REPUBLIC OF KENYA

THIRTEENTH PARLIAMENT – (THIRD SESSION)

THE NATIONAL ASSEMBLY

ORDERS OF THE DAY

TUESDAY, OCTOBER 15, 2024 AT 2.30 P.M.

ORDER OF BUSINESS

PRAYERS

1. Administration of Oath
2. Communication from the Chair
3. Messages
4. Petitions
5. Papers
6. Notices of Motion
7. Questions and Statements

8*. THE ETHICS AND ANTI-CORRUPTION COMMISSION (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 11 OF 2024)
(The Leader of the Majority Party and the Leader of the Minority Party)

Second Reading

(Question to be put)

9*. THE KENYA NATIONAL LIBRARY SERVICE BILL (NATIONAL ASSEMBLY BILL NO. 20 OF 2023)
(The Chairperson, Departmental Committee on Sports and Culture)

Second Reading

(Resumption of debate interrupted on Wednesday, October 9, 2024 – Afternoon Sitting)

10*. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO THE DIVISION OF REVENUE (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 38 OF 2024)
(The Chairperson, Budget and Appropriations Committee)

THAT, the **Senate amendments** to the Division of Revenue (Amendment) Bill (National Assembly Bill No. 38 of 2024) be now considered.

(Schedule of Senate Amendments to the Bill is published in the Notices)

*...../11**

11*. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO THE FOOD AND FEED SAFETY CONTROL CO-ORDINATION BILL (NATIONAL ASSEMBLY BILL NO. 21 OF 2023)
(The Leader of the Majority Party)

THAT, the **Senate amendments** to the Food and Feed Safety Control Co-ordination Bill (National Assembly Bill No. 21 of 2023) be now considered.

(Schedule of Senate Amendments to the Bill is published in the Notices)

12*. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO THE STATUTORY INSTRUMENTS (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 2 OF 2023)
(The Chairperson, Committee on Delegated Legislation)

THAT, the **Senate amendments** to the Statutory Instruments (Amendment) Bill (National Assembly Bill No. 2 of 2023) be now considered.

(Schedule of Senate Amendments to the Bill is published in the Notices)

13*. COMMITTEE OF THE WHOLE HOUSE

(i) Consideration of **Senate Amendments** to the Division of Revenue (Amendment) Bill (National Assembly Bill No. 38 of 2024)
(The Chairperson, Budget and Appropriations Committee)

(Subject to Order No. 10)

(ii) Consideration of **Senate amendments** to the Food and Feed Safety Control Co-ordination Bill (National Assembly Bill No. 21 of 2023)
(The Leader of the Majority Party)

(Subject to Order No. 11)

(iii) Consideration of **Senate amendments** to the Statutory Instruments (Amendment) Bill (National Assembly Bill No. 2 of 2023)
(The Chairperson, Committee on Delegated Legislation)

(Subject to Order No. 12)

(iv) The Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022)
(The Hon. Robert Pukose, M.P.)

(To resume from Clause 55)

*...../14**

14*. MOTION – FIRST REPORT ON THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS ON COMMITTEE REPORTS AND PUBLIC PETITIONS

(The Chairperson, Committee on Implementation)

THAT, this House **adopts** the First Report of the Select Committee on Implementation on the Implementation Status of Reports on Petitions and Resolutions passed by the House, *laid on the Table of the House on Thursday, 26th October 2023*.

(Resumption of debate interrupted on Thursday, September 19, 2024)
(Balance of time – 2 hours 12 minutes)

15*. MOTION – ALLEGED UNFAIR TRADE PRACTICES BY FOREIGN INVESTORS IN KENYA

(The Chairperson, Departmental Committee on Trade, Industry and Cooperatives)

THAT, this House **adopts** the Report of the Departmental Committee on Trade, Industry and Cooperatives on the Inquiry into Alleged Unfair Trade Practices by Foreign Investors in Kenya, *laid on the Table of the House on Thursday, 7th March 2024*.

16*. MOTION – SECOND REPORT ON EMPLOYMENT DIVERSITY AUDIT IN PUBLIC INSTITUTIONS

(The Chairperson, Committee on National Cohesion and Equal Opportunity)

THAT, this House **adopts** the Second Report of the Select Committee on National Cohesion and Equal Opportunity on the Employment Diversity Audit in Public Institutions, *laid on the Table of the House on Thursday, 21st March 2024*.

17*. MOTION – REPORT OF THE EXTRAORDINARY SESSION OF THE SIXTH PAN-AFRICAN PARLIAMENT (PAP)

(Member of the Pan-African Parliament)

THAT, this House **notes** the Report of the Kenya Delegation to the Extraordinary Session of the Sixth Parliament of the Pan-African Parliament, held in Midrand, South Africa, from 20th to 27th March 2024, *laid on the Table of the House on Thursday, 2nd May 2024*.

18*. THE EQUALISATION FUND (ADMINISTRATION) BILL (SENATE BILL NO. 14 OF 2023)

(The Chairperson, Departmental Committee on Finance and National Planning)

Second Reading

19*. MOTION – CONSIDERATION OF REPORTS ON FINANCIAL STATEMENTS OF STATE CORPORATIONS (NYANZA REGION)

(The Chairperson, Public Investments Committee on Governance and Education)

THAT, this House **adopts** the Report of the Public Investments Committee on Governance and Education on its Examination of the Reports of the Auditor-General on the Financial Statements of State Corporations (Nyanza Region) for the financial year 2018/2019, 2019/2020 and 2020/2021, *laid on the Table of the House on Thursday, 25th July 2024*.

20*. THE PUBLIC FINANCE MANAGEMENT (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 38 OF 2022)

(The Chairperson, Procedure and House Rules Committee)

Second Reading

21*. MOTION – THIRD REPORT ON CONSIDERATION OF THE AUDITED ACCOUNTS OF SPECIFIED STATE CORPORATIONS

(The Chairperson, Public Investments Committee on Social Services, Administration and Agriculture)

THAT, this House **adopts** the Third Report of the Public Investments Committee on Social Services, Administration and Agriculture on its consideration of the Report of the Auditor-General on the Financial Statements of the following State Corporations, *laid on the Table of the House on Tuesday, 30th July 2024*—

(i) Kenyatta National Hospital, FY 2018/2019 and 2019/2020;

(ii) Kenya Medical Supplies Authority, FY 2017/2018 and 2018/2019;

(iii) Kenya Veterinary Board, FY 2018/2019, 2019/2022 and 2020/2021;

(iv) National Authority for the Campaign against Alcohol and Drug Abuse, FY 2017/2018, 2018/2019, 2019/2020 and 2020/2021; and

(v) Kenya Broadcasting Corporation, FY 2000/2001, 2001/2002, 2002/2003, 2003/2004, 2004/2005, 2005/2006, 2006/2007, 2007/2008, 2008/2009, 2009/2010, 2010/2011, 2011/2012 and 2012/2013.

Denotes Orders of the Day

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*...../Notices**

NOTICES

I. SENATE AMENDMENTS TO THE DIVISION OF REVENUE (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 38 OF 2024)

It is notified that the Senate made the following amendments to Division of Revenue (Amendment) Bill (National Assembly Bill No. 38 of 2024) —

CLAUSE 2

Senate Amendment

THAT, Clause 2 be amended by deleting the clause and substituting therefor the following new clause—

Object.

2. The object of this Act is to amend the Division of Revenue Act (hereinafter referred to as the "principal Act") to provide for the downward revision of projected ordinary revenue.

CLAUSE 3

Senate Amendment

THAT, Clause 3 be deleted.

CLAUSE 4

Senate Amendment

THAT, Clause 4 amended by deleting the proposed new schedule and substituting therefor the following schedule—

SCHEDULE

(s.4)

ALLOCATION OF REVENUE RAISED NATIONALLY BETWEEN THE NATIONAL GOVERNMENT AND COUNTY GOVERNMENTS FOR THE 2024/25 FINANCIAL YEAR.

Type/Level of allocation	Amount in KSh.	**Percentage (%) of FY 2020/21 audited and approved Revenue i.e. KSh. 1,570,562,945,014**
A. Total Sharable Revenue	**2,631,418,000,000**	
B. National Government	**2,223,301,211,853**	
C. Equalization Fund	**8,000,000,000**	
Of which: a). 0.5 Per Centum	*7,852,814,725*	**0.50%**
b). Arrears	*147,185,275*	
D. County equitable share	**400,116,788,147**	**25.48%**

...../Notices(Cont'd)*

II. SENATE AMENDMENTS TO THE FOOD AND FEED SAFETY CONTROL CO-ORDINATION BILL (NATIONAL ASSEMBLY BILL NO. 21 OF 2023)

It is notified that the Senate made the following amendments to the Food and Feed Safety Control Co-ordination Bill (National Assembly Bill No. 21 of 2023) =

CLAUSE 22

Senate Amendment

THAT, Clause 22 of the Bill be amended in sub-clause (2) by deleteting the words "conduct risk management" appearing immediately after the words " the Controller may" and substituting therefor the words "advise on the appropriate risk management measures ".

(The Committee recommends approval of the Senate amendment)

CLAUSE 25

Senate Amendment

THAT, Clause 25 of the Bill be amended in sub-clause (3) by inserting the following new sub- clause—

3A. On receipt of the report under subsection (3)(b), the governor shall submit the report to the respective County Assembly.

(The Committee recommends approval of the Senate amendment)

FIRST SCHEDULE

Senate Amendment

THAT, the First Schedule be amended by inserting the following new items immediately after item no. 3 —

3A. Each county government department dealing with matters relating to agriculture;

3B. Each county government department dealing with matters relating to health;

(The Committee recommends rejection of the Senate amendment)

……../Notices(Cont'd)*

III. SENATE AMENDMENTS TO THE STATUTORY INSTRUMENTS (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 2 OF 2023)

It is notified that the Senate made the following amendments to the Statutory Instruments (Amendment) Bill (National Assembly Bill No. 2 of 2023) –

CLAUSE 2

Senate Amendment

THAT, Clause 2 of the Bill be amended by deleting the proposed new subsection (5) and substituting therefor the following new subsection —

(5) Where it comes to the attention of the Committee that a Cabinet Secretary responsible for a regulation making authority has failed to submit a statutory instrument in accordance with subsection (1), the Committee may, by a resolution, require the Cabinet Secretary to —

(a) publish a notice in the Gazette within seven days from the date of the resolution, to the effect that the statutory instrument is a nullity; and

(b) submit the published notice to Parliament.

(The Committee recommends approval of the Senate amendment)

CLAUSE 3

Senate Amendment

THAT, Clause 3 of the Bill be deleted.

(The Committee recommends approval of the Senate amendment)

CLAUSE 4

Senate Amendment

THAT, Clause 4 of the Bill be deleted.

(The Committee recommends approval of the Senate amendment)

CLAUSE 5

Senate Amendment

THAT, Clause 5 of the Bill be amended by deleting the clause and substituting therefor the following clause —

Amendment of section 19 of Cap 2A.

5. The principal Act is amended by deleting section 19 substituting therefor the following new section 19 —

5. The principal Act is amended by deleting section 19 substituting therefor the following new section 19 —

Requirements for publishing an annulment.

19. (1) Where Parliament has adopted a report or a resolution that a statutory instrument be annulled—

(a) the instrument shall stand annulled; and

(b) the Clerk of the relevant House shall publish the annulment in the Parliamentary website and shall convey the resolution of the House to the regulation making authority.

(2) Upon receipt of the communication from the Clerk in accordance with this section, the regulation making authority shall publish the annulment in the Gazette within fourteen days.

(The Committee recommends approval of the Senate amendment)

CLAUSE 6

Senate Amendment

THAT, Clause 6 of the Bill be deleted.

(The Committee recommends approval of the Senate amendment)

CLAUSE 7

Senate Amendment

THAT, Clause 7 of the Bill be amended by deleting the clause and substituting therefor the following clause —

Amendment of section 11 of Cap 2A.

7. Section 24 of the principal Act is amended in subsection (5) by deleting the words "twenty thousand shillings" appearing immediately after the words "penalty not exceeding" and substituting therefor the words "one million shillings".

(The Committee recommends approval of the Senate amendment)

...../Notices(Cont'd)*

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

1) Notice is given that the Chairperson of the Departmental Committee on Health intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

LONG TITLE

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

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

CLAUSE 1

THAT, Clause 1 of the Bill be amended by—

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

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

CLAUSE 2

THAT, Clause 2 of the Bill be amended—

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

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

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

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

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

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

(e) by deleting the definition of "enrolled pharmaceutical technologist";
(f) in the definition of "health products and technologies" by inserting the words, "dietary supplements" immediately after the words, "therapeutic cosmetics";
(g) by deleting the definition of "herbal medicine or product";
(h) by deleting the definition of "medical device";
(i) by deleting the definition of "medicinal substance";
(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";
(k) by deleting the definition of "pharmacy";
(l) by deleting the definition of "pharmaceutical technologist";
(m) by deleting the definition of "registered midwife";
(n) in the definition of "scheduled substance" by deleting the phrase "in the relevant schedule under this Act" and substituting therefor the phrase "in the list published by the Cabinet Secretary under section 37";
(o) by deleting the definition of "therapeutic cosmetic"; and
(p) by inserting the following new definitions in their proper alphabetical sequence—

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

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

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

"alternative medicine" means complementary medicine and includes a broad set of health care practices that are not part of Kenya's tradition and are not integrated into dominant health care system;

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

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

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

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

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

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

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

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

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

(b) device modification which may include—

(i) retrofit in accordance with the product owner's modification or design change;
(ii) permanent or temporary changes to the labelling or instructions for use;
(iii) software upgrades including those carried out by remote access;
(iv) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device;
(v) device exchange;
(vi) device destruction; or

(vii) advice given by product owner regarding the use of the device.

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

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

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

"Inspector of Drugs" means a person who is competitively recruited by the Authority as a drug inspector under this Act;

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

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

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

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

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;
(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies,

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

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

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

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

(a) patented health products under the applicable law;
(b) non-patented health products; or
(c) branded generic health products;

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

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

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

"Registrar" means the Director-General of the Authority appointed under section 6;

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

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

"traditional medicine" includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness;

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

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

"wholesale dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

CLAUSE 3

THAT, Clause 3 of the Bill be amended—

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

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

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

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

"(3) This Act shall not apply to the regulation of traditional medicine and alternative medicine."

CLAUSE 4

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

CLAUSE 5

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

CLAUSE 6

THAT, Clause 6 of the Bill be amended—

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

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

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

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

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

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

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

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

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

CLAUSE 7

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

CLAUSE 8

THAT, Clause 8 of the Bill be amended—

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

"(1) The management of the Authority shall vest in a Board appointed under this section."

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

"(2) The Board shall comprise—

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

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

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

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

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

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

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

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

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

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

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

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

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

"(3) The Cabinet Secretary shall appoint the members of the Board under subsection (2) (e), (f), (g), (h) and (i) by notice in the *Gazette*."

CLAUSE 9

THAT, the Bill be amended by deleting Clause 9.

CLAUSE 10

THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "section 12" appearing in paragraph (c) and substituting therefor the words "section 11".

CLAUSE 12

THAT, Clause 12 of the Bill be amended by—

(a) inserting the following paragraphs immediately after paragraph (e)—

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

(b) deleting paragraph (f) and substituting therefor the following new paragraph (f) —

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

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

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

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

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

(e) deleting paragraph (n) and substituting therefor the following new paragraph (n)—

"(n) appoint inspectors who hold a minimum of a diploma in pharmacy and conduct inspection, either by itself or through its agents, of manufacturing premises, medical devices establishments, importing and exporting agents, wholesalers, distributors, pharmacies, including those in health facilities and clinics, retail outlets and any other premises and vessels subject to regulation under this Act";

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

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

(g) inserting the following paragraphs after paragraph (q)—
"(qa) ensure that all health products and technologies manufactured in, imported into or exported from the country including through parallel importation conform to prescribed standards of quality, safety and efficacy;

(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;

(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;

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

(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;

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

CLAUSE 13

THAT, Clause 13 of the Bill be amended by—

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

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

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

"(aa) adopt and implement any such internationally recognized good regulatory practices;

(ab) determine and implement effective and efficient reliance mechanisms;

(ac)issue, suspend, withdraw or revoke any license or compliance certificate granted under this Act;

(ad) levy, collect and utilize fees for services rendered;

(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors;

(af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

CLAUSE 21

THAT, Clause 21 of the Bill be amended—

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

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

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";

(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9) —

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

PART IV

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

"PART III—HEALTH PRODUCTS AND TECHNOLOGIES"

CLAUSE 22

THAT, Clause 22 of the Bill be amended—

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

(b) in sub-clause (1) by—

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

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

"(d) is falsified,";

(c) in sub-clause (3) by—

(i) deleting the word "medicine" appearing in the opening sentence and substituting therefor the words "health product or technology"; and
(ii) deleting the words "pharmaceutical product" appearing in paragraph (b) and substituting therefor the words, "health product or technology".

CLAUSE 23

THAT, Clause 23 of the Bill be amended—

(a) in sub-clause (1) by—

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

(b) in sub-clause (2) by—

(i) deleting the words "one million" appearing in paragraph (a) and substituting therefor the words "two million"; and
(ii) deleting the words "two million" appearing in paragraph (b) and substituting therefor the words "five million".

CLAUSE 24

THAT, Clause 24 of the Bill be amended—

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

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

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

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

(d) in sub-clause (3) by–

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

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

(e) in sub-clause (4) by—

(i) deleting the phrase "one hundred thousand shillings or to imprisonment for a term not exceeding three months" appearing in paragraph (a) and substituting therefor the phrase "one million shillings or to imprisonment for a term not exceeding three years"; and

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

CLAUSE 25

THAT, the Bill be amended by deleting Clause 25.

CLAUSE 26

THAT, Clause 26 of the Bill be amended by—

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

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

CLAUSE 27

THAT, Clause 27 of the Bill be amended by—

(a) deleting the words "medicinal products" appearing in paragraph (a) and substituting therefor the words "health products or technologies";
(b) deleting the words "medicinal products" appearing in paragraph (b) and substituting therefor the words "health products or technologies"; and
(c) deleting paragraph (c) and substituting therefor the following new paragraph (c)—

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

NEW CLAUSES

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

Application for product licence.

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

(2) An applicant under subsection (1) shall—
(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Authority in the declaration page of the application form; and
(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is or has permanent residence or a company incorporated in Kenya.

(3) The application made under subsection (1) shall be accompanied by—
(a) a proposed label for use on the health product or technology;
(b) a copy of the manufacturing licence of the health product or technology, where applicable;

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

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

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

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

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

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

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

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

(i) a copy of the certificate of registration;

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

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

(k) proof that the applicant holds—

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

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

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

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

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

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

Processing of application for registration of health product or technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Registration during emergency.

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

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

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

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

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

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

(c) proof that the applicant holds—

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

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

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

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

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

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

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

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

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

Authorization of unregistered health product or technology.

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

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

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

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

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

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;

(b) written consent of the applicant, where applicable;

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

(6) Where the Authority issues an authorization under subsection (1), the person to whom the authorization is issued shall submit to the Authority—
(a) progress reports after every six months from the date of issuance of the authorization;
(b) any adverse event report, where an adverse event occurred; and
(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—
(a) impose any additional conditions;
(b) request additional information;

(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or
(d) withdraw the authorization to treat the patient.

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

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

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

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

CLAUSE 28

THAT, Clause 28 of the Bill be amended—

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

CLAUSE 29

THAT, Clause 29 of the Bill be amended—

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

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

(c) in sub-section (2) by deleting the phrase "Essential Medicines List or Essential Veterinary Medicines List" and substituting therefor the phrase "Kenya Essential Medicines List, Kenya Essential Diagnostics List, Kenya Essential Medical Supplies List and Kenya Essential Veterinary Medicine List";

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

(e) in sub-clause (4) by—

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

(ii) deleting paragraph (b) and inserting the following new paragraph—

"(b) that the applicant may, within a period of three months after the date of the notification, furnish the Registrar with the comments on the Authority's reasons for not being so satisfied."

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

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

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

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

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

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

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

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

(m) in sub-clause (14) by—

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

(ii) inserting the word "Kenya" immediately before the phrase "Essential Veterinary Medicines List" appearing in paragraph (b).

NEW CLAUSES 29A & 29B

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

Authorization of health products and technologies.

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

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

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

(2) A batch or lot of any registered product shall not be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product and official batch or lot release by the Authority in cases of biological therapeutics.

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

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests

performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the Authority for official batch or lot release in accordance with the prescribed regulations.

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

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

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

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

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

Parallel importation of health products and technologies.

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

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

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

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

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

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

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

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

(4) A person who—

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

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

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

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

CLAUSE 30

THAT, Clause 30 of the Bill be amended—

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

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

"(2A) A person who makes an application under this section shall provide reasons for the proposed amendments to the register."

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

CLAUSE 31

THAT, Clause 31 of the Bill be amended—

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

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

CLAUSE 32

THAT, Clause 32 of the Bill be amended—

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

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

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

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

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

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

(c) in sub-clause (4)–

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

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

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

CLAUSE 33

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

CLAUSE 34

THAT, Clause 34 of the Bill be amended—

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

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

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

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

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

"(1) A pharmacist or an enrolled pharmaceutical technologist may, in consultation with the person prescribing the health product or technology and the patient, dispense an interchangeable multi-source health product or technology instead of the health product or technology prescribed by a medical or dental practitioner, nurse or other person registered under the relevant statutes regulating health professionals."

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

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

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

CLAUSE 36

THAT, Clause 36 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "or products" immediately after the words "herbal medicine"; and

(b) in sub-clause (3) by inserting the phrase "and shall, on conviction be liable to a fine not exceeding one million shillings or imprisonment for a term not exceeding one year, or to both" immediately after the phrase "commits an offence".

NEW CLAUSE 36A

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

Clinical trials.

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

(2) An approval under subsection (1) shall only be granted by the Authority after approval by the relevant ethics body has been granted.

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

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

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

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

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

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

PART V

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

CLAUSE 37

THAT, Clause 37 of the Bill be amended—

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

(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)—

"(3) The Cabinet Secretary shall publish in the *Gazette* the list of scheduled substances prepared under subsection (1)."

(c) by renumbering sub-clause (3) as sub-clause (4);

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

"(5) The Authority shall at least once every two years, review the lists under subsection (3), or whenever necessary in the interest of public health and safety.

(6) Any modification of the list of scheduled substances prepared under this section shall be subject to the procedure provided in subsections (1), (2) and (3)."

CLAUSE 38

THAT, Clause 38 of the Bill be amended—

(a) in sub-clause (1) by—

(i) deleting the phrase "the Limitations prescribed by this sub-section" and substituting therefor the phrase "the following limitations";

(ii) deleting paragraph (c)

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

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

CLAUSE 39

THAT, Clause 39 of the Bill be amended—

(a) in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances";

(b) by deleting sub-clause (5) and substituting therefor the following new sub-clause (5)—

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

CLAUSE 40

THAT, the Bill be amended by deleting clause 40.

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1)—

(i) by deleting paragraph (c);

(ii) by deleting paragraph (e);

(b) in sub-clause (2) —

(i) by deleting paragraph (b)

(ii) by deleting paragraph (c); and

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

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

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

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

CLAUSE 43

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

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

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

(b) in paragraph (b) by—

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

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

(c) by deleting paragraph (c).

CLAUSE 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "five hundred thousand".

CLAUSE 45

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

Automatic machines.

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

(2) The Authority shall develop regulations on the—

(a) classes of substances permitted;

(b) quantities of substances to be dispensed;

(c) records of substances dispensed;

(d) location of automatic machines; and

(e) registration of automatic machines.

CLAUSE 46

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

Electronic sale of health products and technologies.

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

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

(a) licensure of e-pharmacies;

(b) safety of patients;

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

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

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

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

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

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

NEW CLAUSE 46A

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

Dietary supplements.

46A. (1) A dietary supplement shall—

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

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

PART VI

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

CLAUSE 47

THAT, Clause 47 of the Bill be amended—

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

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

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

(c) in sub-clause (3) by deleting the words "medicinal substance" and substituting therefor the words "health product;
(d) in sub-clause (4) by deleting the words "medicinal substance" and substituting therefor the words "health product";

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

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

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

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

CLAUSE 48

THAT, Clause 48 of the Bill be amended by—

(a) renumbering the existing provision as sub-clause (1); and
(b) inserting the following new sub-clauses immediately after the renumbered sub-clause (1)—

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

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

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

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

PART VII

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

NEW CLAUSE 50A

THAT, the Bill be amended by inserting the following new clause immediately after clause 50—

Information that is required to be displayed on the pack.

50A. (1) A person dealing in a therapeutic cosmetic shall indicate—

(a) the common name of the therapeutic cosmetic;

(b) the net weight of the theraupetic cosmetic;

(c) all the cosmetic ingredients in the order of prominence but not including flavours or fragrances;

(d) the name and address of the manufacturer of the therapeutic cosmetic;

(e) a warning statement; and

(f) a statement that the therapeutic cosmetic is capable of curing or treating any disease or medical condition.

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

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

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

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

CLAUSE 51

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

CLAUSE 52

THAT, Clause 52 of the Bill be amended by deleting the phrase "have a therapeutic effect or value shall be treated as a medicine" and substituting therefor the phrase "treat, diagnose or prevent disease, or affect the structure or functions of the body shall be treated as a health product or technology".

CLAUSE 54

THAT, Clause 54 of the Bill be amended by deleting sub-clause (3) and substituting therefor the following new sub-clause (3)—

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

PART VIII

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

CLAUSE 55

THAT, Clause 55 of the Bill be amended by deleting sub-clause (1) and substituting therefor the following new sub-clause—

"(1) The Registrar shall keep in the prescribed form a register of all medical devices approved by the Authority."

CLAUSE 56

THAT, Clause 56 of the Bill be amended by deleting sub-clause (1) and substituted therefor the following new sub-clause—

"(1) A person shall not sell any medical device that is—

(a) not registered by the Authority;

(b) adulterated;

(c) substandard, falsified, falsely labelled or counterfeited; or

(d) which fails to comply in any way with specifications of this Act or any other law."

CLAUSE 57

THAT, Clause 57 of the Bill be amended by inserting the phrase "and shall, on conviction be liable to a fine not exceeding two million shillings, or imprisonment for a term not exceeding three years, or to both" immediately after the words "commits an offence".

CLAUSE 58

THAT, Clause 58 of the Bill be amended—

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

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

"(3) The Authority shall receive from the Kenya Nuclear Regulatory Authority established under the Nuclear Regulatory Act, 2019 documented evidence of radiation required to enable a medical device perform its therapeutic and diagnostic functions and the intended purpose of the device, for issuance of a registration certificate for a medical device.

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

CLAUSE 59

THAT, Clause 59 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "unregistered establishments for medical devices and" immediately after the word "under"; and

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

"(3) A person who sells or supplies unapproved medical devices commits an offence and shall, on conviction be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both."

NEW CLAUSE 59A

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

Registration of medical devices establishment.

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

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

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

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

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

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

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

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

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

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

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

(b) cause the applicant to be notified that the applicant may, within a period of three months from the date of notification, furnish the Authority with additional relevant documentation or evidence in support of the application.

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

NEW PART VIII

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

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

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

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

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

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

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

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

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

PART XI

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

CLAUSE 60

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

Establishment of the National Quality Control Laboratory.

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

(a) the examination and testing of health products and technologies including vaccines and biopharmaceuticals and any material or substance from or with which and the manner in which drugs may be manufactured, processed

or treated and ensuring the quality control of drugs and medicinal substances;

(b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

(c) testing, on behalf of the Government, of locally manufactured and imported health products and technologies in the Kenyan market prior to marketing authorization, redistribution and post-distribution;

(d) providing technical support to local manufacturers and building their capacity in matters pertaining to quality control of regulated products through on site and off site training and laboratory assessments;

(e) conducting investigations into the quality and safety status of regulated products developing and administering a data bank on quality assurance of all health products and technologies and generating scientific evidence and reports on the quality and safety status of the registered products;

(f) conducting research and training and providing high quality analytics and expert knowledge in the areas of health products and technologies and active pharmaceutical ingredients; and

(g) developing and administering a data bank on quality assurance on behalf of the Authority.

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

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

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

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

(6) The Director of the National Quality Control Laboratory shall—

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

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

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

CLAUSE 61

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

PART XII

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

CLAUSE 63

THAT, Clause 63 of the Bill be amended—

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

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

CLAUSE 64

THAT, Clause 64 of the Bill be amended by—

(a) deleting the phrase "a medicine, drug, appliance or article" and substituting therefor the phrase "health product or technology"; and

(b) deleting the phrase "drug, appliance or article" and substituting therefor the phrase "health product or technology".

CLAUSE 65

THAT, Clause 65 of the Bill be amended—

(a) in paragraph (a) by—

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

(ii) deleting the word "extravagant,".

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

CLAUSE 66

THAT, Clause 66 of the Bill be amended—

(a) in sub-clause (1) by—

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

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

(b) in sub-clause (3) by—

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

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

CLAUSE 67

THAT, Clause 67 of the Bill be amended—

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

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

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

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

(b) in a case where the appropriate designation of each of the active constituents or ingredients is written, the appropriate quantitative particulars of the constituents or ingredients:

(1A) Subsection (1) shall not apply to a health product or technology made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person."

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

(d) in sub-clause (3) by—

(i) deleting the word "an article" appearing in the opening statement and substituting therefor the words "a health product or technology";

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

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

CLAUSE 68

THAT, the Bill be amended by deleting Clause 68.

CLAUSE 69

THAT, Clause 69 of the Bill be amended by—

(a) deleting the word "article" and substituting therefor the words "health product or technology"; and

(b) deleting the word "articles" and substituting therefor the words "health products and technologies".

PART XIII

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

CLAUSE 71

THAT, Clause 71 of the Bill be amended—

(a) in the marginal note by deleting the phrase "medicines or medical devices" and substituting therefor the phrase "health products and technologies"; and

(b) in sub-clause (1) by deleting the phrase "or homoeopathic medicine, preparation or medical device" and substituting therefor the phrase "health products and technologies".

CLAUSE 72

THAT, Clause 72 of the Bill be amended—

(a) in the marginal note by deleting the words "medicine or medical devices" and substituting therefor the words "health products and technologies";

(b) in sub-clause (1) by—

(i) deleting the words "a person" and substituting therefor the words "a registered pharmacist"; and

(ii) inserting the phrase "including a health product and technology for emergency use" immediately after the word "technology"; and

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

CLAUSE 73

THAT, Clause 73 of the Bill be amended—

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

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

(c) in sub-clause (2) by deleting the words "drug or article" wherever they appear and substituting therefor the words "health product or technology";

(d) in sub-clause (3) by deleting the words "drug or article"and substituting therefor the words "health product or technology"; and

(e) in sub-clause (4) by deleting the words "drug or article" and substituting therefor the words "health product or technology".

CLAUSE 79

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

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

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

(2) A person who imports a health product or technology and causes it to be released to the market without inspection and verification under subsection (1) commits an offence.

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

CLAUSE 80

THAT, Clause 80 of the Bill be amended—

(a) in sub-clause (1) by—

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

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

(b) in sub-clause (6) by deleting the word "article" and substituting therefor the words "health product or technology";

(c) in sub-clause (7) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

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

(e) in sub-clause (9) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

(f) in sub-clause (10) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";

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

(h) in sub-clause (12) by deleting the word "article" and substituting therefor the words "health product or technology".

CLAUSE 81

THAT, the Bill be amended by deleting Clause 81.

CLAUSE 82

THAT, the Bill be amended by deleting Clause 82.

CLAUSE 83

THAT, the Bill be amended by deleting Clause 83.

CLAUSE 85

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

CLAUSE 86

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

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

CLAUSE 87

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

PART XIV

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

CLAUSE 88

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

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

CLAUSE 90

THAT, Clause 90 of the Bill be amended in sub-clause (2) by deleting the words "think fit" appearing in paragraph (f) and substituting therefor the words "consider appropriate".

CLAUSE 91

THAT, Clause 91 of the Bill be amended—

(a) in sub clause (3) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General"; and

(b) in sub clause (4) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General".

CLAUSE 92

THAT, Clause 92 of the Bill be amended in sub-clause (2) by inserting the phrase ", with the approval of the Cabinet Secretary of the National Treasury" immediately after the word "may".

PART XV

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

CLAUSE 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—

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

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

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

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

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

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

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

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

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

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

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

(xi) deleting paragraph (bb) and substituting therefor the following new paragraph— "(bb) providing for the manner in which a pharmacist, an enrolled pharmaceutical technologist or a person otherwise authorized under this Act may dispense health products or technologies";

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

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

(xiii) deleting the words "generally, for giving effect to this Act" appearing in paragraph (ii);

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

"(jj) on pharmacovigilance and post market surveillance;

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

(ll) pricing of health products and technologies;

(mm) good practices in the regulation of health products and technologies;

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

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

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

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

(rr) to regulate parallel importation of health products and technologies;"

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

CLAUSE 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

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

"(d) all members and staff of the former Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any

rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the former Board."

(ii) inserting the following new paragraph immediately after paragraph (d)—

"(e) the staff of the Pharmacy and Poisons Board for the time being working in the directorate responsible for the regulation of health products and technologies shall be deemed to be staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as staff of the Pharmacy and Poisons Board."

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

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

(c) in sub-clause (3)—

(a) by deleting the word "twelve" appearing in the opening sentence and substituting therefor the words "twenty four";

(b) by inserting the following new paragraph immediately after paragraph (b)—

"(c) after the expiry of the period of twenty four months—

(i) the Pharmacy and Poisons Board shall be dissolved, and the provisions of subsection (1)(a), (b) and (c) shall, with the necessary modifications, apply; and

(ii) the remaining members and staff of the Pharmacy and Poisons Board shall be deemed to be members and staff of the Authority, and subject to the provisions of any rules made under this Act, shall continue in office for the period for which they were appointed as members and staff of the Pharmacy and Poisons Board."

CLAUSE 97

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

SECOND SCHEDULE

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

THIRD SCHEDULE

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

FOURTH SCHEDULE

THAT, the Bill be amended by deleting the Fourth Schedule and substituting therefor the following new Schedule—

FOURTH SCHEDULE (s. 21 (2))
SCIENTIFIC ADVISORY COMMITTEES

1. Human Health Products and Technologies Committee.
2. Pharmacovigilance Committee.
3. Cosmetics and Borderline Products Committee.
4. Clinical Trial Scientific Technical Advisory Committee.
5. Dietary Supplements Committee.
6. Digital Health and Technologies Committee.
7. Veterinary Health Products and Technologies Committee.

SEVENTH SCHEDULE

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

(a) deleting the word "Board" in the paragraph on Cap. 244
(b) deleting the phrase "(s. 116) and substituting the phrase ("s.97").
(c) deleting the paragraph on Cap. 254.

2) Notice is given that the Member for Mathare (Hon. Anthony Oluoch) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

LONG TITLE

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

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

CLAUSE 2

THAT, the Clause 2 of the Bill be amended—

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

(b) in the definition of the term "article" by—

(i) deleting the words "herbal medicine" appearing in paragraph (a); and

(ii) deleting the words "herbal medicine" appearing in paragraph (b);

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

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

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

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

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

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

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

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

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

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

CLAUSE 3

THAT, Clause 3 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraph (c); and
(b) by inserting the following new sub-clause immediately after sub-clause (2)—
(3) This Act shall not apply to the regulation of herbal medicines or products.

CLAUSE 6

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

CLAUSE 8

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

CLAUSE 12

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

CLAUSE 23

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

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

CLAUSE 29

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

CLAUSE 35

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

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36.

CLAUSE 39

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

CLAUSE 41

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

CLAUSE 42

THAT, Clause 42 of the Bill be amended by—

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

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

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

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

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

(c) renumbering sub-clause (2) as sub-clause (3); and
(d) renumbering sub-clause (3) as sub-clause (4).

CLAUSE 51

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

CLAUSE 54

THAT, the Bill be amended by deleting clause 54.

CLAUSE 63

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

3) Notice is given that the Member for Suba North (Hon. Millie Odhiambo-Mabona) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

CLAUSE 1

THAT, Clause 1 of the Bill be amended by deleting the phrase "Kenya Drugs Authority Act, 2022" and substituting therefor the phrase "Kenya Drug and Health Technologies Act, 2022".

CLAUSE 2

THAT, Clause 2 of the Bill be amended—

(q) in the definition of the word "drug" by inserting the words "herbal medicine" immediately after the words "any medicine" wherever it appears ;

(r) in the definition of the term "falsified medicines" by inserting the phrase ";" immediately after the words "of active or other ingredients";

(s) by deleting the definition of the term "health products and technologies" and substituting therefor the following new definitions—

"health products" means chemical substances, therapeutic cosmetics, herbal medicines, medicines, scheduled substances and related products and substances; and

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

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

"herbal medicine" means the use of plants to treat disease and enhance general health and wellbeing; and

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

(u) in the definition of the term "manufacture" by deleting the words "making a product or medicinal substance and includes" and substituting therefor the words "making a medicinal substance or product and includes extracting"

(v) in the definition of the term "registered midwife" by deleting the words "by law to practice the profession of midwife in Kenya" and substituting therefor the words "to practice as such under the Nurses and Midwives' Act";

(w) in the definition of the term "substandard medicines" by inserting the words "under this Act or any other written law" immediately after the words "defined specifications";

(x) in the definition of the term "therapeutic cosmetic" by deleting the words "or altering the complexion"

(y) inserting the following definition in the proper alphabetical sequence—

"alternative medicine" has the meaning assigned to it under the Health Act, 2017;

CLAUSE 7

THAT, Clause 7 of the Bill be amended by —

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

"(a) is a state officer";

(b) deleting paragraph (b); and

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

"(e) is a public officer".

CLAUSE 8

THAT, Clause 8 of the Bill be amended—

(a) in sub-clause (6) by—

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

"(a) is a state officer";

(ii) deleting paragraph (b);

(b) in sub-clause (7) by deleting the words "need for regional balance" and substituting therefor the words "need for youth representation, regional and ethnic balance".

CLAUSE 10

THAT, Clause 10 of the Bill be amended in sub-clause (1) by deleting the words "permission of the" appearing in paragraph (f) and substituting therefor the words "notifying the".

CLAUSE 12

THAT, Clause 12 of the Bill be amended by—

(a) deleting the word "ensure" appearing in paragraph (a) and substituting therefor the word "set";

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

"(b) ensure that there is compliance with existing legislation through a process of active inspection and investigation";

(c) deleting the word "being" appearing in paragraph (g); and

(d) inserting the words "chemicals, medicine" immediately after the words "rational use of" appearing in paragraph (o).

CLAUSE 13

THAT, Clause 13 of the Bill be amended by deleting the words "co-opt in such committees" appearing in paragraph (f) and substituting therefor the words "hire as consultants such".

CLAUSE 17

THAT, Clause 17 of the Bill be amended in sub-clause (2) by inserting the words "youth inclusion" immediately after the words "The principles of".

CLAUSE 21

THAT, Clause 21 of the Bill be amended by—

(a) inserting the following new sub-clause immediately after sub-clause (9)—

"(9A) The Board shall prepare and submit annually a report of its activities including that of any subcommittees to the Cabinet Secretary and the Cabinet Secretary shall submit the said report to parliament."

CLAUSE 22

THAT, Clause 22 of the Bill be amended —

(a) in sub-clause (2) by deleting the words "five years" appearing in paragraph (b) and substituting therefor the words "three years";

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

CLAUSE 24

THAT, Clause 24 of the Bill be amended —

(a) in sub-clause (3) by inserting the following new paragraph (c)—

"(c) is a herbal medicine";

(b) in sub-clause (4) by—

(i) deleting the words "one hundred" appearing in paragraph (a) and substituting therefor the words "five hundred"; and

(ii) deleting the words "two hundred thousand shillings or to imprisonment for a term not exceeding five years" appearing in paragraph (b) and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years".

CLAUSE 27

THAT, Clause 27 of the Bill be amended by—

(a) inserting the following new sub-clause (1)—

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

(b) renumbering the existing sub-clause (1) as sub-clause (2).

CLAUSE 28

THAT, Clause 28 of the Bill be amended in—

(a) sub-clause (1) by inserting the words "and herbal medicines" immediately after the word "medicines";

(b) sub-clause (2) by inserting the words "and herbal medicines" immediately after the word "medicines".

CLAUSE 29

THAT, Clause 29 of the Bill be amended—

(a) by inserting the following new sub-clause (1)—

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

(b) in the existing sub-clause (1) by inserting the words "herbal medicine" immediately after the word "medicine";

(c) in sub-clause (3) by inserting the words "or herbal medicine" immediately after the word "medicine" wherever it appears;

(d) in sub-clause (4) by inserting the words "or herbal medicine" immediately after the word "medicine";

(e) in sub-clause (6) by inserting the words "or herbal medicine" immediately after the word "medicine" wherever it appears;

(f) in sub-clause (7) by inserting the words "or herbal medicine" immediately after the word "medicine";

(g) in in sub-clause (8) by inserting the words "and herbal medicine" immediately after the word "medicine" wherever it appears;

(h) in sub-clause (9) by—
  (i) inserting the words "and herbal medicine" immediately after the word "medicine";
  (ii) inserting the words "under this Act or any other written law" immediately after the words" already registered";
(i) in sub-clause (12) by inserting the words "and herbal medicine" immediately after the word "medicine";
(j) by inserting the following new sub-clauses immediately after sub-clause 12 —

"(12A) The Authority may reject any application if the applicant fails to meet the standards as required by this Act or any other written law.

(12B) A person dissatisfied with the decision of the Registrar may appeal to the Board within sixty days.

(12C) Where a person is dissatisfied with the decision of the Board, the applicant may appeal to the High Court within thirty days from the date of the decision being communicated to him or her."

(k) in the existing sub-clause (13) by deleting the words "appropriate period referred to in sixty days" and substituting therefor the words " appropriate period of appeal".

CLAUSE 30

THAT, Clause 30 of the Bill be amended—
(a) in sub-clause (1) by inserting the words "or herbal medicine" immediately after the word "medicine" wherever it appears;
(b) in sub-clause (3) by inserting the words "or herbal medicine" immediately after the word "medicine" wherever it appears in paragraph (b);
(c) by inserting the following new sub-clause (3)—
"(3) The applicant shall provide reasons for the proposed amendments."

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

CLAUSE 31

THAT, Clause 31 of the Bill be amended in sub-clause (1) by inserting the words "or herbal medicine" immediately after the word "medicine".

CLAUSE 32

THAT, Clause 32 of the Bill be amended—

(a) in sub-clause (1), by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears;
(b) in sub-clause (2), by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears;
(c) in sub-clause (4) by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears;
(d) in sub-clause (5) by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears.

CLAUSE 33

THAT, Clause 33 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears;
(b) in sub-clause (2) by inserting the words "herbal medicine" immediately after the word "medicine" wherever it appears;
(c) by inserting the following new sub-clause immediately after sub-clause (2)—

"(2A) In the case of cancellation of registration of a herbal medicine, the Registrar shall in such case specify-

(a) the name under which the herbal medicine is registered;
(b) the active components of the herbal medicine;
(c) the name of the applicant;
(d) the name of the person who has propriety rights over the herbal medicine;
(e) the registration number allocated to the herbal medicine; and
(f) the conditions if any, subject to which that medicine is registered.

CLAUSE 35

THAT, Clause 35 of the Bill be amended in sub-clause (4) by inserting the following new paragraph (d)—

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

CLAUSE 36

THAT Clause 36 of the Bill be amended by deleting the words "on a commercial scale" appearing after the words "A person who" in sub-clause (1).

CLAUSE 40

THAT, Clause 40 of the Bill be amended—

(a) in sub-clause (4) by deleting the words "whose decision thereon shall be final":
(b) in sub-clause (7) by deleting the words "two hundred thousand shillings or to imprisonment for a term not exceeding two years" and substituting therefor the words "one million shillings or to imprisonment for a term not exceeding three years".

CLAUSE 41

THAT, Clause 41 of the Bill be amended in sub-clause (1) by inserting the words "enrolled pharmaceutical technologist and registered pharmacist" immediately after the word "practitioner" appearing in paragraph (d)

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (2) by deleting the words provided that where a person represents that he urgently requires a Schedule Substances for the purpose of his trade, business or profession and satisfies the seller that by reason of some emergency he is unable before delivery to furnish the order in writing, the seller may forthwith deliver the Scheduled Substances to the purchaser who will within twenty four hours of the sale furnish the seller with the written order" appearing in paragraph (a);
(b) in sub-clause (3) by deleting the words "one hundred thousand" and substituting therefor the words "one million"

CLAUSE 43

THAT, Clause 43 of the Bill be amended in sub-clause (3) by deleting the words "one hundred thousand" and substituting therefor the words "one million".

CLAUSE 44

THAT, Clause 44 of the Bill be amended in sub-clause (3) by deleting the words "two hundred thousand" and substituting therefor the words "one million".

CLAUSE 45

THAT, Clause 45 of the Bill be amended by deleting the words "five hundred thousand" and substituting therefor the words "one million".

CLAUSE 46

THAT, Clause 46 of the Bill be amended by deleting the word "This" and substituting therefor the words "The electronic supply of medicine".

CLAUSE 60

THAT, Clause 60 of the Bill be amended in sub-clause (1) (c) by inserting the words "medicinal herbs" immediately after the words "medicinal substances" wherever it appears.

CLAUSE 63

THAT, Clause 63 of the Bill be amended in sub-clause (1) by inserting the words "medicinal herbs" immediately after the word "medicine" wherever it appears.

CLAUSE 68

THAT, Clause 68 of the Bill be amended in sub-clause (1) by inserting the words "or herbal medicine" immediately after the word "medicine".

CLAUSE 71

THAT, Clause 71 of the Bill be amended in sub-clause (1) by inserting the words "or herbal medicine" immediately after the word "medicine".

CLAUSE 72

THAT, Clause 72 of the Bill be amended in sub-clause (3) by inserting the words "herbal medicine" immediately after the word "medicine".

CLAUSE 95

THAT, Clause 95 of the Bill be amended in sub-clause 2 by—

(a) inserting the words "and herbal medicines" immediately after the word "medicines" appearing in paragraph (v);
(b) inserting the words "herbal medicine" immediately after the word "medicine" appearing in paragraph (bb);
(c) inserting the words "herbal medicines" immediately after the word "medicines" appearing in paragraph (bb);
(d) deleting paragraph (dd) and substituting therefor the following new paragraph (dd)—

"(dd) the compounding of medicines and herbal medicines and the dispensing of medicines, herbal medicines and medical devices".

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph 1(1) by deleting the words "Cabinet Secretary" and substituting therefor the word "Board"; and
(b) in paragraph 2(1) by inserting the words "and herbal medicines" immediately after the words "human medicinal products".

4) Notice is given that the Member for Homa Bay Town (Hon. Peter Kaluma) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

CLAUSE 2

THAT, Clause 2 of the Bill be amended by—

(z) deleting the definition of "veterinary medicine";

(aa) deleting the definition of "enrolled pharmaceutical technologist" and substituting therefor the following new definition—

"enrolled pharmaceutical technologist" means a pharmaceutical technologist whose name appears on the Roll;"

(bb) by deleting the words "or material of inorganic or animal origin" in the definition of "herbal medicine or product".

CLAUSE 3

THAT, Clause 3 of the Bill be amended by deleting sub-clause (2).

CLAUSE 6

THAT, Clause 6 of the Bill be amended in—

(a) sub-clause (4) by inserting the words "established for regulation of pharmacy, medicine or engineering profession" immediately after the word "body" appearing in paragraph (d);

(b) deleting sub-clause (6);

(c) deleting sub-clause (8); and

(d) deleting sub-clause (9).

CLAUSE 7

THAT, Clause 7 of the Bill be amended —

(d) by deleting paragraph (a);

(e) by deleting paragraph (b); and

(f) in paragraph (d) by deleting the word "is" and substituting therefor the words "has been".

CLAUSE 8

THAT Clause 8 of the Bill be amended—

(a) in sub-clause (2) by inserting the words "medical practitioner or medical engineer" immediately after the word "pharmacist" appearing in paragraph (a)(ii);

(b) in sub-clause (6)—

(i) by deleting paragraph (a) and (b); and

(ii) in paragraph (e) by deleting the word "is" and substituting therefor the words "has been";

(c) in sub-clause (7) by deleting the words "regard shall be had of the need for regional balance and the realisation of the principle that at least one third of the members must be from either gender" and substituting therefor the words "regard shall be had to the need for ethnic and regional balance and the need to ensure that person of same biological sex shall not comprise more than two thirds of the members of the Board".

CLAUSE 10

THAT, Clause 10 of the Bill be amended by deleting sub-clause (2).

CLAUSE 13

THAT, Clause 13 of the Bill be amended in paragraph (c) by deleting the word "an" and substituting therefor the word "lawful".

CLAUSE 21

THAT, the Bill be amended by deleting Clause 21

CLAUSE 22

THAT, Clause 22 of the Bill be amended by inserting a new sub-clause (4) as follows—

"(4) Subsection (1) shall not apply to traditional medicines or products."

CLAUSE 31

THAT, Clause 31 of the Bill be amended in sub-clause (1) by deleting the words "who is duly licensed to practice the profession of pharmacy and holds a valid practising certificate to apply for the registration of a medicine".

CLAUSE 32

THAT, Clause 32 of the Bill be amended by deleting sub-clause (5).

CLAUSE 38

THAT, Clause 38 of the Bill be amended in sub-clause (1) by—

(a) deleting the words "on premises registered by the Authority" appearing in paragraph (b);

(b) deleting the words "for mining, agricultural or horticultural purposes" appearing in paragraph (c); and

(c) deleting the words "by a qualified medical practitioner, dentist or veterinary surgeon or by a hospital, dispensary or similar institution" appearing in paragraph (e);

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the words "a qualified pharmacist, medical practitioner or medical engineering practitioner or holder of diploma in pharmacy, pharmaceutical technology" immediately after the words "holding the licence is".

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(d) in sub-clause (1) by—

(i) inserting the words "or pharmaceutical technologist or dispensing chemist" immediately after the word "pharmacist" appearing in paragraph (b);
(ii) deleting the word "or veterinary" appearing in paragraph (d); and
(iii) by deleting the words "by an order whether general or special, of the Cabinet Secretary: but it shall be an offence to sell Scheduled substances to any of the persons or institutions specified in paragraphs (d) and (f) unless a registered pharmacist is in direct control of the scheduled substances at the premises from which they are sold"

(e) in sub-clause (2) by deleting the words "or veterinary surgeon' appearing in paragraph (a);

CLAUSE 43

THAT, Clause 43 of the Bill be amended in sub-clause (1) by deleting the words "or veterinary surgeon'.

CLAUSE 46

THAT, the Bill be amended by deleting the words "This" and substituting therefor the words "Electronic sale of medicines".

CLAUSE 81

THAT, the Bill be amended by deleting the words "or the Director of Veterinary Services, in relation to any matter appearing to affect the general interests of agriculture in Kenya".

CLAUSE 95

THAT, Clause 95 of the Bill be amended by in sub-clause 2 by deleting the words "or veterinary surgeon' appearing in paragraph (aa).

FOURTH SCHEDULE

THAT, the Bill be amended by deleting the Fourth Schedule

SEVENTH SCHEDULE

THAT, the Seventh Schedule of the Bill be amended by deleting the paragraph on No. 14 of 1994.

5) Notice is given that the Member for Rarieda (Hon. (Dr.) Otiende Amollo) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

CLAUSE 2

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

Cap. 244. "pharmacy" has the meaning assigned to it under the Pharmacy and Poisons Act.

CLAUSE 8

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

"(j)one person, not being a Governor, who is a registered pharmacist of good standing, nominated by the Council of Governors";

CLAUSE 39

THAT, the Clause 39 of the Bill be amended in the marginal note by deleting the words "Wholesale Dealer's Licence" and substituting therefor the word "Local Technical Representative Licence".

LIMITATION OF DEBATE

The House resolved on Wednesday, February 14, 2024 as follows—

Limitation of Debate on Bills sponsored by Parties or Committees

V. **THAT**, each speech in a debate on **Bills sponsored by a Committee, the Leader of the Majority Party or the Leader of the Minority Party** shall be limited as follows: A maximum of forty five (45) minutes for the Mover, in moving and fifteen minutes (15) in replying, a maximum of thirty (30) minutes for the Chairperson of the relevant Committee (if the Bill is not sponsored by the relevant Committee), and a maximum of ten (10) minutes for any other Member speaking, except the Leader of the Majority Party and the Leader of the Minority Party, who shall be limited to a maximum of fifteen minutes (15) each (if the Bill is not sponsored by either of them); and that priority in speaking shall be accorded to the Leader of the Majority Party, the Leader of the Minority Party and the Chairperson of the relevant Departmental Committee, in that order.

Limitation of Debate on the Senate Amendments to Bills originating in the National Assembly

VI. **THAT**, each speech in the general debate contemplated under Standing Order 146 (**Consideration of Senate amendments to Bills originating in the National Assembly**) shall be limited as follows:- a maximum of one hour and thirty minutes, with not more than fifteen minutes (15) for the Mover in moving, fifteen minutes (15) for the Chairperson of the relevant Departmental Committee, and five (5) minutes for any other Member speaking, including the Leader of the Majority Party and the Leader of the Minority Party (if the Bill is not party-sponsored), and that five (5) minutes before the expiry of the time, the Mover shall be called upon to reply; and further that priority in speaking shall be accorded to the Leader of the Majority Party, the Leader of the Minority Party and the Chairperson of the relevant Departmental Committee, in that order

Limitation of Debate on Other Committee Reports

VII. **THAT,** each speech in a debate on **Other Committee Reports**, including a Report of a Joint Committee of the Houses of Parliament or any other Report submitted to the House for which limitation of time has not been specified, shall be limited as follows:- A maximum of two and a half hours, with not more than twenty (20) minutes for the Mover in moving and five (5) minutes for any other Member speaking, including the Leader of the Majority Party and the Leader of the Minority Party and the Chairperson of the relevant Committee (if the Committee Report is not moved by the Chairperson of the relevant Committee), and that ten (10) minutes before the expiry of the time, the Mover shall be called upon to reply; and further that priority in speaking shall be accorded to the Leader of the Majority Party and the Leader of the Minority Party, in that order.

Limitation of Debate on Audit Committee Reports

VIII. **THAT**, each speech in debate on **Reports of Audit Committees** be limited as follows: A maximum of sixty (60) minutes for the Mover in moving and thirty (30) minutes in replying, and a maximum of ten (10) minutes for any other Member speaking, except the Leader of the Majority Party and the Leader of the Minority Party, who shall be limited to a maximum of fifteen (15) minutes each; and that priority be accorded to the Leader of the Majority Party and the Leader of the Minority Party, in that order.

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*……../Notice Paper I**

NOTICE PAPER I

Tentative business for

Wednesday (Morning), October 16, 2024

(Published pursuant to Standing Order 38(1))

It is notified that the following business is ***tentatively*** scheduled to appear in the Order Paper for Wednesday (Morning), October 02, 2024 –

A. PROCEDURAL MOTION – EXEMPTION OF BUSINESS FROM THE PROVISIONS OF STANDING ORDER 40(3)
(The Leader of the Majority Party)

B. MOTION: 006/2024 – COMPREHENSIVE REFORM OF EDUCATION BURSARY SCHEMES TO ENSURE FREE BASIC EDUCATION
(The Hon. Esther Passaris, M.P.)

(Resumption of debate interrupted on Wednesday, September 25, 2024 – Morning Sitting)

(Balance of time – 58 minutes)

C. MOTION - CONSIDERATION OF MEDIATED VERSION OF THE WATER (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 33 OF 2023)
(The Leader of the Majority Party)

D. THE KENYA INFORMATION AND COMMUNICATIONS (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 52 OF 2022)
(The Hon. Elisha Odhiambo, M.P.)

Second Reading

E. THE COMMUNITY HEALTH WORKERS BILL (NATIONAL ASSEMBLY BILL NO. 53 OF 2022)
(The Hon. Martin Peters Owino, M.P.)

Second Reading

F. THE HIGHER EDUCATIONS LOANS BOARD (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 58 OF 2022)
(The Hon. Joyce Kamene, M.P.)

Second Reading

G. MOTION: 028/2023 – ESTABLISHMENT OF A SCIENCE MUSEUM
(The Hon. John Kiarie, M.P.)

(Resumption of debate interrupted on Wednesday, October 2, 2024 – Morning Sitting)

(Balance of time – 1 hour 29 minutes)

H. MOTION: 033/2023 – SUPPORTING AND PROMOTING LOCAL FERTILIZER MANUFACTURING INDUSTRIES
(The Hon. Samuel Atandi, M.P.)

I. MOTION: 026/2023 – NATIONAL SENSITIZATION AND SUPPORT FOR COMBATING SICKLE CELL AND HAEMOPHILIA DISEASES
(The Hon. Peter Nabulindo, M.P.)

J. MOTION: 031/2023 – PROVISION OF APPROPRIATE ACCESS TO MARKETS IN THE COUNTRY
(The Hon. Beatrice Kemei, M.P.)

K. MOTION: 035/2023 – GOVERNMENT-TO-GOVERNMENT (G2G) MODEL FOR ACQUISITION AND SUPPLY OF FERTILIZERS TO FARMERS AT SUBSIDIZED COST
(The Hon. Geoffrey Ruku, M.P.)

L. MOTION: 038/2023 – DEVELOPMENT OF MEASURES TO MITIGATE DIGITAL EXCLUSION
(The Hon. Marianne Kitany, M.P.)

M. MOTION: 040/2023 – ESTABLISHMENT OF A NATIONAL POLICY TO COMBAT DISRESPECTFUL CHILDBIRTH PRACTICES IN KENYA
(The Hon. Gathoni Wamuchomba, M.P.)

N. MOTION: 044/2023 – FORMULATION OF A LAND USE POLICY ON ZONING OF LAND FOR AGRICULTURE AND BUILT DEVELOPMENT
(The Hon. Timothy Wanyonyi, M.P.)

O. MOTION: 039/2023 – FORMULATION OF A REGULATORY FRAMEWORK ON ARTIFICIAL INTELLIGENCE IN THE COUNTRY
(The Hon. Marianne Kitany, M.P.)

P. MOTION: 045/2023 – REVIEW OF THE ELIGIBILITY AGE FOR ENROLMENT OF OLDER MEMBERS OF SOCIETY TO THE *INUA JAMII* CASH TRANSFER PROGRAMME
(The Hon. Majimbo Kalasinga, M.P.)

Q. MOTION: 001/2024 – FORMULATION OF A REWARD SCHEME FOR ACCOMPLISHMENTS BY SPORTSPERSONS IN INTERNATIONAL COMPETITIONS
(The Hon. Charles Ngusya, M.P.)

R. **MOTION: 002/2024 –** **EXPANSION OF MAJOR ROADS IN THE COUNTRY TO DUAL CARRIAGEWAYS**
(The Hon. Faith Gitau, M.P.)

S. **HOJA: 003/2024 –** **UUNDAJI WA SERA ZA KUSHUGHULIKIA MATUKIO YA UBAGUZI DHIDI YA WANAFUNZI WA DINI MBALIMBALI KATIKA TAASISI ZA ELIMU NCHINI**
(Mhe. Mohamed Ali, M.P.)

T. **MOTION: 005/2024 –** **INTRODUCTION OF MANDATORY COMMUNITY SERVICE TO ALL LEARNERS UPON COMPLETION OF SECONDARY SCHOOL EDUCATION**
(The Hon. Amos Mwago, M.P.)

U. **THE PARLIAMENTARY POWERS AND PRIVILEGES (AMENDMENT) BILL (SENATE BILL NO. 37 OF 2023)**
(The Hon. Jack Wamboka, M.P. – *Co-Sponsor*)

Second Reading

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*...../Notice Paper II**

NOTICE PAPER II

Tentative business for

Wednesday (Afternoon), October 16, 2024

(Published pursuant to Standing Order 38(1))

It is notified that the following business is ***tentatively*** scheduled to appear in the Order Paper for Wednesday (Afternoon), October 16, 2024 –

A. THE KENYA NATIONAL LIBRARY SERVICE BILL (NATIONAL ASSEMBLY BILL NO. 20 OF 2023)
(The Chairperson, Departmental Committee on Sports and Culture)

Second Reading

(If not concluded on Tuesday, October 15, 2024)

B. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO DIVISION OF REVENUE (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 38 OF 2024)
(The Chairperson, Budget and Appropriations Committee)

(If not concluded on Tuesday, October 15, 2024)

C. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO THE FOOD AND FEED SAFETY CONTROLCO-ORDINATION BILL (NATIONAL ASSEMBLY BILL NO. 21 OF 2023)
(The Leader of the Majority Party)

(If not concluded on Tuesday, October 15, 2024)

D. MOTION – CONSIDERATION OF SENATE AMENDMENTS TO THE STATUTORY INSTRUMENTS (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 2 OF 2023)
(The Chairperson, Committee on Delegated Legislation)

(If not concluded on Tuesday, October 15, 2024)

E. COMMITTEE OF THE WHOLE HOUSE

(i) The Division of Revenue (Amendment) Bill (National Assembly Bill No. 38 of 2024)
(The Chairperson, Budget and Appropriations Committee)

(Subject to Order No. B)

(If not concluded on Tuesday, October 15, 2024)

(ii) Consideration of **Senate amendments** to the Food and Feed Safety Control Co-ordination Bill (National Assembly Bill No. 21 of 2023)
(The Leader of the Majority Party)

(Subject to Order No. C)

(If not concluded on Tuesday, October 15, 2024)

(iii) Consideration of **Senate amendments** to the Statutory Instruments (Amendment) Bill (National Assembly Bill No. 2 of 2023)
(The Chairperson, Committee on Delegated Legislation)

(Subject to Order No. D)

(If not concluded on Tuesday, October 15, 2024)

(iv) The Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022)
(The Hon. Robert Pukose, M.P.)

(If not concluded on Tuesday, October 15, 2024)

F. MOTION – FIRST REPORT ON THE IMPLEMENTATION STATUS OF HOUSE RESOLUTIONS ON COMMITTEE REPORTS AND PUBLIC PETITIONS
(The Chairperson, Committee on Implementation)

(If not concluded on Tuesday, October 15, 2024)

G. MOTION – ALLEGED UNFAIR TRADE PRACTICES BY FOREIGN INVESTORS IN KENYA
(The Chairperson, Departmental Committee on Trade, Industry and Cooperatives)

(If not concluded on Tuesday, October 15, 2024)

H. MOTION – SECOND REPORT ON EMPLOYMENT DIVERSITY AUDIT IN PUBLIC INSTITUTIONS
(The Chairperson, Committee on National Cohesion and Equal Opportunity)

(If not concluded on Tuesday, October 15, 2024)

I. MOTION – REPORT OF THE EXTRAORDINARY SESSION OF THE SIXTH PAN-AFRICAN PARLIAMENT (PAP)
(Member of the Pan-African Parliament)

(If not concluded on Tuesday, October 15, 2024)

J. THE EQUALISATION FUND (ADMINISTRATION) BILL (SENATE BILL NO. 14 OF 2023)
(The Chairperson, Departmental Committee on Finance and National Planning)

Second Reading

(If not concluded on Tuesday, October 15, 2024)

K. MOTION – CONSIDERATION OF REPORTS ON FINANCIAL STATEMENTS OF STATE CORPORATIONS (NYANZA REGION)
(The Chairperson, Public Investments Committee on Governance and Education)

(If not concluded on Tuesday, October 15, 2024)

L. <u>THE PUBLIC FINANCE MANAGEMENT (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 38 OF 2022)</u>
(The Chairperson, Procedure and House Rules Committee)

Second Reading

(If not concluded on Tuesday, October 15, 2024)

M. <u>MOTION</u> – <u>THIRD REPORT ON CONSIDERATION OF THE AUDITED ACCOUNTS OF SPECIFIED STATE CORPORATIONS</u>
(The Chairperson, Public Investments Committee on Social Services, Administration and Agriculture)

(If not concluded on Tuesday, October 15, 2024)

N. <u>MOTION</u> – <u>CONSIDERATION OF SESSIONAL PAPER NO. 5 OF 2023 ON THE NATIONAL POLICY ON LABOUR MIGRATION</u>
(The Chairperson, Departmental Committee on Labour)

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*...../Appendix**

APPENDIX

NOTICE OF PETITIONS, QUESTIONS & STATEMENTS

ORDER NO. 4 - PETITIONS

It is **notified** that, pursuant to the provisions of Standing Order 225, the following Petition will be presented –

No.	Subject	Petitioner(s)	Relevant Committee
17/2024	Failure of Insurance Regulatory Authority (IRA) to protect public transport operators on insurance claims	*To be presented by the Hon. Caleb Mule, MP (Machakos Town) on behalf of concerned citizens of Kenya*	Public Petitions

……../Appendix(Cont'd)*

ORDER NO. 7 - STATEMENTS

It is **notified** that, pursuant to the provisions of Standing Order 44(2)(c), the following Statements will be:

(a) requested—

No.	Subject	Member	Relevant Committee
1.	Accident caused by a Government vehicle in Isiolo County	*Hon. Mumina Bonaya, MP (Isiolo County)*	Administration and Internal Security
2.	School feeding programme by the National Council for Nomadic Education (NACONEK)	*Hon. Protus Akujah, MP (Loima)*	Education
3.	Submersion of learning institutions due to the rising water levels in Lake Turkana	*Hon. Joseph Lekuton, MP (Laisamis)*	Education
4.	Regulation of labour migration through private recruitment agencies	*Hon. Joshua Kandie, MP (Baringo Central)*	Labour
5.	Status of register of Government land	*Hon. (Dr.) Oundo Ojiambo, MP (Funyula)*	Lands

(b) responded to—

No.	Subject	Member	Relevant Committee
1.	Attack on civilians along the Kenya-Ethiopia border in Marsabit County	*Hon. Adhe Wario, MP (North Horr)*	Administration and Internal Security
2.	Land disputes in *Ndoleli-Athiru Ruujine-Kirugugu* Villages	*Hon. Daniel Karitho, MP (Igembe Central)*	Administration and Internal Security
3.	Insecurity in Kacheliba Constituency	*Hon. Titus Lotee, MP (Kacheliba)*	Administration and Internal Security
4.	Disparities in Kenya Defence Forces recruitment	*Hon. Wanami Wamboka, MP (Bumula)*	Defence, Intelligence and Foreign Relations
5.	Spillage of a highly poisonous substance in *Kabembe* area, *Rironi* Town	*Hon. John Kiragu, MP (Limuru)*	Environment, Forestry and Mining

..... /Notice of Questions*

NOTICE OF QUESTIONS

It is notified that, pursuant to the provisions of Standing Order 42A (6B), the **Cabinet Secretary for Roads and Transport** will respond to the following Questions in plenary on Wednesday (Afternoon), October 16, 2024–

QUESTION BY PRIVATE NOTICE

Que. No.	Member	Subject
QPN No. 013/2024	Hon. Wakili Edward, MP *(Gatanga)*	Status of any negotiations for a concession agreement between the Government and the *Adani* Group regarding the management of Jomo Kenyatta International Airport (JKIA).

ORDINARY QUESTIONS

Question No. 167/2023	Hon. Joshua Kandie, MP *(Baringo Central)*	Criteria used and applied by the Kenya Roads Board (KRB) to determine the amount of funds allocated to each Constituency.
Question No. 178/2023	Hon. Gonzi Rai, MP *(Kinango)*	Issuance of demolition notices against the *Mackinon* Road Trading Centre buildings by the Kenya National Highways Authority (KeNHA).
Question No. 013/2024	Hon. (Dr.) Ojiambo Oundo, MP *(Funyula)*	Current status of *Matayos-Ganjala-Nakhasiko-Nangina* road that was tendered under the 10,000KMS Low Volume Sealed Roads (LVSR) procured during the Financial Year 2017/2018.
Question No. 014/2024	Hon. Irene Njoki, MP *(Bahati)*	Status report on the progress and expected timelines for completion of the Lanet Airport Project.
Question No. 70/2024	Hon. Malulu Injendi, MP *(Malava)*	Progress report of construction of class *A1 Kakamega-Kaburengu Road* whose construction commenced in October 2012.

Question No. 71/2024	Hon. Timothy Wanyonyi, MP *(Westlands)*	Policy decision and rationale behind the use of unmarked, unregistered and distorted plates by the Police Service while on public missions on public roads.
Question No. 79/2024	Hon. Robert Basil, MP *(Yatta)*	Reasons behind significant delay in the completion of construction of the *Matuu-Ekalakala-Kiwandini* road to *Kyasioni* road in Yatta Constituency.
Question No. 127/2024	Hon. Sarah Korere, MP *(Laikipia North)*	Reasons for delay in completion of construction works on *Doldol-Nanyuki* road in Laikipia North Constituency.
Question No. 131/2024	Hon. Rael Kasiwai, MP *(West Pokot County)*	Rationale behind the stalling of *Barpelo-Tot-Marich* Road project and the expected date of commencement of the stalled project.
Question No. 132/2024	Hon. Samuel Parashina, MP *(Kajiado South)*	Details on the status of construction of the *Illasit-Rombo-Taveta* road.
Question No. 133/2024	Hon. Kassim Tandaza, MP *(Matuga)*	Update on the progress of construction of *Kwale - Kinango (B92)* road.