shall, subject to this Act, be liable—

(a) in the case of a first conviction, to a fine not more than five hundred thousand Kenya shillings or to imprisonment for a term not exceeding one year, or both;

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

(c) An offence against this section is an offence of strict liability.

Justification: To give more clarity on the issues of offences relating to advertising. There is no subsection 2.

140. Replacing the words ***"article or substance"*** with "Health Product and Technology" in clause 67.

Justification: For consistency of the use of the term "Health product technology "instead of article in the entire Bill.

141. Insertion of the following new clause –

(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or an unapproved drug exported under regulations promulgated for such under this Act) being exported is being exported to a country that has different or additional labelling requirements or conditions for use and such country requires the drug to be labelled in accordance with those requirements or uses, such drug may be labelled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labelled in accordance with the requirements of this Act.(2) If, pursuant to subsection (1), the labelling of an exported drug includes conditions for use that have not been approved under this Act, the labelling must state that such conditions for use have not been approved under this Act. (3) An unapproved drug exported under regulations promulgated for such under this Act is exempt from this section".

Justification: This is to ensure compliance with labelling requirements as approved during marketing authorization by making the fine deterrent.

142. Insertion of the following new clause–

(1) The following information shall appear on the outer packaging and on the immediate packaging of unauthorised investigational medicinal products and unauthorised auxiliary medicinal products:

(a) Information to identify contact persons or persons involved in the clinical trial;

(b) Information to identify the clinical trial;

(c) Information to identify the medicinal product;

(d) Information related to the use of the medicinal product.

(2) The information under subsection (1) shall –
(a) ensure subject safety and reliability and robustness of the data generated in the clinical trial, while taking account of the design of the clinical trial, whether the products are investigational or auxiliary medicinal product, and whether they are products with particular characteristics; and
(b) be clearly legible; and

(3) The Cabinet Secretary shall promulgate regulations to give further effect to subsection (1) and (2); and to provide labelling requirements applicable to –
(a) authorised investigational medicinal products and authorised auxiliary medicinal products
(b) radiopharmaceuticals used as diagnostic investigational medicinal products or as diagnostic auxiliary medicinal products.
(4) The Cabinet Secretary may amend the regulations under subsection (3) in order to ensure subject safety and the reliability and robustness of data generated in a clinical trial or to take account of technical progress
(5) The language of the information on the label shall be English. The medicinal product may be labelled in several languages.

Justification: The labelling requirements for all Health products Technology (HPTs) is not specified in this clause.

143. Amendment of clause 3 (a) by deleting the words ***"two hundred thousand"*** *and substituting thereof the with the words "one million".*

144. Amendment of clause 3 (b) by deleting the words ***"three hundred thousand"*** *and substituting thereof the with the words* ***"two million".***

145. Deletion of clause 68.

Justification: Clause 68 is not relevant as any valid exemptions may be considered.

146. Amendment of clause (1) by deleting the words *"homoeopathic medicine, preparation or medical device" and substitute with the words "health products and technologies".*

Justification: To expands the scope.

147. Amendment by including the words ***"including a health product and technology for emergency use"*** *immediately after the word* ***"technology"*** *in clause 72(1)*

Justification: Includes HPTs for emergency use.

148. Amendment by deleting the entire clause 73(1) and replacing with the following new paragraph— *"(1) A health product and technology or document seized under the provisions of this Act may be retained for a period not exceeding one month or' if within that period proceedings are commenced for an offence under this Act in respect of health product and technology or document, until the final determination of those proceedings".*

Justification: Consistency in use of the term "health product and technology".

149. Amendment by deleting the entire clause 73(2) and replacing with the following new paragraph – *"(2) Where a magistrate is satisfied that any health product and technology is of a perishable nature or that by reason of the fact that the market for the health product and technology is seasonal, or for any other reason, delay in disposing the health product and technology would unduly prejudice the owner, the magistrate may authorize the sale or other disposal of the health product and technology".*

Justification: Consistency in use of the term "health product and technology".

150. Amendment by deleting the entire clause 73(3) and replacing with the following new paragraph – *"(3) where proceedings are taken for an offence under this Act or any rules there under the court by or before which the alleged offender is tried may make such order as to the forfeiture or other disposal of any health product and technology in respect of which such offence was committed as the court shall see fit".*

Justification: Consistency in use of the term "health product and technology".

151. Amend by deleting the entire clause 73(4) and replacing with the following new *paragraph – "In this section references to a health product and technology shall be construed as including the proceeds of a sale effected in accordance with the provisions of subsection (2)"*

Justification: Consistency in use of the term "health product and technology".

152. Insertion of the following new clauses immediately after clause (74)—

153. ***74 (a) Inspection and verification of Health Products and Technologies at the Ports of Entry***

(1) A person who imports health products, medical devices or technology shall notify the KDA inspectors at the Ports of Entry to conduct pre-clearance inspection and verification.
(2) Any person who imports health products, medical devices or technology and causes it to be released to the market without the authorization shall be guilty of an offence.
(3) Fines of concealment, cross border smuggling, misdeclaration and diversion of HPTs to be Kshs. 1 million.

Justification: To give power to the Authority's inspectors to enforce compliance with set or prescribed standards of quality, safety and efficacy of HPTs before release at the ports of entry. To deal with the problem of concealment, misdeclaration, diversion and cross border smuggling of HPTs and other illicit trade practices which endangers public safety.

154. Deletion of clause 79.

Justification: The function is outside the regulatory purview of the Authority.

155. Amendment of Clause 80 (1) (a) by deleting the word ***"article"*** and replaced it with ***"Health products and technologies".***

Justification: For consistent use of HPT instead of article throughout the whole document.

156. Amendment of Clause 801(b) by including immediately after the word ***"vehicle"*** the words *"or any other vessel used as a means of transport"*

Justification: To include all other transport means including bicycles motorcycles etc.

157. Amendment by deleting the entire clause.

Justification: Interferes with independence of the regulatory authority.

158. Amendment by deleting the entire clause.

Justification: Regulation is a function of National Government

159. Amendment by deleting the entire clause 83.

Justification: Interferes with independence of the regulatory authority as recommended by the WHO.

160. Amendment of clause 85(1) and (2) by deleting the word ***"article"*** and replaced it with "***Health products and technologies".***

Justification: To harmonize terminologies in the Bill.

161. Amendment of clause 86(1)(b) by deleting the words "***seven hundred thousand***" and replacing with the words ***"one million".***

Justification: To enhance the fines.

162. Replacing "***a National Quality Control Laboratory***" with *"a Nationally Accredited Quality Control Laboratory" in clause 87(a).* This should be included in the definitions- A Laboratory accredited by KENAS or any other international accrediting body like WHO.

Justification: This is to accommodate other nationally accredited laboratories like KEBS, MEDS, NQCL, Public Health Labs, KEMRI.

163. Amendment of clause 87(c) by deleting the word "article" and replacing with "health products and technologies".

Justification: Harmonization of technologies.

164. Deletion of 'Funds' and substitution with 'Fund' in clause 88(a).

Justification: Nomenclature is 'Consolidated Fund' as outlined in the Public Finance Management Act, No. 18 of 2012

165. Deletion of clause 90(3) and substitution with the following new sub clause–

'The annual estimates shall be approved by the Board of the Authority before the commencement of the financial year to which they relate, and shall be submitted to the Cabinet Secretary for approval. The Authority may at any time before the end of each financial year, prepare and submit to the Board for approval any estimates supplementary to the estimates for that financial year and submit the amendments to the Cabinet Secretary for consent'.

Justification: The introduction of supplementary estimates within the organization will allow for effective execution of the Authority's mandate to adequately execute its regulatory function as need arises.

166. Deletion of clause 91(3) and (4) and substitution with the following new sub clause (3)—

"The Authority shall keep accounts and records of its transactions and affairs and shall ensure that all moneys received are properly brought to account, all payments out of its funds are correctly made and properly authorized and that adequate control is maintained over its property and liabilities the Authority may incur under this Act "

(4) The Director General shall, within three months after the end of each financial year submit to the Kenya National Audit Office, following Board approval, the accounts of the Authority in respect to that year together with

(a) a statement of the income and expenditure of the Authority during the financial year; and
(b) a statement of the assets and liabilities of the Authority on the last day of that financial year.

Justification: Clause 91 (3) introduces the clause on accounting and provides direction on how the Authority will run its affairs in accordance with existing laws and regulations.
Introduction of 'following Board approval' prescribes the process upon which the Authority will present its reports for Audit.

167. Deletion of clause 93(2) and substitution with the following new sub clause—*"The Director General shall, within three months after the end of each financial year, submit to the Board and the Cabinet Secretary the annual report in respect of that year".*

Justification: Introduction of the 'Director General' prescribes the onus on the Authority's accounting officer to prepare the annual report.

168. Insertion of the following new paragraphs after paragraph (ii) in clause 95 (2) —

(iia) to regulate illicit use of narcotic and psychotropic substances;

(iib) to regulate parallel importation of medicines.

Justification: To give the Authority power to make rules pertaining to illicit use of narcotic and psychotropic substances and parallel importation of medicines.

169. Insertion of the following new paragraphs after paragraph (b) in clause 95 (2)—

"(ba) on Pharmacovigilance and Post market surveillance.

"(bb" Official Regulatory Lot Release of vaccines and other biological products imported and manufactured in Kenya.

"bc") Good Practices (GXP) in the regulation of medical products.

"bd" Inspections, licensure and certification of the manufacture of medical products by health facilities

"be" Inpections, licensure and certification of manufacture of medical products and other regulated product by facilities not directly regulated by the Kenya drug Authority including steel industries, sugar industries

"bf" Inspection and recognition of Pharmaceutical Quality Control Laboratories.

Justification: Inclusion of a clause on making regulations on pharmacovigilance and post market surveillance which are critical to the attainment of WHO maturity level 2There is an existing subsidiary legislation, the Pharmacy and Poisons Board (Pharmacovigilance and Post Market Surveillance) Rules, 2022. although the Pharmacy and Poisons Act, Cap 244 is silent on safety monitoring and pharmacovigilance.

170. Deletion of "former Board" and substitution with "former Boards" in clause 96(1).

Justification: To avoid ambiguity and contradiction of clause 96 (3)(a).

171. Deletion of Board of National Quality Control Laboratory established under CAP 244 in clause 96(2).

Justification: This provision is pegged on determination of contentious issues in clause 61 on the governance structure of the NQCL.

172. Amendment of clause 96(3) by deleting the words 12 months and substituting therefor the word 24 months.

Justification: To give adequate time for stakeholder involvement on pharmacy practice regulation.

173. Amendment of clause 97(1) by adding the following words at the end of the subsection "with reference to 96 (3)".

Justification: To ensure that Cap. 244 remains in force for regulation of practice and there is no gap upon repeal of Cap. 244 with regard to regulation of HPTs as prescribed in the Seventh Schedule.
Consider addressing the specific consequential amendments to the Public Health Act if any.

174. Reference of the Bill to the Board under the Public Health Act is erroneous because repealing this Board introduces implementation challenges to the Public Health Act.The Board referred to here is under the Food Chemicals and substances Act.

Justification: To cure the ambiguity and bring clarity on the two legislations especially interpretation challenges.

175. Deletion of paragraph (1) of the Fourth Schedule.

Justification: Food is outside the purview of the Bill.

176. Deletion of paragraph (2) of the Fourth Schedule.

Justification. There is an established Scientific Advisory Committee, PERAC that conducts causality assessment, risk management and scientific, expert advice on pharmacovigilance related issues for HPTs. The Committee issues recommendations to the CEO, PPB based on scientific evidences. Besides human medicines, the Committee handles incidences following use of medical

devices and transfusion reactions issues. Its scope is wider than that of human medicines only. This ensures the independence of the Authority to take regulatory actions, that may arise from such recommendations.

177. Deletion of the whole repeal of cap. 254.

Justification: The provisions of Cap 254 are majorly on food that is outside the object and scope of the Bill. Cap 254 is the mother Act for food in Kenya, other legislations and standards regulating food and implemented by other regulatory agencies are referenced to the Act. Repealing it will create a huge gap in food control in the Country. The Act is currently under review to align with the constitution and to be in tandem with the changing trends in food safety.

178. Deletion of clause 79 in the Memorandum of objects and reasons.

179. In general, the Ministry noted that there is need for the Bill to comprehensively provide for local manufacturing as the government is keen on expanding local manufacturing including HPTs to ensure commodity security and to promote sustainability, accessibility and affordability. The Bill should therefore provide as follows -

The Authority will develop standards for the manufacture of health products from time to time.
The cabinet secretary in collaboration with the Authority shall prescribe the minimum standards to be applied in a manufacturing site that handles health products.

(2) Obligations for manufacturing including: -
(a) the standards to be maintained, and the equipment to be used, at premises used for the manufacturing of health products;
(b) procedures for quality assurance and quality control to be employed in the manufacturing of health products;
(c) the qualifications and experience required of persons employed in the manufacture of health products;
(d) the manufacturing practices to be employed in the manufacturing of health products; or
(e) other matters relevant to the quality, safety and efficacy of health products
(f) may include codes of good manufacturing practice.

Justification:
To align with the Trade-related Aspects of Intellectual Property Rights (TRIPS) flexibility and the African Union strategy of local manufacturing agenda. The Kenya Pharmaceutical Sector Development Strategy, 2012) provided a framework for implementing local pharmaceutical production that envisaged ambitious solutions to the core challenges to the pharmaceutical sector in Kenya.

3.2.3 THE PHARMACY AND POISONS BOARD (PPB)

In its memoranda, the PPB proposed the following amendments:

180. Deletion of the definition of the term "therapeutic cosmetic" and substituting therefor the following definition "Therapeutic cosmetic" means a cosmetic which offers an additional benefit to a person over an ordinary cosmetic; contains a bioactive product formulated from an animal

ingredient that may have visible and measurable short- or long-term effects on a person; may include a product that may be absorbed through the skin or a mucous membrane.

Justification: The 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.

181. Amendment of the definition of the term "health products and technologies", "article" and "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic".

Justification: Food/dietary supplement is missing. It should be listed among the HPTs.

182. Deletion of the definition of the term "medicinal substance" and substituting therefor the following definition—"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;

183. Deletion of the definition of the term "medical device" and substituting therefor the following definition "medical device" 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 purposes. They indicated that, 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.

184. Insertion of the following new definitions including "in-vitro diagnostics medical device", Inspector of Drugs, active surveillance, Clinical Trial, adverse event, adverse drug reaction, Centre, passive surveillance, pharmacovigilance, Premises, vessel, substandard, unregistered medical products, falsified medical products, and lot/sub-lot.

Justification: As per WHO definitions. It is best practice to adopt internationally recognized definitions.

185. Amendment of the definition of the term "herbal medicine or product" to include "herbs, herbal materials, herbal preparations, finished herbal products that contain active ingredients, parts of plants or other plant materials or combinations".

Justification: To expand the scope to include herbal materials and herbal combinations.

186. Amendment of clause 12 by inserting the following new paragraphs immediately after paragraph (e)—

"(ea) disposal of health products and technologies"; "(eb) monitor the market for the presence of unregisterea and illegal health products and technologies"; "(ec) conducting analytical tests of health products and technologies".

Justification: These are critical functions of the Authority.

187. Amendment of clause 12 of the Bill by deleting paragraph (f) and substituting the following new paragraph (f) *"ensure continuous monitoring of the safety of health products and technologies regulatea*

under this Act by 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: In country safety monitoring of health products and technologies takes precedence. However, safety information from other National Regulatory Authorities may be considered through regulation and reliance mechanisms for decision making.

188. Amendment of clause 12 by deleting paragraph (g) and substituting the following paragraph (g)—

"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. The best global best practice for clinical trial oversight requires entrenchment of clinical trials in law and applicable regulations. The WHO benchmarking tool further specifies the minimum legal requirements".

Justification: These minimums are not captured in the KDA bill as currently proposed. The details below as per the last CAP 244 amendments provide the minimum requirements for clinical trials oversight.

189. Amendment of clause 12 of the Bill by inserting a new paragraph immediately after clause (g) *"(ga) approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use".*

Justification: This is to cater for emergency situations in public health.

190. Amendment of clause 12 of the Bill by inserting a new paragraph immediately after clause (ga), *"(gb) carry out pharmacovigilance audits and inspections in order to ensure compliance with Good Pharmacovigilance Practices and the prescribed requirements".*

Justification: The Bill does not provide for conduct of Good Pharmacovigilance Practice Inspections, which are key towards ensuring that marketing authorization holders, local technical representatives, parallel importers, distributors and outsourced persons or companies meet the prescribed requirements towards ensuring safety of the health products and technologies they have received marketing authorization for.

191. Amendment of clause 12 by deleting paragraph (n) and substituting therefor the following paragraph (n)—

"appoint inspectors and order inspection of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, retail outlets and any other premises subject to this Act".

Justification: To clarify premises subject to the inspections.

192. Amendment of clause 12 by inserting a new paragraph after clause (o), *"(oa) Conduct National Regulatory Authority lot release (official authority batch release) of specified biological 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".*

Justification: The regulatory function involves lot release which is a key component in vaccine production.

193. Amendment of Clause 12 by inserting the following new paragraphs after clause (q)—

"(qa) Ensure that all health products and technologies manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy

(qb) Enforce the prescribed standards of quality, safety and efficacy of all 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 either the single convention on Narcotic drugs of 1961, the convention on Psychotropic substances 1971 and the UN 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: Control over health product and technology import and export is a critical regulatory function.

194. Amendment of clause 13 by deleting paragraph 13 (a) and substituting therefor the following paragraphs *(a) Collaborate with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate and in furtherance of the purpose for which the Authority is established, (aa) Adopt and implement any such internationally recognized good regulatory practices (ab) Determine and implement effective and efficient reliance mechanism. (ac) Issue, suspend, withdraw/revoke any license, compliance certificate (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) Formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products".*

Justification: This is to comply with the WHO requirements for regulatory functions in the Global Benchmarking Tool Control over imports and exports is critical for any regulatory authority.

195. Amendment of clause 21 (1),21 (3) and 21 (4)by deleting the words ***'Cabinet Secretary'*** and substituting therefor the words, ***'the Board of the Authority'***,

196. Amendment of clause 21 (9) by deleting the words ***'Cabinet Secretary'*** and substituting therefor the words ***'the Board of the Authority'*** and by deleting the word ***'Parliament'*** and substituting therefor the words ***'Cabinet Secretary'***.

Justification: These are technical committees of the Authority tasked with guiding the Board in effectively carrying out its mandate.

197. Deletion of clause 22 (d) and substitution with (d) ***"falsified"***.

Justification: The terminology is globally used and recommended by WHO.

198. Amendment of clause 22 by inserting new clause immediately after clause 22 (1) *"22 (1) **"a"** (1) A person shall not import any medicines or medical devices unless: The imported medicine(s) or medical device(s) has been authorized through issuance of an import permit or any written authorizations by the*

authority. The imported health products and technologies be inspected and verified by the authority's inspectors at the ports of entry before release".

Justification: To adopt the offences and charges in subclause (1) and to cater for importation of HPTs.

199. Insertion of a new clause immediately after clause 24-

Clinical trials

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

(2) Any person who intends to commence a clinical trial on a pharmaceutical product 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 a 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 section 24 (1) shall put up a robust quality assurance system to ensure that the clinical trial is carried out so as to ensure the integrity of data generated, the safety and well-being of study participants.

(6) The Authority shall carry out inspections of the clinical trials so as to ensure compliance of the clinical trials with the prescribed requirements.

(7) Any protocol amendments applications shall be submitted to the Authority for approval before implementation.

Justification: This is for effective regulation by the Authority on the clinical trial function.

200. Insertion of the following new clause immediately after clause 26—

Factors relevant to the determination of application for product license

(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 Form 1 set out in the First Schedule.

(2) An applicant 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 has permanent residence or a company incorporated in Kenya.

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

(a) a proposed label for use on the health product;
(b) a copy of the manufacturing licence of the health product, 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 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;
(h) proof of ownership of the site for the manufacture of the health product, if 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 in accordance with section 9A of the Act;
(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;
(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;
(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or
(v) a valid manufacturing licence issued in accordance with section 35A of the Act; and
(l) proof of payment of the application fees set out in the Second Schedule.
(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.

(1) The Authority shall consider the application made under rule 4, 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 Form 2 set out in the First Schedule.

(2) The Authority may, while considering the application made under rule 4, 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;

(c) the statement of the representations to be made for the promotion of the health product regarding (i) the claim to be made for the health product; (ii) the route of administering the health

product; (iii) the dosage of the health product; (iv) the storage conditions of the health product; (v) the contra-indications, the side effects and precautions, if any of the health product; and (vi) the package size of the health product.

(3) When evaluating an application made under rule 4, the Authority may:

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

(b) consider the evaluation report of an institution that has evaluated the health product.

(4) The Authority shall issue a certificate of registration under sub rule (1) if the applicant has (a) a valid practicing license issued in accordance with section 9A of the Act; (b) a valid wholesale dealer's license issued in accordance with section 27 of the Act; (c) a valid license to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act; (d) a valid license to sell Part II poisons issued in accordance with section 32 of the Act; or (e) a valid manufacturing license issued I accordance with section 35A of the Act. (5) If the Authority is not satisfied as to the quality, safety efficacy and performance, or economic value of the health product, it may, after providing an opportunity to the applicant to be heard, reject the application made under rule 4 and inform the applicant the reasons for rejection in writing.

Register of health products and technologies.

The Registrar shall maintain a register of health products and technologies registered in under their Rules in Form 3 set out in the First Schedule.

201. Insertion of the following new clause immediately after clause 46—

Dietary supplement

46A. (1) A dietary supplement shall not (a) contain controlled drugs; (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 prescribed guidelines by the Kenya Drugs Board.

Justification: Details on contents of dietary supplements help the Authority effectively regulate food supplements.

202. Insertion of the following new clause immediately after clause 51—

Information that is required to be displayed in the pack 51A. (1) A person dealing in a therapeutic cosmetic shall indicate—

(iv) the common name of therapeutic cosmetic;
(v) the net weight;
(vi) all the cosmetic ingredients (except flavors and fragrances) must appear on the product label in the order of prominence;
(vii) the name and address of manufacturer;

(viii) a warning statement; and
(ix) a statement that the therapeutic cosmetic is capable to cure or treat any disease or medical condition.

Justification: For transparency with regards to the ingredients in the prescribed requirements.

203. Amendment of clause 52 by deleting the words "have a therapeutic effect or value" and substituting therefor the words "to treat, diagnose or prevent disease, or affect the structure or functions of the body".

Justification: Therapeutic may not necessarily mean treatment. The fact that the term therapeutic cosmetic is used this already means the cosmetic has therapeutic effect.

204. Insertion of the words "and in-vitro diagnostics medical devices register" immediately after the words "human medical devices register" in clause 55.

Justification: To cater for in-vitro diagnostics.

205. Insertion of new terms: *Falsified, falsely-labeled, counterfeited* after clause 56(1)(c).

206. Insertion of the following new subclauses immediately after clause 56(2) –

(3) "A person who manufactures, sells, supplies, packages a medical device shall provide for the service and maintenance of the medical devices at the time of installation and on operationalization of the use of the medical device".

(4) "A person who manufactures, sells, supplies, packages a medical device shall remove from the hospital, health center or any other entity where they have supplied the medical device after the life cycle of the medical device is realized".

(5) "A person who manufactures, sells, supplies, packages a medical device shall ensure requisite quality audits of the manufacturer to meet the required quality management systems is conducted before a medical device is registered for sale in Kenya".

Justification: Enables the Authority effectively regulate medical devices.

207. Insertion of the words *"unregistered establishments for medical devices" immediately after the word "under"* appearing in clause 59 (1).

Justification: There is need to register establishments for Medical Devices.

208. Insertion of the following new clauses immediately after clause (74)

"74 (A) Inspection and verification of Health Products and Technologies at the Ports of Entry

(1) A person who imports health products, medical devices or technology shall notify the KDA inspectors at the Ports of Entry to conduct pre-clearance inspection and verification.
(2) Any person who imports health products, medical devices or technology and causes it to be released to the market without the authorization shall be guilty of an offence.
(3) Fines of concealment, cross border smuggling, misdeclaration and diversion of HPTs to be Kshs. 1 million."

Justification: To give power to the Authority's inspectors to enforce compliance with set or prescribed standards of quality, safety and efficacy of HPTs before release at the ports of entry. To deal with the problem of concealment, misdeclaration, diversion and cross border smuggling of HPTs and other illicit trade practices which endangers public safety.

209. Under clause 91, insertion of the following new subclauses immediately after subclause (1)

"(1A) The Authority shall establish an audit committee which shall be a minimum of three members excluding a person who shall be appointed to represent the National Treasury and a maximum of five. (2) The Accounting Officer shall ensure that the organizational structure of the internal audit unit facilitates—

(a) the entity to accomplish its internal audit responsibilities;
(b) the internal auditor with sufficient authority to promote independence and to ensure broad audit coverage, adequate consideration of internal audit reports;
(c) appropriate action to be taken on internal audit recommendations; and
(d) the internal auditor to be independent of the programs, operations and activities he or she audits to ensure the impartiality and credibility of the internal audit work undertaken.

Justification: Alignment with the requirements of the Public Finance Management Regulations, 2015 (regulation 162 and 174) and *Mwongozo* Code of Governance for State Corporations.

210. Deletion of the words "***Kenya National Audit Office***" and substituting therefor the words ***"Auditor-General"*** in clause 91(3).

Justification: This is a requirement under the Public Finance Management (National Government) Regulations, 2015.

211. Deletion of paragraph (1) of the Fourth Schedule.

Justification: Food is outside the purview of the Bill.

212. Deletion of paragraph (2) of the Fourth Schedule.

Justification: There is an established Scientific Advisory Committee, PERAC that conducts causality assessment, risk management and scientific, expert advice on pharmacovigilance related issues for HPTs. The Committee issues recommendations to the CEO, PPB based on scientific evidences. Besides human medicines, the Committee handles incidences following use of medical devices and transfusion reactions issues. Its scope is wider than that of human medicines only. This ensures the independence of the Authority to take regulatory actions, that may arise from such recommendations.

3.2.4 THE NATIONAL QUALITY CONTROL LABORATORY (NQCL)

In its memorandum, the NQCL proposed as follows:

213. Deletion of and substituting clause 60 with the following new clause

"60. (1) There is to be 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 such as Near Infrared Spectroscopy, Raman Spectroscopy and High-performance thin-layer chromatography 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; and

(g) Conduct research and training and provide high quality analytics and expert knowledge in the areas of medicinal products and active pharmaceutical ingredients.

(2) The National Quality Control Laboratory shall be the official government agency for quality control of drugs, health products and technologies.

Justification: NQCL plays a critical role in assuring the safety and quality of HPTs in the country. To effectively discharge its mandate, the NQCL's governance and structures should be set out in the Bill.

214. Deletion of the words ***"Director-General"*** appearing immediately before the words "signed by the" and inserting the words "Director Laboratory Services".

Justification: A certificate of analysis is a document that communicates the results of a scientific test done on an HPT. In compliance with WHO best practice, the certificate should be issued by a person that will ensure the authenticity of the test samples.

215. Insertion of the following new clauses—

"61A Director Laboratory Services

(1) "The Director of Laboratory Services shall be a registered pharmacist and shall possess a Master's degree in science from a recognized university".

(2) "The Director of Laboratory Services who shall be Chief Executive of the Laboratory responsible to the authority for day-to-day management of the laboratory".

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

216. Insertion of the following new clauses—

61B Powers of the Director Laboratory Services

"The Director Laboratory Services shall have power: (a) to develop and administer a data bank on quality assurance on behalf of the Authority; (a) to advise and obtain advice from the Authority in regard to any other matter within his purview under this Act.

61C Functions of the Director

The Director Laboratory Services 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 drugs and health products;

(e) perform any other duties assigned by the Authority from time to time;

(f) handle appeals on test results shall be the expert witness in court on HPT quality matters

(g) where the laboratory lacks capacity, the director shall subcontract laboratory testing services.

Justification: Health products need to be safeguarded by a reliable system and by qualified professional custodians from development to formulation, quality assurance, distribution, administration to the patient up to disposal. The NQCL should be provide with the necessary resources for its maintenance and sustainability.

217. Insertion of the following new paragraphs after paragraph (ii) in clause 95 (2)

"(iia) to regulate illicit use of narcotic and psychotropic substances;

(iib) to regulate parallel importation of medicines".

Justification: Gives the Authority power to make rules pertaining to illicit use of narcotic and psychotropic substances and parallel importation of medicines.

218. Insertion of the following new paragraphs after paragraph (b) in clause 95 (2) — *"(ba) on Pharmacovigilance and Post market surveillance.*

"(bb)" Official Regulatory Lot Release of vaccines and other biological products imported and manufactured in Kenya.

("bc") Good Practices (GXP) in the regulation of medical products.

("bd") Inspections, licensure and certification of the manufacture of medical products by health facilities

("be") Inspections, licensure and certification of manufacture of medical products and other regulated products by facilities not directly regulated by the Kenya drug Authority including steel industries, sugar industries

("bf") Inspection and recognition of Pharmaceutical Quality Control Laboratories"

Justification: Inclusion of a clause on making regulations on pharmacovigilance and post market surveillance. There is an existing subsidiary legislation, the Pharmacy and Poisons Board (Pharmacovigilance and Post Market Surveillance) Rules, 2022. These are critical to the attainment of WHO maturity level 2 by the vigilance function. The Pharmacy and Poisons Act, Cap 244 was silent on safety monitoring or pharmacovigilance. The regulations are within statutory instruments for the better carrying of regulatory functions by the Authority.

219. In general, the Bill in its present form is vague on the identity of professionals to handle and regulate HPTs which should ideally be handled by qualified pharmaceutical professionals. The NQCL should be properly anchored in law with clear provisions on its governance structure and administration so as to effectively discharge its mandate.

3.2.5 THE NATIONAL GENDER AND EQUALITY COMMISSION (NGEC)

In its memorandum, the NGEC proposed as follows:

220. The deletion of the words "*Public Service Commission through a transparent and competitive process, with the approval of Parliament*" and substitution with the words "*the Board*" in clause 8.

Justification: It is the duty of the Board to hire and remove the CEO and senior management of an organization under the *Mwongozo* Code of Governance for State Corporations.

221. Deletion of clause 8(2) (c) and (h) and insertion of a new sub-clause as follows: "*The Board shall co-opt other members as deemed fit for the conduct of its business.*"

Justification: To reduce Board membership from 11 to 9 for compliance with the *Mwongozo* Code of Governance for State Corporations. Representatives from the Pharmaceutical Association and the Director General may be co-opted as the Chairperson must have pharmaceutical qualifications and the PS, MOH is a member of the Board.

222. Insertion of the words "and fair representation of persons with disabilities" immediately after the words "gender" in clause 8(7).

Justification: Compliance with the *Mwongozo* Code of Governance for State Corporations that all Board appointments should comply with the principle of inclusion in Article 27 and 232 of the Constitution.

223. Deletion of the words "*with the approval of Parliament*" and insert the words "*notice in the gazette*" immediately after the words "*shall be appointed*" in clause 8(3).

Justification: This is for compliance with *the Mwongozo Code of Governance for State Corporations*

224. Deletion of clause 10(e) as it is prejudicial to persons with mental and physical disabilities.

Justification: The Convention on the Rights of Persons with Disabilities and the Persons with Disabilities Act, No. 14 of 2003 provides for reasonable accommodation, rehabilitation and habilitation of PWDs.

225. Deletion of paragraph 2(b)-(f) of clause 10 providing for a selection panel and for the nominees to appear before Parliament and deletion of the words "are determined by the Cabinet Secretary in charge of finance in consultation with a Committee of the National Assembly designated by the

National Assembly for that purpose" and substitution with the words "are approved by the Salaries and Remuneration Commission" in paragraph (7) in the third schedule.

Justification: The Constitution specifies the offices that need the National Assembly's approval. The Board nominees are non- executive and should be appointed by the Cabinet Secretary by notice in the *gazette* as provided in *the Mwongozo Code of Governance for State Corporations* and the State Corporations Act, Cap. 446. Determination of allowances and benefits is a mandate of the Salaries and Remuneration Commission under the Constitution.

226. In general, proposed the review the State Corporations Act to align with the Constitution and *the Mwongozo Code of Governance for State Corporations*

3.2.6 THE KENYA ASSOCIATION OF MANUFACTURERS (KAM)

In its memorandum, the Kenya Association of manufacturers proposed:

227. Deletion of *"Drugs" and substitute with "Medicines* "in the term "drugs"

Justification: This gives the term a narrow interpretation which will leave out critical components such as medical devices and in vitro diagnostics.

228. Substitution of the word "therapeutic cosmetic" with "therapeutic product" in clause 2 and wherever it appears in the Bill and the term "therapeutic product" defined to include any substance or mixture of substances manufactured, sold or represented that contain scheduled substances.

Justification: For clarity and compliance with the East African Standard on cosmetics which will enhance free trade in the East African Community region.

229. The definition of therapeutic cosmetic is ambiguous as it does not distinguish between a therapeutic cosmetic and an ordinary cosmetic. It adopts the general definition of a cosmetic. An ordinary cosmetic is a substance deigned to be used on any external part of the body to change its odour or appearance, cleanse, protect or keep it in good condition e.g., perfume, make-up, nail polish while a therapeutic is used to prevent, diagnose or treat a disease or its symptoms or affect the structure or functions of the human body such as sunscreens and skin whitening lotions. "

Justification: A therapeutic is used to prevent, diagnose or treat a disease or its symptoms or affect the structure or functions of the human body such as sunscreens and skin whitening lotions.

230. Deletion of the definition of a "therapeutic cosmetic" and substitution with a new definition that *"Cosmetics with therapeutic effects" means any cosmetic product that contains a scheduled substance. This includes steroids and hydroquinone containing creams.*

Justification: The current definition of a therapeutic cosmetic is ambiguous as the Bill does not differentiate between a therapeutic cosmetic and an ordinary cosmetic. In order to ensure that a cosmetic product is regulated by the relevant Authority, all ingredients that have any physiological activity will be added to the list of Scheduled Substances.

231. Substitution of the definition of "**chemical substance**" with a new definition to mean "*any substance or mixture of substances prepared, or sold which the Authority may declare to be a chemical substance. Because including germicides, pesticides, insecticides, rodenticides and vermicides in the definition of chemical substance creates a duplication with the mandate of the Pest Control Products Board established under section 5 of the Pest Control Products Act".*

Justification: The Board under the Bill regulates the manufacture, packaging, storage, display, distribution, use or advertisement of any pest control product in the country.

232. Deletion of the words "or detergent" in the definition of the chemical substance.

Justification: To exclude detergents which are used for cleaning inanimate objects and would not fall under the purview of the medicines' regulations.

233. Inclusion of the definition of the term *"cosmetics"* to *mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."*

Justification: The definition is necessary in order to distinguish between a cosmetic product and a therapeutic cosmetic (cosmetics with therapeutic effects).

234. Deletion of the words "related products and technologies" and deletion of the reference to "chemical substances" and substitution of the term "therapeutic cosmetics" with "therapeutic products" in the definition of the term "health products and technologies".

Justification: The definition is too general and may be prone to abuse.

235. Substitution of the definition of the term "manufacture" with "all operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products and the related controls".

Justification: To adopt the globally accepted WHO definition which is more precise.

236. Add a new definition of the term "enrolled pharmaceutical technologist".

Justification: Most clauses only deal with registered pharmacists and yet there are several enrolled pharm-techs in the country.

237. Deletion of reference to chemical substances and substitution of the term "therapeutic cosmetics" with the term "therapeutic products" in clause 3.

Justification: The current definition of a therapeutic cosmetic is ambiguous.

238. The pharmaceutical association referred to in clause 8(2)(h) should be specified.

Justification: For clarity as there are many pharmaceutical associations in the country such as KPA, PSK and the Federation of Kenya Pharmaceutical Manufacturers.

239. Under clause 28, introduction of a medical device register.

Justification: To cure the exclusion of medical devices which falls within the mandate of the Authority.

240. Under clause 29, enhancement of the period provided from one month to sixty (60) days in clause 29(4)(b).

Justification: The appeal period provided is too short.

241. Deletion of clause 29(9).

Justification: Currently, the product registration validity has not been finalized for five years.

242. Inclusion of a provision to the effect that the details of the product owner or local representative be published in the *gazette* in clause 32(2).

Justification: An applicant may be a local representative and not the product owner and vice versa.

243. Insertion of the words "or enrolled pharmaceutical technologist" immediately after the word "pharmacist" in clause 39(4).

Justification: Retail premises managed by licensed pharm-techs are part of the distribution chain.

244. Insertion of the words "or pharmaceutical technologist" immediately after the word "pharmacist" in paragraph (b) and (f) of clause 41(1).

Justification: Pharmaceutical technologists routinely superintend licensed premises. Licensed or enrolled pharmaceutical technologists keep and dispense scheduled substances.

245. Insertion of the word "*human*" immediately after the word "*any*" in clause 47(1).

Justification: To specify that the clause applies to human and not veterinary medicines. The Veterinary Medicines Directorate already regulates the manufacture and handling of veterinary medicines and other animal health products in the country. The Directorate should remain the sole regulator of veterinary medicines.

246. Deletion of clause 48.

Justification: The clause is unclear on which regulatory body will issue the good manufacturing practices certificate.

247. Redrafting of clause 50 to clarify the role of the Authority in the Bill and that of the Kenya Bureau of Standards (KEBS) especially in the regulation of cosmetics.

Justification: There may be duplication of roles in the cosmetic sector which will increase the cost of compliance and reduce the ease of doing business. Therapeutic and non-therapeutic cosmetics are regulated by PPB and KEBS respectively.

248. Redrafting of clause 51 as follows *"Any person who sells, prepares, preserves, packages, conveys, stores or displays for sale any therapeutic substances under good manufacturing practices."*

Justification: For recognition of Good Manufacturing practices' requirements and ISO standards. Compliance with GMP may be made mandatory and needs to be stated by the manufacturer.

249. Provision be made for a lighter notification process based on an online portal prior to placing on the market of cosmetic products instead of a register. **Justification:** This is the current practice in the European Union.

250. Deletion of clause 54.

Justification: The Bill does not set out the procedure to be used by the Authority in determining the probation of an ingredient in a cosmetic. KEBS has a standard listing of all prohibited ingredients in cosmetics. The Authority engages in a consultative process involving the cosmetic sector in Kenya that will be used to determine how ingredients will be banned.

251. Insertion of the following new Part immediately after Part IX—.

PART IXA-The National Pharmacovigilance System

The Authority shall through the National Pharmacovigilance Centre manage the nationa' pharmacovigilance and post marketing surveillance system to receive and maintain all relevant informatio about suspected adverse drug reactions and adverse events to health products or technologies which have been authorized by the Authority. The Authority shall conduct both passive and active surveillance of healtl. products and technologies. The Authority shall carry out pharmacovigilance audits and inspections in orde to ensure compliance with Good Pharmacovigilance Practices and the prescribed requirements.

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. The entities in subsection (4) shall submit safety information to the Authority as prescribed. The consumers, general public, health care professionals shall report adverse reactions and events to the Authority as prescribed"

Justification: The Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules,2022describe these roles but it is important to have them as the overarching statements in the Bill that would then serve as guidance on development or review of existing regulations. To anchor the regulatory role of pharmacovigilance in the Bill that would then serve as guidance on development or review of existing regulations.

252. Under clause 60, inclusion of a provision that testing will only be applicable to human medicines and medicinal products and allow other laboratories to do product analysis.

Justification: The NQCL only tests human products and should not be given the mandate to test veterinary products. The NQCL is constrained in terms of capacity.

253. KAM submitted that the Authority's mandate overlaps with the mandate of existing bodies such as KEBS which will lead to duplication of efforts. The Authority has taken the functions of the latter. There is no clear demarcation of the roles of the Authority and KEBS in terms of standardization and quality control. KEBS promotes standardization in industry and commerce pursuant to the Standards Act, Cap. 496 while the Authority will prescribe standards for HPTs pursuant to the Bill. This may bring confusion even in dispute resolution as the decisions of the Standards Tribunal may contradict the Authority's decisions. Further, under the Bill, products regulated by the Authority will not be regulated by any other authority. Will this lead to dual regulation? Does one have to get registered with KDA then go to KEBS for testing or will the Authority do the testing? Does the Authority have the capacity to do testing? KAM also noted that the Bill facilitates the realization of the aim of African Union Model law which is to increase collaboration across countries and to provide a conducive regulatory environment for HPTs.

254. The Food, Drug and Chemical Substances Act, Cap. 254 is being repealed without direction on how and who will regulate the medical examination of food handlers and licensing of food premises and markets.

255. The Bill is not aligned with the regulation and facilitation of trade as it is majorly concerned with safe and quality HPTs.

256. Proposed the inclusion of new clauses as follows—

i. *on in-market control (set out the main elements for in-market control, define who is responsible for the safety of the product and how the safety will be managed)*

ii. *require that every therapeutic product placed on the Kenyan market should have a technical Product Information File (PIF). This provision to require that the cosmetic product be notified free of charge and using an electronic portal. The notification should give general information about the main purpose of the product. It should also provide mutual recognition for products already notified in other regulatory jurisdictions such as the EU becoming automatically notified in Kenya.*

iii. *provide for borderline products such as borderline cosmetics, medicine or medical device or a combination of both.*

Justification: In-market control allows regulators to achieve a high level of consumer safety in a scenario of innovative and fast-moving consumer goods by:

a) allocating clear legal responsibilities for safety and compliance to the actors in the supply chain;
b) setting safety requirements and defining safety standards;
c) submitting companies to random controls and inspections by local authorities.

257. Inclusion of a provision on Product Information file (PIF) which is a mandatory document that is necessary for every cosmetic product, maintained by the person responsible for placing the product in the market and is availed to competent authorities during audit as part of cosmetic compliance. The PIF should contain information on:

Justification: To prevent future regulatory uncertainty in relation to borderline products.

3.2.7 THE KENYA LAW REFORM COMMISSION (KLRC)

The KLRC submitted as follows:

258. The Commission emphasized that the Bill needs to handle the transition from the Pharmacy and Poisons Act, Cp. 244 effectively and provide for the transition mechanism in the regulation, training and licensing of professionals in the pharmacy sector.

259. The Commission further submitted that the Bill is an excellent contribution towards delivering a progressive HPT regulatory law however the Bill presents numerous opportunities for improvement that:

(a) Extensive stakeholder involvement should be undertaken in order to comprehensively address all aspects of HPT regulation;
(b) The wording of the Bill should promote clarity of the provisions;
(c) The name of the Bill should reflect the function of the Bill which extends beyond establishment of an Authority to regulate drugs;
(d) To prevent errors in interpretation, the Bill should use internationally accepted definitions;
(e) The Bill to provide for regulation and monitoring of clinical trials, HPT manufacturing, product packaging, post marketing etc.
(f) Establishment and governance of regulatory institutions under the Bill should align with the State Corporations Act, cap. 446. Their governance structures should further promote effective service delivery and stewardship of resources;

(g) The Bill to provide for interaction of the regulatory institutions with county governments as may be necessary;
(h) The Bill should not overlap with other laws such as the Food, Drugs and Chemical Substances Act, Cap. 254 and the Nuclear Regulatory Act, No. 29 of 2019; and
(i) A comprehensive plan should be provided for the regulation of pharmacists and pharmaceutical technologists upon the repeal of the Pharmacy and Poisons Act, Cap. 244.

3.2.8 THE PHARMACEUTICAL SOCIETY OF KENYA (PSK)

In its memorandum, the PSK proposed the following amendments;

260. Deletion of the long title since the scope of the Act is wider than drugs and substitution of the name of the Authority from the Kenya Drugs Authority to the *"the Kenya Medicines and Health Products Authority"*.

261. Deletion *of the phrase "Kenya Drugs" and substituting with the phrase "Kenya Medicines and Health Products". The use* of the term "drugs" gives it a narrow interpretation as it leaves out critical components e.g., medical devices and Invitro diagnostics.

262. The term "***medicines***" is appropriate as the term drugs means medicines and non-medicinal drugs such as heroin that are not regulated under the Bill.

263. The term *"health products"* is used by WHO and covers medical devices, cosmetics, blood and blood components.

264. The title connotes that, the subject matter of the Bill relates to the establishment of the Authority whereas the content of the Bill relates to the regulation of medicines, therapeutic cosmetics, medical devices, scheduled substances, blood and blood products and tobacco products.

Justification: This contradicts the legislative drafting principles on drafting of a Bill title in relation to its subject matter.

265. Deletion and substitution of clause3 (1) with the following new sub-clause *"(l) This Act applies to regulation of, Human medicines, medical products & technologies, Veterinary medicines, medical products & technologies, Medical devices including radiation emitting products, Radiopharmaceuticals, Complementary, alternative or herbal medicines, Cosmetics and Borderline Products Committee, Clinical trial Scientific Technical Advisory Committee, Nutraceuticals & Dietary supplements, Digital Heath and technologies, Controlled substances, Chemical substances and Biological products for use in humans and the starting materials used in their manufacture"*.

Justification: To provide for a comprehensive scope of regulatory categories.

266. Amendment of clause 4 by deleting the phrase *"Kenya Drugs"* appearing in sub clause (1) and substituting therefor the phrase *"Kenya Medicines and Health Products"*.

267. Deletion of sub-clause 6 (1) and (2).

Justification: The provision contradicts the legal framework for recruitment of CEOs of State Corporations or Semi-Autonomous Government Agencies. The Director General is appointed by the Authority. The Director General is therefore not a State Officer and as such his or her recruitment does not require vetting by Parliament.

268. Deletion of the words ***"Kenya Drugs"*** and substitution with the phrase ***"Kenya Medicines and Health Products"*** in clause 8(1).

Justification: The name of the Board and its composition should reflect the proposed title of the Bill.

269. Deletion of paragraph (2)(b), 2(c), 2(d), 2(e), 2(h), 2(i), 2(k) in clause 8

Justification: Board membership should constitute professional mix directly related to medicines and health products. With regulation of medical devices being a key function of the Authority, one of the Board members should have expertise in biomedical engineering.

270. Insertion of the following words ***"and an ex officio member of the Board"*** immediately after the secretary appearing in clause 8(2)(l).

271. Deletion of clause 8(3) and substitution with following new sub clause (3)—

The Cabinet Secretary shall appoint the members of the Board under paragraph (2)(c), (d), (e), (h), (j) and (k);

272. Insertion of the phrase ***"and economic value"*** after the word "***efficacy***" in paragraph (c) and insertion of the words "***regulate clinical trials***" before the words ***"ensure that clinical trials"*** in paragraph (g) of clause 12.

273. Deletion of paragraphs (f), (n), (p) of clause 12.and substitution with the following new paragraphs *"(f) ensure continuous monitoring of the safety of health products and technologies regulated under this Act; (n) appoint inspectors and order inspection of the premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, retail outlets and any other premises subject to this Act; (p) provide medicines information and promote rational use of medicines and health products";*

274. Insertion of the following new paragraphs after paragraph (a) of clause 12—

"(aa) provide oversight and capacity development over national or county governments pharmacies";

"(ab) regulate schedule medicines and health products";

"(ac) carry out pharmacovigilance of medicines and health products";

"(ad) carryout and promote research related to medicines and health products;(ae) ensure quality control and assurance in medicines and health products"

"(af) regulate the disposal of medicines and health products and technologies";

"(ag) regulate complementary, alternative or herbal medicines";

"(ah) monitor the market for the presence of unregistered and illegal health products and technologies;(ai) conduct analytical tests of health products and technologies";

"(aj) approve the use of any unregistered medicinal substance for purposes of clinical trials, compassionate use and emergency use;"

"(ak) carry out pharmacovigilance audits and inspections in order to ensure compliance with goo pharmacovigilance practices and the prescribed requirements";

"(am) conduct research on biologicals to ensure quality, safety and efficacy of biological products through regulatory release system in compliance with established approaches, policies, guidelines, procedures and i line with World Health Organization and internationally recognized guidelines"

";(an) ensure that all health products and technologies manufactured in, imported into or exported from th country conform to prescribed standards of quality, safety and efficacy";

"(ao) enforce the prescribed standards of quality, safety and efficacy of all health products and technologie manufactured, imported into or exported out of the country; (ap) grant or revoke licenses and permits for th manufacture, importation, exportation, distribution and sale of health products and technologies";

"(aq) maintain a register of all authorized health products and technologies manually or electronically;"

"(ar) inspect and license manufacturing premises, importing and exporting agents, wholesalers, distributors pharmacies, including those in hospitals and clinics and other retail outlets"

(aq) maintain a register of all authorized health products and technologies manually or electronically";

"(ar) inspect and license manufacturing premises, importing and exporting agents, wholesalers, distributors pharmacies, including those in hospitals and clinics and other retail outlets; The Authority's functions should encompass the whole spectrum of matters covered under regulatory regime dealing with medicines and health products".

275. Deletion of clause 13 and substitution with the following new clause13—

"The powers of the Authority shall be to;

(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) adopt and implement any such internationally recognized good regulatory practices;
(c) determine and implement effective and efficient reliance mechanism;
(d) issue, suspend, withdraw or revoke any license, compliance certificate;
(e) levy, collect and utilize fees for services rendered;
(f) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; and
(g) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products.

Justification: For compliance with WHO requirements for regulatory functions in the Global Benchmarking Tool. Controls over imports and exports is critical for any regulatory authority.

276. Deletion of clause 22(1) and substitution with the following—

(3) There shall be established such Scientific Technical Committees of the Authority, appointed by the Board, for the effective performance of the functions of the Authority. Delete the word "advisory" and substitute with the word "technical" in sub-clause (2) and insert the following new sub clause immediately after sub clause (2) (2a) The Board shall in addition to the Committees established under subsection (1), establish the following Committees—

(a) Biologics Committee;

(b) *Pharmacovigilance Committee;*
(c) *Complementary, Alternative or Herbal Medicines Committee;*
(d) *Radiopharmaceuticals Committee;*
(e) *Cosmetics and Borderline Products Committee*
(f) *Clinical Trial Scientific Technical Advisory Committee;*
(g) *Health Technology Assessment Committee;*
(h) *Nutraceuticals and Dietary Supplements Committee;*
(i) *Digital Health and Technologies Committee;*
(j) *Veterinary Medicines and Medical Products Committee; and*
(k) *Medical Devices and Health Technologies Committee*

277. Redrafting of clause 35(2) to read *"A medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals may, in consultation with a licensed pharmacist, prevent the interchange of a medicine as contemplated in subsection (1).*

Justification; To enhance the safety of patients.

278. Deletion of clause 37(1) and (2) and substitution with the following new sub clauses

"(1)A person who intends to manufacture, prepare, supply, sell, distribute, export or import herbal medicine which is presented to the public to have therapeutic effect when consumed, applied or inhaled, shall obtain a license from the Board".

"(2) The Cabinet Secretary shall in consultation with the Authority, make regulations for the better carrying into effect this section".

Justification: To ensure that the level of culpability is provided as the offence is a strict liability offence. It requires proof of "*mens rea* (intent, wilful, reckless, negligent)" is required.

279. Deletion of clause 37(4) and substitute therefor the following new sub clause (4) The Authority shall at least once every three years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.

Justification: One year is too short and impractical. The Authority may act where need arises.

280. Deletion and substitution therefor clause 36(5) with the following new sub clause *"(5) A licence issued under this section shall be valid for a period one year, renewable annually".*

Justification: The provision is punitive for those who apply in the middle of the year.

281. Deletion and substitution of clause 45 with the following new clause—

45 Automatic machines

"(1) An authorized seller may use an automatic machine to dispense over-the-counter Scheduled Substances.

(2) The Authority shall develop regulations on

(a) classes of substances permitted;
i. quantities of substances to be dispensed;
(b) records of substances dispensed;
(c) location of automatic machines; and

(d) *registration of automatic machines.*

Justification: Automatic machines to be included as part of medical devices/ technologies. To provide for the use of automatic machines in dispensing selected scheduled substances in an effort to embrace technological advances.

282. Deletion and substitution clause 46with the following new clause 46.

46 *Electronic sale of medicines*

(1) The Authority shall for the effective implementation of this section, develop regulations.

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

(a) licensure of e-pharmacies;

(b) safety of the patient;

(c) verification of the identity and traceability of the patient;

(d) verification of the identity and traceability of the prescriber; and

(e) integrity, legitimacy and authenticity of the prescription including avoidance of multiple use of the same prescription.

(3) In the case of a prescription-only medicine, the prescription shall have been obtained as a result of at least one physical interaction between an authorized practitioner and the patient.

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

Justification: Many online platforms already sell medicines to consumers. The Authority needs to develop appropriate regulations on telemedicine, e-pharmacy, authenticity of prescriptions, traceability, online dispensing, and related platforms with consumer safety in mind. To enhance the fine for sale of scheduled substance using electronic means.

283. Deletion and substitution of clause 51 with following new *clause--*

51 Manufacturing of cosmetics

(1) The Cabinet Secretary shall for the effective implementation of this section, develop regulations.

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

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

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

Justification: For transparency with regards to the ingredients in the prescribed requirements in line with GMP and other guidelines.

284. Insertion of the following new subclauses immediately after subclause (2) –

"(3) A person who manufactures, sells, supplies, packages a medical device shall provide for the service and maintenance of the medical devices at the time of installation and on operationalization of the use of the medical device.

(4) A person who manufactures, sells, supplies, packages a medical device shall remove from the hospital, health center or any other entity where they have supplied the medical device after the life cycle of the medical device is realized.

(5) A person who manufactures, sells, supplies, packages a medical device shall ensure requisite quality audits of the manufacturer to meet the required quality management systems is conducted before a medical device is registered for sale in Kenya.

Justification: To enable the Authority effectively regulate medical devices.

285. Insertion of the words "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" immediately after the word "Authority" appearing in sub clause (2).

Justification: WHO publishes globally recognized good manufacturing standards that should set the benchmark for Kenya.

286. Insertion of the words ***"unregistered establishments for medical devices"*** immediately after the word "***under***" appearing in clause 59 (1).

Justification: There is need to register establishments for Medical Devices.

287. Deletion of the words "***of the Authority"*** appearing in sub clause (1);

288. Insertion of the following new sub clause immediately after sub clause (1)-

(2) The Laboratory established under sub section (1), shall be a body corporate with perpetual succession and a common seal, and shall in its corporate name—

(a) have power to sue and be sued; and
(b) to acquire, hold and dispose of movable and immovable property.

289. Insertion of the following new clauses immediately after clause 60—

"60A Board of management"

(1) The Laboratory shall be managed by a Board consisting of—
- (a) *a non-executive chairperson appointed by the President;*
- (b) *the Principal Secretary of the Ministry for the time being responsible for matters relating to health or their representative;*
- (c) *the Principal Secretary of the Ministry for the time being responsible for matters relating to Finance or their representative;*
- (d) *Director-General Kenya Medicines and Health Products Regulatory Authority or a representative nominated in writing;*
- (e) *four other members nominated and appointed by the Cabinet Secretary, as follows—*
  - *(i) three person who are qualified Pharmacists nominated by Pharmaceutical Society of Kenya; and*
  - *(ii) a pharmaceutical technician nominated by the Kenya Pharmaceutical Association; and*
- (f) *the chief executive officer who shall be the secretary and ex officio member of the laboratory.*

(2) The chairperson and members of the Board of Management, except for the ex-officio members, shall serve for a term of three years, renewable once subject to satisfactory performance.

(3) For purposes of this section, the ex officio members include the members appointed under paragraph. (1)(b)(c)(d).

(4) The Board of Management shall be responsible for the performance of the functions of the Laboratory set out under section 60 of this Act.

(5) The chairperson and members of the Board of Management, shall be paid such allowances as may be determined by the Cabinet Secretary in consultation with the Salaries and Remuneration Commission.

(6) The Board shall regulate the procedure for the conduct of its business and affairs.

(7) The Cabinet secretary shall prescribe regulations for effective management of the Laboratory.

60B Chief executive officer

(1) There shall be a chief executive officer of the Laboratory, who shall be competitively recruited and appointed by the Board, on such terms and conditions as may be specified in the instrument of appointment.

(2) A person qualifies for appointment as the chief executive officer, if the person—

(a) is a citizen of Kenya;

(b) holds a bachelor's degree in Pharmacy, Quality Assurance or related discipline from a university recognized in Kenya;

(c) has at least ten years' post qualifications experience in the relevant field, five of which shall be at a management level; and

(d) meets the requirements of Chapter Six of the Constitution and the Leadership and Integrity Act.

(3) The chief executive officer shall hold office for a term of three years and may subject to satisfactory performance, be eligible for re-appointment for a single further and final term of three years.

(4) The chief executive officer shall—

(a) be the accounting officer of the Laboratory;

(b) secretary and accounting officer of the Board; and

(c) under the direction of the Board, be responsible for—

(i) the implementation of the decisions of the Board;

(ii) the day-to-day management of the affairs of the Laboratory;

(iii) the organization and management of the staff of the Laboratory; and

(iv) the performance of any other function that may be assigned by the Board.

60C Staff of the Laboratory

(1) The Board shall on such terms and conditions it may determine, competitively recruit such number of staff as it may consider necessary for the efficient discharge of the functions of the Laboratory under this Act.

(2) The Board shall, in the recruitment of the staff of the Laboratory under subsection (1), ensure—

(a) that the appointment reflects ethnic and regional diversity of the people of Kenya;

(b) equalization of opportunity for the persons with disabilities; and

(c) that not more than two thirds of its staff are of the same gender.

Justification: NQCL should be an independent Institution so as to complement the KDA's laboratory through provision of second opinions on products being tested.
Making NQCL independent will guarantee reliable results as best practice has noted that laboratories are an essential and fundamental part of all health systems and their goal to improve health and achieve maturity level 3.

290. Insertion of the following new sub clauses immediately after clause 63 (3) and *(4)*—

Sub section (1) shall not apply to advertisements directed exclusively to—

(a) medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists or dental therapists; or persons who are—

(i) engaged in the business of wholesaling therapeutic products; or

(ii) purchasing officers in hospitals.

(5) The Authority in consultation with the Cabinet Secretary may prescribe the classes of persons referred to under paragraph (4)(b)(i).

Justification: For inclusion of pharmaceutical technologists.

291. Introduction of consequential amendments to the Pharmacy and Poisons Act, Cap. 244 either as Clause 97 (3)(c) in the Bill or as a separate amendment to accompany Bill as follows—

Amend section 3 of the Pharmacy and Poisons Act by—

a) deleting paragraph (2)(d), (e) and (g) and substituting therefore the following new paragraph—

(d) six other persons appointed by the Cabinet Secretary, of whom—

(i) four persons shall be registered pharmacists one each with expertise in supply chain, community/hospital, academia and manufacturing subsectors of pharmacy nominated by the Pharmaceutical Society of Kenya

(ii) two persons shall be an enrolled pharmaceutical technologist with expertise in academia and community pharmacy nominated by the Kenya Pharmaceutical Association

b) Renumber paragraph (f) to be (e)

(e) the Chief Executive Officer, who shall be an ex officio member

c) deleting sub clause (2) and substituting therefore the following new sub clause—

*(2) **The persons appointed under subsection (1)(d)** shall be appointed by the Cabinet Secretary from among members nominated by their relevant professional associations, each of which shall nominate two candidates in each category taking into consideration gender, ethnicity and regional balance.*

d) Deleting sub clause (3) and substituting therefore the following sub clause –

***(3) A person shall not qualify for appointment as a member of the Board under subsection** (1)(d) unless such person is the holder of a minimum of a diploma in the relevant field from an institution recognized in Kenya and has at least five years managerial experience.*

Justification: To alleviate the vacuum that may be created by the repeal of Cap. 244.

292. Deletion of the word ***"Advisory"*** appearing immediately below the Fourth Schedule and substitution with the word ***"Technical";***

293. Deletion of paragraph 1 of the Fourth Schedule.

294. **Justification:** Food is outside the scope of the Bill.

3.2.9 THE KENYA PHARMACEUTICAL ASSOCIATION (KPA)

In its memorandum, the KPA proposed the following amendments;

295. The name of the Bill be changed as is not appropriate while the target of the Bill is HPTs.

296. Adoption of the definition of "***enrolled pharmaceutical technologist***" provided in the Pharmacy and Poisons Act, Cap. 244 without cross referencing.

297. Definition of the term "***Roll***" to mean the Roll of pharmaceutical technologists kept by the registrar.

298. Inclusion of a definition of the term "***pharmacy practitioner***".

299. Redrafting of the definition of "***pharmacy***"

300. Redrafting of clause 6(4)(a) as follows "holds a degree from a university recognized in Kenya in either pharmacy or medicine or equivalent fields;" such that the Authority will be managed by medical practitioners or pharmacy professionals dealing with the practice.

301. Redrafting of clause 8(2)(h) as follows "two persons nominated by the Kenya Pharmaceutical Association".

302. Redrafting of clause 8(2)(a)(i) as follows "be a registered pharmacist or enrolled pharmaceutical technologist of good standing with a degree in pharmacy or diploma in pharmacy with additional degree in a relevant medical field". This is for clarity and appropriate representation of pharmaceutical technologists based on expertise and numbers.

303. The manner of removal of the Chairperson is not clearly set out under clause 11.

304. Substitution of the word "brand" with the word "generic" in clause 35(3).

Justification: An interchangeable multi-source medicine should be dispensed using generic names for cost effective treatment outcomes. No brand gives superiority of the same molecule over the other. This gives pharmacy professionals room to use their expertise and knowledge.

305. Deletion of clause 35(4) or redrafting as follows "A pharmacist/pharmaceutical technologist shall, (after consultation with the prescriber) substitute for a prescribed medicine an interchangeable multi-source medicine—"

Justification: This may be used to deny the public access to other drugs for selfish promotion of brands through the influence of medical representatives.

306. Insertion of the words "/pharmaceutical technologist" wherever the word "pharmacist" appears in clause 35.

Justification: To redress the exclusion of pharmaceutical technologists.

307. Deletion of clause 38(1)(c) and substitution with "(c)a person for whom the Scheduled Substance has been lawfully supplied or dispensed by an authorized person under this Act or any other written law;"

Justification: To professionalize supply and dispensing.

308. Inclusion of pharmacists/pharmaceutical technologists only in wholesale dealership in medicines and health technologies clause 39(1) and (4).

Justification: To enable the public access drugs timely from professional pharmacy practitioners.

309. Redrafting of clause 41(1)(b) and deletion of clause 41(2) (b) and (c).

Justification: To capture the two pharmacy cadres. To ensure that hospital facilities are licensed and employ the two pharmaceutical cadres.

310. Definition of the term "***authorized seller***" used in clause 43(2) as a registered pharmacist or an enrolled pharmacist technologist.

Justification: To prevent quacks by ensuring that the government employs qualified staff for health security.

Substitution of clause 43(1) with "(1) An authorized seller 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" OR "(1) A qualified medical practitioner, dentist or veterinary surgeon, registered pharmacist, enrolled pharmaceutical technologist with a therapeutic value for..." and addition of the words "registered pharmacist or enrolled pharmaceutical technologist" immediately before the words "Authorized Sellers" in clause 63(2)(d).

Justification: For inclusion of pharmaceutical technologists.

311. Addition of the words ***"registered pharmacist or enrolled pharmaceutical technologist"*** immediately before the words ***"Authorized Sellers"*** in clause 63(3)(b)(ii).

Justification: For inclusion of pharmaceutical technologists.

312. Deletion of clause 79 and 80 and substitution with a clause on regulatory officers for HPTs to include drug inspectors and facility inspectors under enforcement.

Justification: Regulatory inspectors, drug inspectors and facility inspectors are crucial in enforcement of regulation and standards.

313. Deletion of the clause 81 and substitution with a clause on regulatory officers for HPTs to include drug inspectors and facility inspectors under enforcement.

Justification: Relates to food. Falls outside the ambit of the Bill.

314. Deletion of the words "***or the Director of Veterinary Services***, in relation to any matter appearing to affect the general interests of animal husbandry in Kenya, and the Director of Agriculture in relation to any matter appearing to affect the general interests of agriculture in Kenya," in clause 81 and insertion of the word "***human***" immediately before the words ***"health product or technology"***.

Justification: Matters of animal health and agriculture are regulated elsewhere. The Bill should only concern itself with human health products and technologies.

315. Deletion of clause 82, 83, 84, 85, 86 and 87 and substitution with clauses on regulatory officers for HPTs to include drug inspectors and facility inspectors under enforcement.

Justification: Relates to food. Falls outside the ambit of the Bill.

316. Definition of the term "class" as used in clause 95(2)(q).

Justification: For clarity.

317. Definition the term "Board" as used in the Schedule.

Justification: The Bill introduces a new term that conflicts with the Kenya Drugs Board established under clause 8.

318. Deletion of the Third and Fourth Schedule.

Justification: The Schedules deals with a strange Board and are beyond the scope of the Bill as they deal with food and establishe strange Committees whose membership is unrelated to KDA.

The Schedule

319. Under the Seventh Schedule, the Pharmacy and Poisons Act, Cap. 244 should not be repealed.

Justification: Repeal will have adverse impact on pharmacy practice.

3.2.10 AGNES KUVUNA MAINA, A QUALIFIED PHARMACEUTICAL TECHNOLOGIST

In her memorandum, Ms. Maina made the following submissions: Adoption of the definition of "***enrolled pharmaceutical technologist***" provided in the Pharmacy and Poisons Act, Cap. 244.

320. Redrafting the definition of "***pharmacy***" as the Pharmacy and Poisons Act, Cap. 244 will be repealed.

Justification: To include pharmaceutical technologist who are currently excluded.

321. Deletion of Clause 8(2)(h) and replace with: One person nominated by the Pharmaceutical Society of Kenya and One person nominated by the Kenya Pharmaceutical Association.

Justification: The term "pharmaceutical association" is ambiguous as it is not defined. There are two representative umbrella organizations namely Pharmaceutical Society of Kenya (PSK) and KPA of pharmacists and pharmaceutical technologists respectively. For inclusion of pharmaceutical technologists in the Kenya Drugs Board. Section 3 of the Pharmacy and Poisons Act currently recognizes the two cadres in pharmacy and the Kenya Pharmaceutical Association (KPA) as the umbrella body of pharmaceutical technologists.

322. Inclusion of pharmaceutical technologists as part of the classes of persons falling under defence for offences related to advertisements as to certain diseases in clause 63(2).

Justification: To redress the exclusion of pharmaceutical technologists.

323. Inclusion of pharmaceutical technologists as part of the classes of persons falling under defence for offences related to advertisements as to certain diseases in clause 66(3)(b).

Justification: To redress the exclusion of pharmaceutical technologists.

324. Insertion of the words "***, an enrolled pharmaceutical technologist***" immediately after the word "***pharmacist***" in clause 95(2) (bb).

Justification: For inclusion of pharmaceutical technologists. Training of pharmaceutical technologist is a continuous process.

325. She submitted that the Bill does not recognize the two different cadres of pharmacy practitioners (pharmacists and pharmaceutical technologists) in Kenya that are already recognized by the

current legislation, the Pharmacy and Poisons Act, Cap. 244. Pharmaceutical technologists have been marginalized, ignored and omitted by the Bill. They have been left out in the key definitions of pharmacy practice and are not participating in the key decision-making entities established by the Bill contrary to the principles of equality, fairness and fair labour practices.

3.2.11 MATHEW WAMUIGA GATURUKU, AN ENROLLED PHARMACEUTICAL TECHNOLOGIST

In his memoranda, Mr. Gaturuku made the following submissions:

326. It appears that the legislation for the regulation of the pharmacy practice in clause 96 (3)(b) envisions two parallel Boards which does not amount to prudent use of resources.

327. The proposed amendments to the laws governing the pharmacy practice do not fully recognize the noble roles played by pharmacy diploma holders who are the majority in both public and private healthcare practice

328. The Bill does not give the full description of enrolled pharmaceutical technologist and instead emphasizes the definition of pharmacists.

329. The Bill does not provide for a single representative of pharmaceutical technologists in the proposed Board even though this cadre forms the majority of pharmacy practitioners.

330. If the Bill passes in its current state, then it will have negative repercussions on the health of the general public and ultimately hampering the realization of universal health care.

3.2.12 WILLIAM KOMEN

In his memoranda, Mr. Komen made the following submissions:

331. The Bill does not define the terms ""enrolled pharmaceutical technologist" and "pharmaceutical technologist"

Justification: The Bill makes reference to the Pharmacy and Poisons Act, Cap. 244 which will be repealed.

332. There is need to specify the cadre that will be responsible for handling scheduled substances with therapeutic value.

Justification: Pharmaceutical technologists or pharmacists and veterinary officers to handle human medicines and veterinary medicines respectively so as to prevent quacks.

333. The composition of the Human Medicines Committee in paragraph (2)(2) of the Fourth Schedule leaves out pharmacy professionals by providing that the members of the Committee should have knowledge of human medicines.

Justification: This may lead to appointment of non-medicines experts and yet pharmacy professionals are known drug experts.

3.2.13 VINCENT GATHUKIA AND ROBERT NGETICH

In their memoranda, Mr. Gathukia and Mr. Ngetich made the following submissions:

334. Insertion of the words ***"or pharmaceutical technologist"*** immediately after the words "registered pharmacist" in paragraph (a) and (b) of the definition of the word ***"pharmacy"***.

Justification: For inclusion of pharmaceutical technologist who are currently registered and regulated by the PPB. They constitute over 70% of the workforce in the public and private health sector.

335. The Pharmacy and Poisons Act has been changed frequently and such changes should not be done in a private members' bill.

336. The Bill should provide for the two cadres of pharmacy (pharmacists and pharmaceutical technologists) as well as for the two cadres in veterinary (veterinary doctors and Para veterinary practitioners). Pharmaceutical technologists and Para veterinary practitioners should be represented in the KDA Board.

Justification: The Bill does not provide for the two cadres in the pharmacy and veterinary professions. Pharmaceutical technologists and Para veterinary practitioners are the majority and have been in existence longer than pharmacists and veterinary doctors.

337. Under the Memorandum of Objects and Reasons, the Bill should not be enacted as it will occasion unnecessary government expenditure and yet PPB has been doing a good job.

Justification: Available resources to be channelled to PPB.

3.2.14 DUNCAN SIMWA AND BERNARD KARIUKI

338. In their memoranda, Mr. Simwa and Mr. Kariuki proposed the insertion of the words "or an enrolled pharmaceutical technologist" immediately after the words "registered pharmacist" in paragraph (b) of the definition of the word "pharmacy".

Justification: For inclusion of pharmaceutical technologist who are currently recognized by Pharmacy and Poisons Act, Cap. 244 and regulated by the PPB.

3.2.15 BENJAMIN MUNYAO NTHUMO

339. In his memoranda, Mr. Nthumo proposed the insertion of the words ***"enrolled pharmaceutical technologist"*** immediately after the words ***"registered pharmacist"*** in paragraph (a) of the definition of the word "pharmacy".

Justification: Pharmaceutical technologists are diploma holders are a majority cadre in the pharmacy profession. They also took over the profession of pharmacy from the colonial government.

3.2.16 DR. JOHN NGETHE AND DR. NAONI NGETHE

In their memoranda, Dr. John and Dr. Naoni submitted that they rejected the Bill the following reasons—

(a) It allows persons who are not pharmacy professionals such as medical doctors, engineers to become members of the KDA Board.

(b) It does not facilitate the research and development in health and generics manufacturing in Kenya and in Africa generally. It only benefits big pharma's which will slow down the reduction in the prices of medicines.

3.2.17 DR. ALEX OGERO OKARU, PHD

In his memoranda, Dr. Okaru made the following submissions:

340. The definition of ***"substandard medicines"*** is incomplete and should be redefined to mean pharmaceutical products that do not meet quality standards and specifications due to factors like incorrect ingredients, poor manufacturing, contamination and deceptive packaging.

341. The Bill does not define substandard health technologies which are healthcare devices or technologies that do not meet established quality standards, posing risks to patient safety and efficacy.

Justification: The definitions should be provided as proposed to prevent misinterpretation and improper enforcement of the law.

342. The current definition of ***"therapeutic cosmetics"*** as including cleansing agents extends the scope of regulation to include household soaps.

Justification: This may stifle growth in the cosmetics sector.

343. The Bill regulates chemical substances which encompasses a broad category of substances ranging from simple substances such as water to complex mixtures such as pigments in paints.

Justification: The Bill lacks specific qualifications or criteria for inclusion of chemical substances. The lack of qualifications for regulation of chemical substances may lead to misinterpretation and improper enforcement of the law.

344. Designation of Nairobi as the headquarters of the Authority is unnecessary and restricts the flexibility of the KDA.

Justification: The Authority to have autonomy to have discretion in organizing its functions and offices.

345. Requiring parliamentary approval of the Director General and inclusion of professional qualification from other fields disregards the necessary and specific expertise and qualifications required of the Director General.

Justification: There is need to maintain the connection between the pharmacy profession and the regulation of medicines.

The Chairperson of the KDA should have a Masters' Degree in Pharmacy and the pharmaceutical association referred to in clause 8(2)(h) should be specified as the Pharmaceutical Society of Kenya.

346. Insertion of the word ***"Pharmaceutical"*** immediately before the word ***"manufacturers"*** in paragraph (i) of sub-clause (2).

347. Removal of the requirement of parliamentary approval of the Board members in clause 8(3).

348. Removal of the requirement of the third gender principle in clause 8(7).

Justification: It is unnecessary as equity principles in the public service already encompass gender considerations.

349. A person seconded by the same government should be considered an employee of the same government and therefore should be ineligible.

350. Part IV addresses the profession of pharmacists and may conflict with the proposed Practitioners Bill.

351. Dispensing of controlled substances by dentists, medical practitioners and veterinary surgeons raises concerns about separation of duties and its impact on public health.

352. Designation of the Director General as the signatory of the certificate of analysis issued by NQCL is not aligned to international best practice such as the WHO guidance.

Justification: International best practice emphasizes independence in laboratory operations.

353. In its current form, the Bill poses significant risks to the regulation of medicines and medical devices in the country and will hinder the country's progress towards the achievement of WHO maturity level 3.

354. The idea that the Bill will improve the ease of doing business neglects the primary objective of regulated products laws, which is public health. Further, the oversight role of pharmacists has been undermined through the removal of medicines from the purview of the pharmacy profession which will adversely affect public health and the subsequent handling of emerging challenges such as anti-microbial resistance.

3.2.18 WINFRED WAMBUI NDIRANGU

In her memoranda, Ms. Ndirangu made the following submissions:

355. specification that authorized sellers are enrolled pharmaceutical technologists and registered pharmacists under clause 2 of the Bill.

Justification: To prevent abuse by placing scheduled substances under the control of the two cadres have elaborate training on drugs.

356. Placement of therapeutic cosmetics under the control of qualified medical practitioners.

Justification: Kenyans are buying therapeutic cosmetic products from unregulated outlets posing great health hazards.

357. Redrafting of the definition of "***pharmacy***" to mean either, the profession of pharmacy as carried out by registered pharmacists and/or pharmaceutical technologists; or the duly licensed premises from which pharmacy services are provided by a registered pharmacist and/or pharmaceutical technologist."

358. Insertion of the words "***enrolled pharmaceutical technologist***" immediately after the words "***registered pharmacist***" in paragraph (a) of the definition of the word "pharmacy".

359. Insertion of the words "***or an enrolled pharmaceutical technologist***" immediately after the words "***registered pharmacist***" in paragraph (b) of the definition of the word "pharmacy".

360. Insertion of the words *"or pharmaceutical technologist"* immediately after the words *"registered pharmacist"* in paragraph (a) and (b) of the definition of the word "pharmacy".

361. Specification of the type of Masters' degree required referred to in clause 6 (4) and deletion of the requirement of a degree in medicine. The Masters' degree requirement allows engineering courses which are not medical related. Engineers are regulated by the Engineering Board of Kenya which is not mentioned in the Bill.

362. Inclusion of a requirement of active membership in the professional body referred to in clause 6 (4) (d).

363. **Justification:** Active membership sustains professional bodies.

364. Deletion and substitution paragraph (h) of sub-clause (2) in clause 8 with the following new paragraph "(h) one person nominated by Kenya Pharmaceutical Association" Pharmacists are represented in the Board by the Chairperson.

Justification: The KPA is the only pharmaceutical association that is registered under the Societies Act.

365. Deletion of clause 8 (2)(d).

Justification: The practice of lawyers is different from what the Bill seeks to achieve.

366. Provision of minimum qualifications for appointment as inspectors under clause 12 (n).

Justification The minimum qualification should be Diploma in Pharmacy.

367. Placement of the custody of drugs, medical devices and herbal drugs under pharmacists and enrolled pharmaceutical technologists under clause 12(o).

Justification: Rational drug use requires the guidance of the right professional cadre.

368. Enrolled pharmaceutical technologists and registered pharmacists should be mandated to dispense scheduled substances with therapeutic value.

Justification: Allowing any member or staff of a hospital or dispensary to supply or dispense scheduled substances will lead to mishandling of prescriptions causing many court cases.

369. Inclusion of enrolled pharmaceutical technologists under clause 63(2)(d) as part of persons who will be covered by a defence.

Justification: Pharmacy practice is usually the key target area by pharmaceutical companies.

370. Inclusion of enrolled pharmaceutical technologists under clause 66(3)(b) (ii) and (iii) as part of persons who will be covered by a defence.

Justification: Training of pharmaceutical technologist is a continuous process.

371. Insertion of the words ", an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in clause 95(2) (bb).

Justification: For inclusion of pharmaceutical technologists. Training of pharmaceutical technologist is a continuous process.

372. Provision of a timeframe within which parliament should enact the law on regulation of pharmacy practice in clause 96(3)(b).

Justification: The country needs the Pharmaceutical Technologists Council Bill for the regulation of pharmaceutical technologists.

3.2.19 DANIEL KIIRU MWANGI OF KIMANJO SUB-COUNTY HOSPITAL

In his memoranda, Mr. Mwangi made the following submissions:

373. Definition of an enrolled pharmaceutical technologist according to Article 26 of the Constitution.

Justification: A pharmtech is a trained health profession who is a member of a licensed body and regulated to provide technical expertise in the pharmacy profession. The Health Workforce Forecast Kenya (2013) notes that the ratio of pharmtechs to population is 14.8 to 100,000 while pharmacists is 5.3 to 100,000.

374. Inclusion of a pharmaceutical technologist in the definition of the word ***"pharmacist"***

Justification: The profession of pharmacy comprises of both pharmacists and pharmaceutical technologist.

375. Inclusion of pharmaceutical technologists in the business of retail pharmacy business.

Justification: Pharmaceutical technologists have been engaged in the business of retail pharmacy under the Pharmacy and Poisons Act, Cap. 244 in line with their scope of training.

376. The Director General should be a pharmacy professional.

Justification: A pharmacy professional understands the diversity of medicine and medical devices management from their knowledge and skills earned through their period of practice.

377. Increment of the number of professions in the Board from two to five to include the diverse fields of pharmacy such as quality assurance, pharmacovigilance, research institutions, industry and TVETs.

Justification: The Food and Drug Authorities of USA and other middle-income countries manage pharmaceuticals and non-pharms by pharmacy specialty.

378. Increment of the number of Pharmtechs in the Board from one to four drawn from TVETs, community practice, hospital practice and association or regulator.

Justification: To enhance cohesiveness in pharmacy practice. Pharmtechs are over 11,000.

379. Inclusion of pharmtechs in dispensing of multisource medicine.

Justification: Pharmtechs are healthcare professionals with expertise in pharmaceutical training. They also work in the rural areas which over 70% of the Kenyan population.

380. Inclusion of Pharmtechs in the provision of licence under sub-clause (4).

Justification: Section 12 of the Health Act, No. 21 of 2017 provides for inclusion of health professionals in the delivery of expert services.

381. Provision of one licence for pharmacy professions in sub-clause (3).

Justification: The current clause will create ambiguity in the pharmaceutical practice.

382. Inclusion of the holders of higher national diploma in clinical pharmacy, renal pharmacy and pharmacy to provide wholesale business services in clause 41(1)(b).

Justification: According to the Kenya National Qualification Authority, higher diploma in pharmacy is equivalent to a degree. These Diploma holders have the capacity, knowledge and skills.

383. Insertion of the words ", an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in clause 95(2) (bb).

Justification: For inclusion of pharmaceutical technologists. Training of pharmaceutical technologist is a continuous process.

3.2.20 PEST CONTROL PRODUCTS BOARD (PCPB)

In its memoranda, the PCPB proposed as follows:

384. The deletion of the words "***pesticides, insecticides, rodenticides and vermicides***" in the definition of the "chemical substances.

Justification: The current definition brings about confusion, overlap of mandate and duplicity of roles as pesticides, insecticides, rodenticides and vermicides are already regulated by the PCPB under the Pest Control Products Act, Cap. 346 and the Veterinary Medicines Directorate (VMD) under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011 for animal products.

385. The application and scope of the Bill in Clause 3(2) includes chemical substances which takes away the mandate of PCPB and Veterinary Medicines Directorate to regulate pesticides, insecticides, rodenticides and vermicides which are treated as chemical substances in clause 2 of the Bill.

386. The functions of the Authority relate to the regulation of HPTs which are defined in clause 2 and 3(2) as including chemical substances.

Justification: The clause takes away the mandate of PCPB and Veterinary Medicines Directorate to regulate pesticides, insecticides, rodenticides and vermicides treated as chemical substances in clause 2 of the Bill.

387. The Bill does not disclose what constitutes Scheduled Substances.

Justification: This may lead to overlap of regulation with other regulatory agencies.

388. Establishment of the National Food Safety Committee overlaps with the mandate of the National Food Safety Co-ordinating Authority.

Justification: A new National Food Safety Co-ordination Bill is currently being developed.

389. The PSCPB appreciates the importance of the Bill in addressing some weaknesses in the regulation of drugs however the Bill should not deal with pest control products which are regulated under the Pest Control Products Act, Cap. 346a d should be alive to the fact that regulation of chemical substances in Kenya is domiciled in many agencies as provided for in various statutes.

3.2.21 THE VETERINARY MEDICINES DIRECTORATE (VMD) IN THE MINISTRY OF AGRICULTURE AND LIVESTOCK DEVELOPMENT

In its memorandum, the VMD, whilst objecting to the Bill, submitted as follows:

390. Deletion of pesticide; insecticide; rodenticide; vermicide; or detergent in the definition of the word "chemical substances".

Justification: These are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

391. Deletion of the words "***or veterinary health benefits***" in the definition of ***"herbal medicine or product".***

Justification; These are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

392. Deletion of the words ***"or animals"*** in the definition of "medical device", "medicinal substance" and "medicine".

Justification: Animal medicines are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011

393. Deletion of the veterinary surgeon" or "veterinary practitioner".

Justification: Already defined under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

394. Deletion of the definition of "veterinary medicine".

Justification: Animal medicines are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

395. Deletion of the word "any" appearing in paragraph (a) and (b) and delete the words "or animals" in sub-paragraph (i) and (ii) in the definition of the word "drugs".

Justification: Veterinary medicines are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

396. Insertion of the word ***"human"*** immediately before the words "***health products and technologies***" in clause 3(1) and paragraphs (a), (c), (d), (e), (f), (g), (l) of clause 12.

Justification: To differentiate from animal health products and technologies which are regulated under other Acts.

Deletion of the words "***or Essential Veterinary Medicines List***" in clause 29(2) and deletion of clause 29(14)(b).

Justification: The Essential Veterinary Medicines List is prepared under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

397. Deletion of the word "Every "and "any" and substitution with the word "A" in clause 29(7), clauses 34(a) 47(1) and 47(3). 56(1) and (2) clause 59(1) and deletion of the word "*any*" in clause 29(6).

Justification: To exclude veterinary medicines.

398. Deletion of the words "and dealers in mining, agricultural or horticultural accessories" in clause 37(2)(a) and deletion of clause 38(1)(c), clause 40, clause 41(1)(c) .

Justification: To exclude mining, agricultural or horticultural accessories which are regulated under other statutes.

399. Deletion of the words "or veterinary surgeon" and "or veterinary treatment" in clause 41(1)(d), clause 43(1), 63(2)(c)., 63(3)(b) (i) and deletion of the words "or veterinary surgeon" in clause 41(2)(a)and clause 38 (1)(e).

Justification: Veterinary surgeons are regulated under the Veterinary Surgeon and Veterinary Paraprofessionals Act, No. 29 of 2011.

400. Deletion of the words "***and veterinary medical devices register,***" and the word "***all***" appearing in clause 55(1).

Justification: Veterinary medical devices are regulated under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

401. Delete the words "***or the British Veterinary Codex***" in clause 67(2)(b).

Justification: Veterinary codex is relevant for veterinary medicines which are regulated under the VSVP Act.

402. Deletion clause 79.

403. **Justification:** Animals and meat are regulated under the Animal diseases Act and Meat Control Act.

404. The memorandum of objects and reasons of the Bill is misleading.

Justification: International best practice requires separation of regulation of human and veterinary medicines.

405. Indicated that it objects the Bill for the following reasons—

a) Sessional Paper No. 2 on the National Livestock Policy, in paragraph 3.4.8, separated the regulation of veterinary medicines from that of human medicines and placed it under the ministry responsible for livestock affairs. The PPB appeared to lack capacity to handle the inordinate abuse and misuse of veterinary medicines in the country.

b) The VMD was established vide the Veterinary Surgeons and Veterinary Paraprofessionals Act, 2011 to regulate veterinary medicines under veterinary domain in line with international best practice under the World Organization for Animal Health (WOAH) which Kenya is a signatory. These laws were enacted in compliance with requirements of treaties ratified by Kenya namely World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, particularly Article 3, and the International Agreement for the Creation of World Organization for Animal Health, particularly Chapter 3.4 of the Terrestrial Animal Health Code. The Bill therefore deviates from the provisions of, and obligations under, these treaties, thereby also breaching the Constitution in Article 2(5) and Article 2(6).

c) The veterinary medicine profession is satisfied with the regulation of veterinary medicines under the Veterinary Surgeons and Veterinary Paraprofessionals Act (Veterinary Medicines Directorate Regulations) 2015.
d) Veterinary medicines pose public health risk through presence of their residues in food of animal origin such as milk, if withdrawal periods are not observed. Livestock also play a major role in the zoonotic diseases cycle.
e) The Bill is not addressing a felt need as there is in place adequate legislation, human resources and capacities to regulate matters drugs and pesticides.
f) The Bill is relating professionals from their central role in drugs matters and replacing them with a largely non-professional board.
g) The Bill is not implementing a known policy as no public policy precedes it.
h) No public participation was conducted during the development of the Bill as envisaged by the Constitution of Kenya 2010.
i) The VMD is the recognized National Regulatory Authority (NRA) for veterinary medicines under the East African Community Mutual Recognition Procedure (EAC-MRP) established for joint evaluations and inspections of manufacturing facilities.

3.2.22 AGROCHEMICALS ASSOCIATION OF KENYA (AAK)

In its memoranda, the AAK proposed as follows—

406. The deletion of the words "pesticides, insecticides and rodenticides" in the definition of the "chemical substances.

Justification: The Pest Control Products Act, Cap. 346 regulates pesticides and other public health products such as insecticides and rodenticides.

407. Deletion of clause 8(2)(f).

Justification: The Director of Veterinary services should be a Board Member of the Authority as he chairs the Veterinary Medicines Directorate Council (VMDC) domiciled in the State Department of Livestock. The Council regulates veterinary medicines under the Veterinary Surgeons and Veterinary Paraprofessionals (Veterinary Medicines Directorate) Regulations, 2015.

408. Deletion of everything in the Bill that relates to veterinary medicine, veterinarians and animals.

Justification: There is no *lacuna* in the regulation of veterinary medicine. Enactment of the Bill will present enforcement challenges such as increased licensing costs arising from double regulation due to duplication with the existing veterinary medicines regulatory framework. Veterinary products are best regulated under the State Department of Livestock rather than the Ministry of Health. The World Organization for Animal Health (WOAH) vide Article 3.4.11 of the Terrestrial Animal Health Code-10/08/2022 recommends the enactment of a veterinary law for the regulation of the manufacture, importation, wholesale, retail and usage of veterinary medicinal products anchored the Ministry that deals with animal diseases. Further, pharmacists under the Bill do not have capacity to regulate veterinary medicine practice and to handle pharmacovigilance, the practice of surveillance and monitoring of adverse events of veterinary medicines on animals following administration.

3.2.23 THE KENYA NATIONAL UNION OF PHARMACEUTICAL TECHNOLOGISTS (KNUPT)

In its memorandum, KNUPT submitted as follows:

409. Pharmaceutical technologists are left out in the key definition of pharmacy practice which is discriminatory and the definition of "enrolled pharmaceutical technologist" cross references the Pharmacy and Poisons Act, cap. 244.

Justification: The Pharmacy and Poisons Act, Cap. 244 to be repealed.

410. Deletion of paragraph (h) of clause 8(2) with the following new paragraph "(h) one person nominated by the Kenya Pharmaceutical Association"

Justification: For clarity on the institution to nominate the representative of pharmaceutical technologists in the KDA Board.

411. The Bill does not provide the transitional provisions on how practitioners practicing under the Pharmacy and Poisons Act, Cap. 242 will be regulated once the law is enacted.

412. The Bill includes one cadre (pharmacists) and discriminates against pharmaceutical technologists. The two cadres are not included at every level of the drug management cycle (from quantification, procurement, storage of products and technologies including their retailing and wholesaling). The Bill should further provide for a pharmaceutical technologist council.

Justification: The pharmaceutical technologist council to regulate more than 12,000 pharmaceutical technologists in the country.

3.2.24 THE KENYA MEDICAL ASSOCIATION (KMA)

In its memoranda, the KMA proposed the following amendments:

413. Insertion of the following new paragraph in clause 8(2) "(m) one person nominated by Kenya Medical Association".

Justification: The inclusion of KMA in the Kenya Drugs Board for representation of prescribers of drugs who will also give feedback on the quality, efficacy and safety of drugs.

414. Inclusion of KMA in the composition of the NQCL Board.

Justification: Pathologists who are members of KMA would be suitable leads in NQCL.

415. The PPB to be made the Pharmacy Practice Council and KMA to be member of its Board.

Justification: Inclusion of KMA for representation of prescribers of drugs who will also give feedback on the quality, efficacy and safety of drugs.

416. Inclusion of prescribers in all the scientific advisory committees.

Justification: Inclusion of doctors who will give feedback on the quality, efficacy and safety of drugs.

3.2.25 THE LAW SOCIETY OF KENYA (LSK)

417. In its memoranda, the LSK proposed the following amendments: The deletion of the word "if" and substitute therefor the word "of" in sub-paragraph (ii) in the definition of the word "drug".

Justification: This is to correct a typographical error.

418. Deletion of the words "Act. regulation under this" and substitute therefor the words "regulation under this Act" in sub-clause (f).

Justification: This is to correct a typographical error.

419. Under clause 21, the number of committee members for each advisory committee should be specified as well as the expertise that these members should have and where they should be drawn from.

Justification: The provision may be misused.

420. Under clause 29, a timeline within which an application for registration of a medicine is to be granted should be provided.

Justification: For accountability purposes.

3.2.26 THE KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY (KAPI)

421. In its memoranda, KAPI proposed the following amendments: The definition of borderline to be expanded.

Justification: The current definition (which provides that "borderline product" means a health product whose chemical characteristics and form may be categorized either as a medicine or a product such as a cosmetic depending on presence of certain substances and claim of their purpose) would pose a challenge with the regulator who may identify borderline as medicine.

422. The definition of a pharmacist to include both registered and licensed, not just registered only.

Justification: To require that a pharmacist is both licensed and registered.

423. The Chairperson and Director General of the Board to be a registered and licensed Pharmacist.

Justification: To require that a pharmacist is both licensed and registered.

424. It is impractical to disqualify a person who has been involved in the production, manufacture, importation or distribution from being a Board Member. Persons with over 10 years' experience have been involved in production, manufacture, importation and distribution

Justification: One can be involved in these activities without conflict of interest arising in their capacity as a Board Member provided that the declaration or statement of consent is provided.

425. Deletion of subsection 3,4,5,6 and 8 with regard to the grant of Market Authorization Licence on publication in the local dailies and limit publication to the authority's website. The forty-eight hours provided for recall of medicine by the Authority should be for communication of intended recall to the Market Authorization Licence Holder and not the recall process itself. The twenty-four hours for issuance of notice should be expanded to a more feasible duration. The KDA to prescribe procedures and standards for recall of medicines and health products.

Justification: The Board should approve the application and stop it at that and may publish the same on its website. Communications to be done in forty-eight hours while the actual operations of recall should be as per guidelines developed by the authority.

426. Dispensing of Schedule 2 drugs should not be limited to Pharmacists only but also extended to Pharmaceutical Technologists.

Justification: Pharmacy retail outlets are also manned by pharmaceutical technologists.

427. In PART VIII, the Bill should provide that the Authority shall prescribe procedure and standards for recall of medicines and health products waste which shall be in accordance with the standards and procedures prescribed by the World Health Organization., provide for the application for registration under this section shall be prepared and submitted by a qualified biomedical engineer, a registered pharmacist and all professionals with relevant medical training as may be prescribed, who is certified by the Authority, in the prescribed form, as a qualified agent for medical devices registration. Marking of conformity should be omitted in its entirety from the Bill.

Justification: The Authority to prescribe the standards for Medical Devices, not the Cabinet Secretary. Application should not be limited to biomedical engineers and registered Pharmacists only. Other qualified and relevant professionals to be incorporated. Conformity to set standards of medical devices is being regulated by Kenya Bureau of standards.

3.2.27 THE MINISTRY OF AGRICULTURE AND LIVESTOCK DEVELOPMENT

The Ministry submitted as follows:

428. The Bill should be limited to the regulation of human medicines and devices while the VMD is allowed to undertake its regulatory mandate over veterinary medicines.

Justification: Veterinary medicines are regulated under a standardized law on veterinary medicine based on WOAH templates

429. The Bill should exclude veterinary medicines from the scope and long title and remove all issues concerning the regulation of animal medicines and other veterinary inputs in all clauses including the definition of drugs, herbal medicine or products, section 29 and 43 and the Fourth Schedule on the Veterinary Medicines Committee.

Justification: The memorandum of objects and reasons makes reference to the WHO providing international standards on human health. It does not make reference to the Word Organization for Animal Health (WOAH) which provides standards on animal health and veterinary medicines. Distinct regulatory regimes for human and veterinary medicines is aligned to international good practice and standards and is backed by the Livestock Policy and the Veterinary Policy approved by the Cabinet in 2020. Deviating from this would expose Kenyans to violative drug residues in animals and animal products. It also makes Kenya non-complaint with Terrestrial and Aquatic Animal Health Codes of WOAH enforced under the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures.

430. From 1957 until six years ago, all veterinary medicines were regulated by PPB under Cap. 244, which is being replicated by the Bill. At the time, Kenya could not access lucrative markets for animal and animal products because of a weak regulatory regime for veterinary medicines.

Justification: This was subsequently addressed with the establishment of the VMD which regulates the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines and poisons.

431. The Bill should focus on human medicines utilized in hospital setups and allow the VMD to regulate veterinary medicines that are dispensed on farms and homesteads where only veterinary professionals have access and the necessary animal health training.

Justification: VMD and KDA as competent authorities will collaborate for the safety of Kenyan. The Food and Feed Safety Control Coordination Bill, 2022 will also address the coordination of safety of food for humans.

3.2.28 THE KENYA VETERINARY BOARD

The Kenya Veterinary Board submitted as follows:

432. The Bill as currently drafted is not implementable as Kenya as a signatory to the World Trade Organization (WTO) must abide by the rules-based trade under the WTO including the Agreement on Application for Sanitary and Phytosanitary Measures (SPS Agreement). Under this Agreement, Kenya may set its own laws and regulations, provided they are not in conflict with the provisions of this Agreement and they are based on the international guidelines and recommendations adopted by the Codex Alimentarius Commission (Codex).

Justification: Human medicines are regulated under the Pharmacy and Poisons Act, Cap. 244 by the PPB as provided in the national Pharmaceutical Policy and guided by WHO standards.

433. For effective regulation, veterinary medicines regulation was separated from human medicines in 2016 as provided in the Veterinary Policy and Livestock Policy. These medicines are regulated by the Veterinary Medicines Directorate through the Veterinary Medicines Regulations under the Veterinary Surgeons and Veterinary Paraprofessionals Act of 2011 guided by global standards set by the World Organization for Animal Health (WOAH).

434. The Bill needs to review the Pharmacy and Poisons Act, Cap. 244 to strengthen it to provide for effective regulation of human medicines and devices in line with the standards set by WHO devoid of any regard to regulating medicines and veterinary medicinal products.

435. The Veterinary Surgeons and Veterinary Paraprofessionals Act, 2011 and the Veterinary Medicines Regulations, 2015 should be reviewed for effective regulation of veterinary medicines and devices in line with the standards set by the World Animal Health Organization.

436. Legislative proposals that pose huge risks to critical sectors such as health and food security should be discouraged.

PART IV

4.0 COMMITTEE OBSERVATIONS

437. The Committee having considered the Kenya Drugs Authority Bill, 2022, National Assembly Bill No. 54 of 2022 and submissions from stakeholders made the following observations:

(a) The Bill expands the functions of the current Pharmacy and Poisons Board and reengineers the new regulator based on international best practice in regulation of human health products and technologies including therapeutic cosmetics. This reengineering will enable the country attain the recommended World Health Organization (WHO) maturity level 3;

(b) The Bill strengthens the functions of the National Quality Control Laboratory which will improve the quality of tests, analyses and research for quality control. This in turn ensures

that the health products and technologies used in the country meets international quality standards thereby guaranteeing patient safety. The Bill therefore fulfills the country's obligation in the war against poor quality medicines in line with its commitment under the recently ratified African Union establishment of the African Medicines Agency Treaty;

(c) The Bill strengthens the regulation of medicines by providing a comprehensive regulatory framework which enables the country to comply with good manufacturing practices as envisioned under the African Union Model Law on Regulation of Medical products. This ensures that health products and technologies used in the country are safe and effective in line with section 66 of the Health Act, No. 21 of 2017;

(d) The Bill also encourages local manufacturing of health products and technologies as espoused in the Kenya Universal Health Coverage Policy (2020-2030). The Bill is therefore in line with the government's plan of promoting local manufacturing especially in the pharmaceutical sector, a key contributor of Kenya's economy. The Bill will hasten the attainment of the government's vision for national economic transformation; and

(e) The Bill further improves the availability of health products and technologies and enhances access to priority health products and technologies. The Bill also improves the efficiency of operations, quality and pricing of medicines and vaccines which are key components and enablers for the successful realization of universal health coverage.

PART V

5.0 COMMITTEE RECOMMENDATIONS

Upon considering the Kenya Drugs Authority Bill, 2022, National Assembly Bill No. 54 of 2022 and submissions from stakeholders, the Committee recommends the following amendments:

Long Title

THAT the Long Title of 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 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: This 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: This 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.

CLAUSE 2

THAT Clause 2 of the Bill be amended by—

(a) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" in the definition of the term "article";

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

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

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

(c) deleting the words "pesticide; insecticide; rodenticide; vermicide; or detergent" in the definition of the word "chemical substances";

Justification: To exclude detergents which are used for cleaning inanimate objects and would not fall under the purview of the medicines' regulations. To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(d) in the definition of the word "drugs", by—

(i) deleting word "any" appearing in paragraph (a) and (b);

(ii) deleting the words "or animals" in sub-paragraph (i) and (ii); and

(iii) deleting the word "if" and substituting therefor the word "of" in sub-paragraph (ii).

Justification: Veterinary medicines are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(e) deleting the definition of "enrolled pharmaceutical technologist" and substituting therefor the following new definition—

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

(f) deleting the definition of "pharmaceutical technologist".

Justification: The current definitions of terms "enrolled pharmaceutical technologist" and "pharmaceutical technologist" cross references the Pharmacy and Poisons Act, cap. 244 which will be repealed as provided under clause 97. The Pharmacy and Poisons Act, cap. 244 provides that a pharmaceutical technologist must be enrolled.

(g) inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic" in the definition of the term "health products and technologies";

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

(h) deleting the definition of the word "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 human 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;

Justification: To expand the scope to include herbal materials and herbal combinations and to exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(i) deleting the definition of the term "medical device" and substituting therefor the following definition—

"medical device" 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 and/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.

Justification: To expand the scope to cover all aspects of the use of medical devices in relation to human health.

(j) Deleting the definition of the term "medicinal substance" and substituting therefor the following definition—

"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;

Justification: To expand the scope to cover all aspects of the use of medicinal substances in relation to human health.

(k) deleting the words "or animals" wherever it appears in the definition of the term "medicine";

Justification: Veterinary medicines are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

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

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

(m) deleting the definition of the word "pharmacy" and substituting therefor the following new definition—

"pharmacy" means either—
(a) the profession of pharmacy as carried out by registered pharmacists or enrolled pharmaceutical technologists; or
(b) the duly licensed premises from which pharmacy services are provided by a registered pharmacist or enrolled pharmaceutical technologist"

Justification: To provide for the two cadres in the pharmacy profession.

(n) deleting the definition of the term "registered midwife"

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

(o) deleting the words "or animals" in paragraph (c) in the definition of the term "substance recommended as a medicine";

Justification: Veterinary medicines are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(p) deleting the definition of the term "therapeutic cosmetic" and substitute therefor the following definition—

"therapeutic cosmetic" means a cosmetic which—

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

(b) contains a bioactive product formulated from an animal ingredient that may have visible and measurable short- or long-term effects on a person;

may include a product that may be absorbed through the skin or a mucous membrane.

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.

(q) deleting the definition of the terms "veterinary surgeon" or "veterinary practitioner";
(r) deleting the definition of "veterinary medicine";

Justification: Veterinary medicines are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(s) Insert the following new definition—
"Board" means the Board of the Authority established under section 8;

Justification: To identify the Board as used in the Bill.

(t) Inserting the following new definitions in proper alphabetical sequence—

"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;

"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;

"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;

"Centre" means the National Pharmacovigilance Centre;

"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, to 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 may contain one or more dietary ingredient and includes vitamins, minerals, herbs;

"falsified medical products" means the products that deliberately or fraudulently misrepresent their 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 including—

(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; and
(vii) advice given by product owner regarding the use of the device.

"health products" includes human medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products;

"health technologies" 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;

"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;

"passive surveillance" means not taking active measures to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importation" means the importation into Kenya, by a licensed importer of 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;
(d)

"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;

"premises" includes any land, any building, dwelling-place and any other place whatsoever; 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 products" means registered medical products that fail to meet either their quality standards or specifications, or both;

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

"vessel" means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means that are used to convey health products and technologies;

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

CLAUSE 3

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

(l) This Act applies to regulation of—

(a) human 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 heath 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 human health products and technologies.

CLAUSE 4

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

Justification: This accords with international best practice on the establishment of a centralized regulatory authority for human 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 by—

(a) deleting sub-clause (1) and (2) and substituting therefor the following new sub-clauses—

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

(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.

(b) deleting the word "four" appearing in sub clause (3) and substitute 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.

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

(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 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.

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.

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

Justification: The content included in the proposed sub-clause (1).

CLAUSE 7

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

Justification: To correct a minor error in drafting.

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 phrase "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.

(b) in sub clause (2) by—

(i) deleting the words "managerial" and substituting therefor the words "senior management" level in paragraph (a)(ii);

(ii) deleting paragraph (d), (e), (f), (g), (h), (i), (j), (k), (l) and substituting therefor the following new paragraphs—

(d) one person nominated by the Pharmaceutical Society of Kenya;
(e) one person nominated by the Kenya Pharmaceutical Association;
(f) one person nominated by the Kenya Medical Association;
(g) a 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;
(h) a person, not being a public officer, representing consumer protection nominated by the Consumer Federation of Kenya; and
(i) the Director General of the Authority who shall be the secretary and an *ex officio* member of the Board.

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

(3) The Cabinet Secretary shall appoint the members of the Board under subsection (e), (f), (g), (h) and (i).

Justification: The members of the Board Members are not State Officers and hence their appointment does not require approval by Parliament.

CLAUSE 9

THAT Clause 9 of the Bill be amended by deleting the entire clause.

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 paragraph (c) by deleting the words "section 12" and substituting therefor the words "section 11".

Justification: To correct the wrongful cross reference. Clause 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 word "human" immediately before the words "health products and technologies" in subclause (a);
(b) inserting the word "human" immediately before the words "health products and technologies" in subclause (c);
(c) inserting the word "human" immediately before the words "health products and technologies" in subclause (d);
(d) inserting the word "human" immediately before the words "health products and technologies" in subclause (e);

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(e) inserting the following new subclauses immediately after subclause (e)—

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

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

(f) deleting subclause (f) and substituting the following new subclause —

(f) ensure continuous monitoring of the safety of human 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.

(g) deleting subclause (g) and substituting therefor the following subclause—

(g) regulate clinical trials and ensure that clinical trial protocols of human 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.

(h) inserting the following new subclauses immediately after subclause (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.

(i) inserting the word "human" immediately before the words "health products and technologies" in subclause (l);

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(j) deleting subclause (n) and substituting therefor the following subclause —

(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.

(k) inserting a new subclause after subclause (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) carryout and promote research related to medicines and human 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.

(l) inserting the following new subclauses after clause (q)—

(qa) ensure that all human 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 all human 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 human health products and technologies;
(qd) maintain a register of all authorized human health products and technologies manually or electronically;

(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with either the single Convention on Narcotic drugs of 1961, the Convention on Psychotropic substances 1971 and 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 human 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 deleting subclause (a) and substituting therefor the following new subclauses —

(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;
(aa) adopt and implement any such internationally recognized good regulatory practices;
(ab) determine and implement effective and efficient reliance mechanism;
(ac)issue, suspend, withdraw or revoke any license or compliance certificate;
(ad) levy, collect and utilize fees for services rendered;
(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; and
(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 subclause (1) and substituting therefor the following new subclause—

There shall be established such scientific advisory committees of the Authority, appointed by the Board, for the effective performance of the functions of the Authority.

(b) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority" in subclause (3);

(c) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority" in subclause (4);

(d) in subclause (9) by—

(i) deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority"; and

(ii) deleting the words "and the Cabinet Secretary shall lay a copy of each report before Parliament" and substituting therefor the words "and the Board shall submit a copy of each report to the Cabinet Secretary".

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

Part IV

THAT the title of Part IV of the Bill be amended by deleting the expression "PART IV—MEDICINES" and substituting therefor the expression "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 subclause (1) by—

(i) deleting the words "sell any medicine" and substituting therefor the words "sell, manufacture, supply, distribute or dispense any health product and 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 with the following new paragraph—

(d) falsified.

Justification: For alignment with international best practice.

(b) in sub-clause (3) by—

(i) deleting the words "or animal" in paragraph (b);

(ii) deleting the word "medicine" and substituting therefor the words "health product or technology";

(iii) deleting the word "pharmaceutical product" and substituting therefor the words "health product or technology" paragraph (b);

(c) 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.

CLAUSE 23

THAT Clause 23 of the Bill be amended—

(a) by deleting the word "medicines" and substituting therefor the words "health products or technologies" in subclause (1)(a);
(b) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (1)(b); and
(c) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (1)(b).

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) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology" in subclause (1)
(b) by deleting the words "medicine" and "drug" and substituting therefor the words "health product or technology" in subclause (2);
(c) by deleting the word "medicine" and "drug" wherever it appears and substituting therefor the words "health product or technology" in subclause (3);
(d) 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.

(e) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three months" and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years" in subclause (4)(a);
(f) by deleting the words "two hundred thousand" and substituting therefor the words "two million" in subclause (4)(b); and

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

CLAUSE 25

THAT Clause 25 of the Bill be amended by deleting the entire clause.

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 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.

CLAUSE 27

THAT Clause 27 of the Bill be amended—

(a) by deleting the words "medicinal products" and substituting therefor the words "health products or technologies" in subclause (a);
(b) by deleting the words "medicinal products" and substituting therefor the words "health products or technologies" in subclause (b);
(c) by deleting the words "medicinal products" and "products" wherever it appears and substituting therefor the words "health products or technologies" in subclause (c);

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

(d) by inserting the following new clauses immediately after clause 27—

27A. Application for product license

(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 prescribe 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 has permanent residence or a company incorporated in Kenya.

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

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

(b) a copy of the manufacturing licence of the health product, 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 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;

(h) proof of ownership of the site for the manufacture of the health product, if 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.

27B. Processing of application for registration of health product or technology

(1) The Authority shall consider the application made under section 26A, 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;

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

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

(ii) the route of administering the health product;

(iii) the dosage of the health product;

(iv) the storage conditions of the health product;

(v) the contra-indications, the side effects and precautions,

(vi) if any of the health product; and

(vii) the package size of the health product.

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

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

(b) consider the evaluation report of an institution that has evaluated the health product.

(4) If the Authority is not satisfied as to the quality, safety efficacy and performance, or economic value of the health product, 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.

27C. Registration during emergency

(1) The Authority may, where it considers it necessary to protect public health or in the event of a threat to human life or health, the Authority, 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 sub section (1) shall apply to the Authority, in 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 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 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.

(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 medicinal products, 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.

27D. Authorization of unregistered health product or technology

(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 that is not registered.

(2) A health product 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 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 with the health product concerned;

(b) witnessed informed written consent document, where applicable;

(c) details of registration or pending registration of the health product with any other regulatory authority, if available;

(d) evidence of compliance of the manufacturer of the health product with good manufacturing practice standards as determined by the Authority;

(e) reasons why a registered health product 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) 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.

(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 when the authorization was issued;

(b) any adverse event report, whenever an adverse event occurs; and

(c) a progress report within thirty days after the completion or termination of the use of the health product.

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

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product 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 authorized under this rule 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 for the handling of applications of product licences by the Authority.

CLAUSE 28

THAT Clause 28 of the Bill be amended—

(a) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register" in subclause (1);
(b) by deleting the words "medicines register" and substituting therefor the words "health products and technologies register" in subclause (2);
(c) in the marginal note 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) by deleting the words "medicines or medical device" and "medicines" wherever it appears and substituting therefor the words "health product or technology" in subclause (1);
(b) by deleting the words "or Essential Veterinary Medicines List" and "or veterinary" in subclause (2);
(c) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology" in subclause (3);

(d) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology" in subclause (4);

(e) in subclause (6) by—

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

(ii) deleting the word "any".

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

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

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

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

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

(k) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (12);

(l) in subclause (14) by—

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

(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) deleting paragraph (b) of sub-clause (14).

(m) in the marginal note by deleting the words "medicines and medical devices" and substituting therefor the words "health products and technologies";

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(n) inserting the following new clauses immediately after clause 29—

29A. Authorization of health products and technologies

(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 any written authorization by the Authority; and

(b) the imported health products and technologies are inspected and verified by the inspectors of the Authority at the ports of entry before 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 which 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, 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 Registrar 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 to issue 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.

29B. Parallel importation of health products and technologies

(1) A person shall not parallel import 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 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 through the sourcing,

manufacturing, packaging, storage, transport and delivery to the health facility, institution or private practice where the health product or technology is used.

(4) A person who—

(a) is the holder of 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 a 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 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, and to make provision for parallel importation of health products and technologies.

CLAUSE 30

THAT Clause 30 of the Bill be amended—

(a) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (1);
(b) by deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology" in subclause (3)(b).

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) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (1);
(b) by deleting the word "medicine" and substituting therefor the words "health product or technology" in subclause (3)(c).

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 the word "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology" in subclause (1);
(b) by deleting the word "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology" in subclause (2);
(c) by deleting the word "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology" in subclause (4);
(d) by deleting the word "medicine or medical device" wherever it appears and substituting therefor the words "health product or technology" in subclause (5);

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 by deleting the word "medicine or medical device" and substituting therefor the words "health product or technology" in subclause (1);

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 by—

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

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and 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) in subclause (1) by—

(i) inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(ii) deleting the word "medicine" wherever it appears and substituting therefor the words "health product or technology";

(b) in subclause (2) by—

(i) inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(ii) deleting the word "medicine" and substituting therefor the words "health product or technology";

(c) in subclause (3) by—

(i) inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(ii) deleting the word "medicine" and substituting therefor the words "health product or technology";

(d) in subclause (4) by—

(i) inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";

(ii) 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 and for inclusion of pharmaceutical technologists in the dispensing of interchangeable multi-source medicine.

CLAUSE 36

THAT Clause 36 of the Bill be amended by—
(a) deleting clause 36;

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

(b) inserting the following new clause immediately after clause 36—

36A. Clinical trials
(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) Any 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 a 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 up a robust quality assurance system to ensure that the clinical trial is carried out in a manner that ensures the integrity of data generated, the safety and well-being of study participants.

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

(7) 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 title of Part V of the Bill be amended 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) by deleting the words "and dealers in mining, agricultural or horticultural accessories" in subclause (2)(a);

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

(b) by deleting subclause (4) and substituting therefor the following new subclause—

(4) 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.

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.

CLAUSE 38

THAT Clause 38 of the Bill be amended in subclause (1) by—

(a) deleting paragraph (c); and

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

(b) deleting the words "or veterinary surgeon" in paragraph (e).

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

CLAUSE 39

THAT Clause 39 of the Bill be amended—

(a) inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in clause (4).

Justification: For inclusion of pharmaceutical technologists in wholesale dealership in medicines and health technologies.

(b) deleting subclause (5) and substituting therefor the following new subclause—

(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 Clause 40 of the Bill be amended by deleting the entire clause.

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 subclause (1) by—

(i) inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist" in paragraph (b);

Justification: To give pharmaceutical technologists power to sell scheduled substances.

(ii) deleting paragraph (c);

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

(iii) deleting paragraph (e);

Justification: 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.

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

(d)a qualified medical practitioner or dentist for purposes of medical or dental treatment respectively;

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(v) deleting paragraph (f) and substituting therefor the following new paragraph—

(f) a licensed hospital, dispensary or similar institution or a person or institution concerned with scientific education or research where such hospital, dispensary, institution but it shall be an offence to sell Scheduled Substances to any of these unless a registered pharmacist or an enrolled pharmaceutical technologist is in direct control of the Scheduled Substances at the premises from which they are sold;

Justification: To give pharmaceutical technologists power to sell scheduled substances and to ensure that hospital facilities are licensed and employ pharmaceutical cadres.

(b) in subclause (2) by—

(i) deleting paragraph (b);
(ii) deleting paragraph (c);

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

(c) by deleting the subclause (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 by deleting the words "three years" and substituting therefor the words "one year" in subclause (3).

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—

(a) by deleting subclause (1) and substituting therefor the following new subclause—

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

Justification: To restrict dispensing of scheduled substances to authorized persons and to exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(b) by inserting the word "and" immediately after the word "supplied" in subparagraph (iii) of clause 43(1)(b) and deleting the word "and" immediately after the word "given" in subparagraph (iii) of clause 43(1)(b);

Justification: To correct a minor drafting error.

(c) by deleting paragraph (c) in subclause (1).

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

CLAUSE 45

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

45. Automatic machines

(1) An authorized seller may use an automatic machine to dispense over-the-counter Scheduled Substances.

(2) The Authority shall develop regulations on—

(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 Clause 46 of the Bill be amended by—

(a) deleting and substituting the following new clause—

46. Electronic sale of health products and technologies

(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 section (1) shall provide for—

(f) licensure of e-pharmacies;

(g) safety of the patient;

(h) verification of the identity and traceability of the patient;

(i) verification of the identity and traceability of the prescriber; and

(j) integrity, legitimacy and authenticity of the prescription 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 the 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 pertaining to this type of supply.

(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 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.

(b) inserting the following new clause immediately after clause 46—

46A. Dietary supplements

(1) A dietary supplement shall not—

(a) 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 prescribed guidelines 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 title of Part VI of the Bill be amended 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 subclause (1) by—
  (i) deleting the word "medicinal substance" and substituting therefor the word "health product;
  (ii) deleting the word "any" and substituting therefor the word "a";

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(b) deleting subclause (2) and substituting therefor the following new subclause—

(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 subclause (3) by—
  (i) deleting the word "medicinal substance" and substituting therefor the word "health product;
  (ii) deleting the word "any" and substituting therefor the word "a";

(d) in subclause (1) by deleting the word "medicinal substance" and substituting therefor the word "health product;

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(e) inserting the following new subclauses—

(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) 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 upon 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 clause as subclause (1) and inserting the following new subclauses—

(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 may 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 title of Part VII of the Bill be amended 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 Clause 51 of the Bill be amended by inserting the following new clauses—

51A. Information that is required to be displayed on the pack

(1) A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of therapeutic cosmetic;

(b) the net weight;

(c) all the cosmetic ingredients in the order of prominence but not including flavors or fragrances;

(d) the name and address of manufacturer;

(e) a warning statement; and

(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

51B. Manufacturing of cosmetics

(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 "to 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 deleting subclause (3) and substituting therefor the following new subclause—

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

(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 provide for a penalty for the offence of manufacturing or selling therapeutic cosmetics that contain prohibited ingredients and to allow for the making of regulations on use of prohibited ingredients in relation to therapeutic cosmetics.

Part VIII

THAT the title of Part VIII of the Bill be amended 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—

(a) in subclause (1)—

(i) inserting the words "and in-vitro diagnostics medical devices register" immediately after the words "human medical devices register";

Justification: To make provision for in-vitro diagnostics.

(ii) deleting the words "and a veterinary medical devices register" and deleting the word "all";

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

CLAUSE *56*

THAT Clause 56 of the Bill be amended by—

(a) inserting the words "falsified, falsely-labeled, counterfeited" in paragraph (c) of subclause (1).

Justification: To incorporate internationally accepted terminology.

(b) deleting the word "any" and substituting therefor the word "a" in subclause (1) and (2).

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

CLAUSE *58*

THAT Clause 58 of the Bill be amended by—

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

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

(b) inserting the following new subclause—

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

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.

(c) inserting the following new subclause immediately after subclause (3)—

(3) 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 require importers, distributors or dealers to keeping of records of medical devices submitted to the Authority.

CLAUSE 59

THAT Clause 59 of the Bill be amended by—

(d) inserting the words "unregistered establishments for medical devices and" immediately after the word "under" in subclause (1);

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

(e) deleting the word "any" and substituting therefor the word "a" in in subclause (1);

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(f) inserting the following new clause immediately after clause 59—

59A. Registration of Medical devices establishment

(1) Applications 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) If the Authority is satisfied that the application under subsection (1) meets the prescribed requirements, the Registrar 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; or

(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 (7), 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, if 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.

(g) inserting the following new Part immediately after the new subclause (3)—

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

60. Pharmacovigilance

The Authority shall through the National Pharmacovigilance Centre manage the national pharmacovigilance and post marketing surveillance system to 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.

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

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

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

The entities in subsection (4) shall submit safety information to the Authority in the prescribed manner.

The consumers, general public and health care professionals shall report adverse reactions and 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 title of Part XI of the Bill be amended 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 Clause 60 of the Bill be amended by—

(a) deleting and substituting clause 60 with the following new clause—

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

(h) 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;

(i) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(j) 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;

(k) field testing of regulated products using screening techniques;

(l) 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;

(m) 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;

(n) conducting research and training and providing high quality analytics and expert knowledge in the areas of medicinal products and active pharmaceutical ingredients; and

(o) 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 human 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 National Quality Control Laboratory shall—

(h) oversee and coordinate all operations and administration of the National Quality Control Laboratory and provide technical guidance on quality control;

(i) ensure timely quality control testing of all samples in conformity with national and international standards;

(j) co-ordinate and supervise the activities of the National Quality Control Laboratory including staff;

(k) collaborate with other laboratories, regulatory and law enforcement agencies, manufacturers of pharmaceutical and other health products to ensure quality in health products and technologies;

(l) handle appeals on test results;

(m) where the laboratory lacks capacity, subcontract laboratory testing services;

(n) advice the Authority on matters of testing and quality control over health products and technologies; and

(o) perform any other duties assigned by the Authority from time to time.

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.

CLAUSE 61

THAT Clause 61 of the Bill be amended by deleting the expression "Director-General" and substituting therefor the words "Director National Quality Control Laboratory" immediately after the words "signed by the" in subclause (1).

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 title of Part XII of the Bill be amended 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 62

THAT Clause 62 of the Bill be amended by inserting the word "human" immediately before the words "health product" in subclause (1) and (2).

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

CLAUSE 63

THAT Clause 63 of the Bill be amended—

(a) in subclause (1) 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.

(b) in subclause (2)—

(i) by deleting the words ", dentists and veterinary surgeons" and substituting therefor the words "and dentists" in paragraph (c);

(ii) by inserting the word "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" in paragraph (d);

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and 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 subclause (a) by—
  (i) deleting the word "article" and substituting therefor the words "health product or technology".
  (ii) deleting the word "extravagant,".

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

Justification: To ensure objectivity and to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment and

CLAUSE *66*

THAT Clause 66 of the Bill be amended—

(a) in subclause (1) (a) and (b) by deleting the words "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.

(b) in subclause (3) by—

  (i) renumbering clause (3) as clause (2).

Justification: To correct a typographical error.

  (ii) by deleting the words ", dentists and veterinary surgeons" and substituting therefor the words "and dentists" in paragraph (b)(i);

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

  (iv) by deleting the words "veterinary surgeons" and substituting therefor the words "enrolled pharmaceutical technologists" in paragraph (b)(iii);

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and 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) in subclause (1), (2) and (3) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(b) in the marginal note by 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.

(c) in subclause (2) by deleting the words "*or the British Veterinary Codex*" in paragraph (b).

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

(d) by deleting the words "two hundred thousand" and substituting therefor the words "one million";

(e) deleting the words "three hundred thousand" 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 Clause 68 of the Bill be amended by deleting the clause.
Justification: It is preferable to make provision for valid exemptions through regulations as opposed to providing defences to the offences relating to labeling of medicines.

CLAUSE 69

THAT Clause 69 of the Bill be amended by deleting the word "article" and "articles" and substituting therefor the words "health product or technology" and "health products and technologies" respectively.

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

Part XIII

THAT the title of Part XIII of the Bill be amended 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 by—

(a) deleting the words "or homoeopathic medicine, preparation or medical device" and substituting therefor the words "health products and technologies" in subclause (1); and

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

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 by—

(a) inserting the words "including a health product and technology for emergency use" immediately after the word "technology" in subclause (1);

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

(b) deleting the words "medicine or medical device product" and substituting therefor the words "health product or technology" in subclause (3); and

(c) deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies" in the marginal note.

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 by—

(a) deleting the words "drug, article" wherever it appears and substituting therefor the words "health product or technology" in subclause (1);

(b) deleting the words "drug or article" wherever it appears and substituting therefor the words "health product or technology" in subclause (2);

(c) deleting the words "drug or article" and substituting therefor the words "health product or technology" in subclause (3);

(d) deleting the words "drug or article" and substituting therefor the words "health product or technology" in subclause (4); and

(e) deleting the word "goods" and substituting therefor the words "health products and technologies" in the marginal note.

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

CLAUSE 75

THAT Clause 75 of the Bill be amended by deleting the words "or veterinary surgeon" in subclause (2).

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

CLAUSE 78

THAT Clause 78 of the Bill be amended by inserting the words "or enrolled pharmaceutical technologist" in subclause (1)(b).

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

CLAUSE 79

THAT Clause 79 of the Bill be amended by—

(a) deleting clause 79:

Justification: The function of inspection of animals intended for slaughter is outside the regulatory purview of the Authority.

(b) inserting the following new clause—

79. Inspection and verification of Health Products and Technologies at the Ports of Entry

(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: To enable 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 by—

(a) deleting the words "article" and "articles" wherever it appears and substituting therefor the words "health product or technology" and "health products and technologies" respectively in subclause (1), (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) inserting the words "or any other vessel" immediately after the word "vehicle" in paragraph (b) of subclause (1).

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

CLAUSE 81

THAT Clause 81 of the Bill be amended by deleting the entire clause.

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 Clause 82 of the Bill be amended by deleting the entire clause.

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

CLAUSE 83

THAT Clause 83 of the Bill be amended by deleting the entire clause.

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" and substituting therefor the words "health product or technology" in subclause (1) and (2).

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 by deleting paragraph (b) of subclause (1) and substituting therefor the following new subclause—

(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 by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology" in paragraph (c) in subclause (1).

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

Part XIV

THAT the title of Part XIV of the Bill be amended 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 the wordS "Consolidated Funds" and substituting therefor the words "Consolidated Fund" in paragraph (a).

Justification: For proper reference to the Consolidated Fund as designated under Article 206 of the Constitution.

CLAUSE 91

THAT Clause 91 of the Bill be amended by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General" in subclause (3) and (4).

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 title of Part XV of the Bill be amended 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 by—

(a) in subclause 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 "any" in paragraph (a)(iii) and paragraph (c);

(iv) deleting the word "any" and substituting therefor the word "a" in paragraph (b);

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

(vi) deleting the words "any drugs" and substituting therefor the words "health products or technologies" in paragraph (h);

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

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

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

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

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

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

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

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

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

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

(xv) deleting the words "dentist or veterinary surgeon" and substituting therefor the words "or dentist" in paragraph (aa);

(xvi) deleting the word "any" appearing in paragraph (a)

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011 and to harmonize the terms used in the Bill with the Title of the Bill as proposed for amendment.

(xvii) 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.

(xviii) deleting paragraph (ii);

Justification: The general provision on the making of regulations is set out in subclause (1)

(xix) inserting the following new paragraphs 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) good practices in the regulation of medical products;
(mm) inspections, licensure and certification of the manufacture of medical products by health facilities;
(nn) 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;
(oo) inspection and recognition of pharmaceutical quality control laboratories;
(pp) to regulate licit use of narcotic and psychotropic substances; and
(qq) to regulate parallel importation of medicines;

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.

(b) in sub-clause (3), by renumbering subclause (2) as subclause (3).
Justification: To correct the error in numbering in the clause.

CLAUSE 96

THAT Clause 96 of the Bill be amended by—
(a) in subclause (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) 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) in subclause (2), by deleting the subclause (2) and substituting therefor the following new paragraph—

(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 subclause (3), by deleting the word "twelve" 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 subclause (1).

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

SECOND SCHEDULE

THAT the Second Schedule of the Bill be amended by deleting the entire 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 Third Schedule of the Bill be amended by deleting the entire 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 the paragraph (1) to (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.

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 and veterinary medicine which are outside the scope of the Bill as amended.

FIFTH SCHEDULE

THAT the Fifth Schedule of the Bill be amended by deleting the words "The British Veterinary Codex..... (B.Vet.C)".

Justification: To exclude veterinary medicines which are regulated separate from human medicines under the Veterinary Surgeons and Veterinary Para-Professionals Act, No. 29 of 2011.

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.

SIGN.....DATE.....5/9/2023

HON. DR. ROBERT PUKOSE, MP
CHAIRMAN, DEPARTMENTAL COMMITTEE ON HEALTH.