REPUBLIC OF KENYA

THIRTEENTH PARLIAMENT – (SECOND SESSION)

THE NATIONAL ASSEMBLY

ORDERS OF THE DAY

TUESDAY, OCTOBER 24, 2023 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*. COMMITTEE OF THE WHOLE HOUSE

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

9*. MOTION – REPORTS OF THE AUDITOR-GENERAL ON THE FINANCIAL STATEMENTS FOR THE NATIONAL GOVERNMENT CONSTITUENCIES DEVELOPMENT FUND FOR TWELVE CONSTITUENCIES IN KAKAMEGA COUNTY
(The Chairperson, Decentralized Funds Accounts Committee)

THAT, this House **adopts** the Report of the Decentralized Funds Accounts Committee on its consideration of the Reports of the Auditor-General on the Financial Statements for the National Government Constituencies Development Fund for twelve constituencies in Kakamega County for Financial Years 2013/2014, 2014/2015 and 2015/2016, *laid on the Table of the House on Thursday, 27th July 2023.*

(Resumption of debate interrupted on Thursday, October 19, 2023)

10*. MOTION – 1970 UNESCO CONVENTION ON THE MEANS OF PROHIBITING AND PREVENTING THE ILLICIT IMPORT, EXPORT AND TRANSFER OF OWNERSHIP OF CULTURAL PROPERTY

(The Chairperson, Departmental Committee on Sports and Culture)

THAT, this House **adopts** the Report of the Departmental Committee on Sports and Culture on its consideration of the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, *laid on the Table of the House on Thursday, 12th October 2023* and pursuant to the provisions of section 8 (4) of the Treaty Making and Ratification Act, 2012, **approves** the *ratification of the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property*.

11*. MOTION - INSPECTION OF VARIOUS ONE STOP BORDER POSTS IN THE NORTHERN CORRIDOR IN THE EAST AFRICAN COMMUNITY

(The Chairperson, Select Committee on Regional Integration)

THAT, this House **adopts** the Report of the Select Committee on Regional Integration on its Inspection of Various One-Stop Border Posts in the Northern Corridor in the East African Community, *laid on the Table of the House on Wednesday, 5th July 2023*.

12*. MOTION - SESSIONAL PAPER NO. 1 OF 2023 ON KENYA NATIONAL POPULATION POLICY FOR SUSTAINABLE DEVELOPMENT

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

THAT, this House **adopts** Sessional Paper No. 1 of 2023 on Kenya National Population Policy for Sustainable Development, *laid on the Table of the House on Wednesday, 4th October 2023*.

13*. MOTION - THE 4TH GENERAL ASSEMBLY OF THE EASTERN AFRICA PARLIAMENTARY ALLIANCE ON FOOD SECURITY AND NUTRITION (EAPA-FSN) HELD IN KIGALI, RWANDA

(The Chairperson, EAPA-FSN Caucus)

THAT, this House **notes** the Report of the Kenya Delegation to the 4th General Assembly of the Eastern Africa Parliamentary Alliance on Food Security and Nutrition, held in Kigali, Rwanda from 7th to 9th December 2022, *laid on the Table of the House on Tuesday, 11th April 2023*.

…… ……/14*

14*. **MOTION – LOANS CONTRACTED BY THE NATIONAL GOVERNMENT BETWEEN MAY 2022 AND APRIL 2023**

(The Chairperson, Public Debt and Privatization Committee)

THAT, this House **adopts** the Report of the Public Debt and Privatization Committee on its consideration of the loans contracted by the National Government between May 2022 and April 2023, *laid on the Table of the House on Thursday, 28th September 2023*.

15*. **MOTION – REPORTS OF THE AUDITOR-GENERAL ON TWENTY-THREE NON-COMPLIANT STATE CORPORATIONS**

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

THAT, this House **adopts** the Report of the Public Investments Committee on Social Services, Administration and Agriculture on its consideration of the Report of the Auditor-General on twenty-three Non-Compliant State Corporations, *laid on the Table of the House on Wednesday, 23rd August 2023*.

16*. **MOTION – PROCEEDINGS OF THE SECOND ORDINARY SESSION OF THE SIXTH PAN-AFRICAN PARLIAMENT (PAP)**

(Member of the Pan-African Parliament)

THAT, this House **notes** the Report of the Record of Proceedings of the Second Ordinary Session of the Sixth Pan-African Parliament (PAP) held in Midrand, South Africa, from 15th May to 2nd June 2023, *laid on the Table of the House on Thursday, 24th August 2023*.

17*. **MOTION – PROCEEDINGS OF THE 2023 UNITED NATIONS HIGH LEVEL POLITICAL FORUM ON SUSTAINABLE DEVELOPMENT**

(The Vice Chairperson, Parliamentary Caucus on Sustainable Development Goals (SDGs) and Business)

THAT, this House **notes** the Report of the Parliamentary Caucus on Sustainable Development Goals (SDGs) and Business on the Proceedings of the 2023 United Nations High Level Political Forum on Sustainable Development (HLPF 2023) held in New York, United States of America (USA) from 10th to 21st July 2023, *laid on the Table of the House on Thursday, 24th August 2023*.

…..…..*/18**

18*. THE NATIONAL GOVERNMENT CONSTITUENCIES DEVELOPMENT FUND (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 13 OF 2023)

(The Leader of the Majority Party and the Leader of the Minority Party)

Second Reading

19*. THE CONFLICT OF INTEREST BILL (NATIONAL ASSEMBLY BILL NO. 12 OF 2023)

(The Leader of the Majority Party)

Second Reading

Denotes Orders of the Day

NOTICES

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

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

LONG TITLE

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

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

CLAUSE 1

THAT, Clause 1 of the Bill be amended by—

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

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

CLAUSE 2

THAT, Clause 2 of the Bill be amended—

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

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

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

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

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

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

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

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

(g) by deleting the definition of "herbal medicine or product";

(h) by deleting the definition of "medical device";

(i) by deleting the definition of "medicinal substance";

(j) in the definition of "package" by inserting the words "dietary supplement" immediately after the words "therapeutic cosmetic";
(k) by deleting the definition of "pharmacy";
(l) by deleting the definition of "pharmaceutical technologist";
(m) by deleting the definition of "registered midwife";
(n) in the definition of "scheduled substance" by deleting the words "in the relevant schedule under this Act" and substituting therefor the words "in the list published by the Cabinet Secretary under section 37 of this Act";
(o) by deleting the definition of "therapeutic cosmetic"; and
(p) by inserting the following new definitions in their proper alphabetic sequence—

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

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

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

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

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

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

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

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

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

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

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

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

(b) device modification which may include—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"therapeutic cosmetic" means a cosmetic which—

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

(b) contains a bioactive product formulated from an animal ingredient that may have visible and measurable short or long-term effects on a person,

and may include a product that may be absorbed through the skin or a mucous membrane;

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

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

CLAUSE 3

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

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

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

CLAUSE 4

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

CLAUSE 5

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

CLAUSE 6

THAT, Clause 6 of the Bill be amended—

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

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

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

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

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

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

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

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

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

CLAUSE 7

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

CLAUSE 8

THAT, Clause 8 of the Bill be amended—

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

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

"(2) The Board shall comprise—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAUSE 9

THAT, the Bill be amended by deleting Clause 9.

CLAUSE 10

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

CLAUSE 12

THAT, Clause 12 of the Bill be amended by—

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

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

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

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

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

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

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

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

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

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

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

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

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

(qb) enforce the prescribed standards of quality, safety and efficacy of health products and technologies manufactured, imported into or exported out of the country;
(qc) grant or revoke licenses and permits for the manufacture, importation, exportation, distribution and sale of health products and technologies;
(qd) maintain a register of all authorized health products and technologies manually or electronically;
(qe) regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic substances,1971 or the United Nations Convention against Illicit Traffic of Precursor Chemical Substances, 1988;
(qf) inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies including those in hospitals and clinics and other retail outlets;"

CLAUSE 13

THAT, Clause 13 of the Bill be amended by—

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

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

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

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

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

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

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

(ae) grant or withdraw licenses and permits to manufacturers, wholesalers, retailers, importers, exporters and distributors; (af) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products".

CLAUSE 21

THAT, Clause 21 of the Bill be amended—

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

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

(b) in sub-clause (3) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(c) in sub-clause (4) by deleting the words "Cabinet Secretary" and substituting therefor the words "Board of the Authority";
(d) by deleting sub-clause (9) and substituting therefor the following new sub-clause (9) —
"(9) An advisory committee shall submit, at least once every six months, a report to the Board of the Authority, with respect to its activities and the Board shall submit a copy of each report to the Cabinet Secretary".

PART IV

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

PART III—HEALTH PRODUCTS AND TECHNOLOGIES

CLAUSE 22

THAT, Clause 22 of the Bill be amended—

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

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

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

"(d) is falsified,";

(c) in sub-clause (3) by—

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

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

CLAUSE 23

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

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

CLAUSE 24

THAT, Clause 24 of the Bill be amended—

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

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

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

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

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

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

CLAUSE 25

THAT, the Bill be amended by deleting Clause 25.

CLAUSE 26

THAT, Clause 26 of the Bill be amended by—

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

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

CLAUSE 27

THAT, Clause 27 of the Bill be amended—

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

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

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

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

NEW CLAUSES 27A, 27B, 27C & 27D

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

Application for product licence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) a copy of the certificate of registration;

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

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

(k) proof that the applicant holds—

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

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

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

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

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

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

Processing of application for registration of health product or technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Registration during emergency.

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

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

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

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

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

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

(c) proof that the applicant holds—

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

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

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

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

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

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

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

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

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

Authorization of unregistered health product or technology.

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

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

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

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

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

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

(ii) a valid wholesale dealer's licence issued in accordance with this Act;
(iii) a valid licence to sell health products or technologies issued in accordance with this Act; or
(iv) a valid manufacturing licence issued in accordance with this Act; and
(v) proof of payment of the application fees as prescribed by the Authority.

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

(a) progress reports after every six months from the date of issuance of the authorization;
(b) any adverse event report, where an adverse event occurred; and
(c) a progress report within thirty days after the completion or termination of the use of the health product or technology.

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

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

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

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

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

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

CLAUSE 28

THAT, Clause 28 of the Bill be amended—

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

CLAUSE 29

THAT, Clause 29 of the Bill be amended—

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

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

(c) in sub-clause (3)–
(i) by deleting the word "medicine" appearing in paragraph (a) and substituting therefor the words "health product or technology";
(ii) by deleting the word "medicine" appearing in paragraph (b) and substituting therefor the words "health product or technology";
(iii) by deleting the word "medicine" appearing in paragraph (c) and substituting therefor the words "health product or technology";

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

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

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

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

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

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

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

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

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

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

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

NEW CLAUSES 29A & 29B

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

Authorization of health products and technologies.

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

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

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

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

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

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

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

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

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

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

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

Parallel importation of health products and technologies.

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

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

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

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

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

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

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

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

(4) A person who—

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

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

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

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

CLAUSE 30

THAT, Clause 30 of the Bill be amended—

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

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

CLAUSE 31

THAT, Clause 31 of the Bill be amended—

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

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

CLAUSE 32

THAT, Clause 32 of the Bill be amended—

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

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

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

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

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

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

(c) in sub-clause (4)–

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

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

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

CLAUSE 33

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

CLAUSE 34

THAT, Clause 34 of the Bill be amended—

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

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

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

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

(b) in sub-clause (1) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(c) in sub-clause (2) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist";
(d) in sub-clause (3) by inserting the words "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist"; and
(e) in sub-clause (4) by inserting the word "or an enrolled pharmaceutical technologist" immediately after the word "pharmacist".

CLAUSE 36

THAT, the Bill be amended by deleting Clause 36

NEW CLAUSE

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

Clinical trials.

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

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

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

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

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

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

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

PART V

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

CLAUSE 37

THAT, Clause 37 of the Bill be amended—

(a) in sub-clause (2) by deleting the words "and dealers in mining, agricultural or horticultural accessories" appearing in paragraph (a);
(b) by inserting the following new sub-clause (3) immediately after sub-clause (2)—
"(3) The Cabinet Secretary shall publish the list of scheduled substances prepared under subsection (1) in the *Gazette."*

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

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

CLAUSE 38

THAT, Clause 38 of the Bill be amended—
(a) in sub-clause (1) by—
(i) deleting the words "the Limitations prescribed by this sub-section" and substituting therefor the words "the following limitations";
(ii) deleting paragraph (c)
(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

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

CLAUSE 39

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

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

CLAUSE 40

THAT, the Bill be amended by deleting clause 40.

CLAUSE 41

THAT, Clause 41 of the Bill be amended—

(a) in sub-clause (1) by deleting paragraphs (c) and (e);
(b) in sub-clause (2) by deleting paragraph (b) and (c); and
(c) by deleting sub-clause (3).

CLAUSE 42

THAT, Clause 42 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "paragraph (b) of Section 53(2)" appearing in paragraph (a) and substituting therefor the words "section 41(2)(b)"; and
(b) in sub-clause (3) by deleting the words "three years" and substituting therefor the words "one year"

CLAUSE 43

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

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

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

(b) in paragraph (b) by—
(i) inserting the word "and" immediately after the word "supplied" appearing in sub-paragraph (iii); and
(ii) deleting the word "and" appearing in sub-paragraph (iv);

(c) by deleting paragraph (c).

CLAUSE 45

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

Automatic machines.

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

(2) The Authority shall develop regulations on the—

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

CLAUSE 46

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

Electronic sale of health products and technologies.

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

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

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

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

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

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

NEW CLAUSE

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

Dietary supplements.

46A. (1) A dietary supplement shall—

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

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

PART VI

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

CLAUSE 47

THAT, Clause 47 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicinal substance" and substituting therefor the words "health product";
(b) by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

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

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

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

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

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

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

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

CLAUSE 48

THAT, Clause 48 of the Bill be amended—

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

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

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

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

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

PART VII

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

NEW CLAUSES 51A & 51B

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

Information that is required to be displayed on the pack.

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

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

Manufacturing of cosmetics.

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

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

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

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

CLAUSE 52

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

CLAUSE 54

THAT, Clause 54 of the Bill be amended by—

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

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

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

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

PART VIII

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

CLAUSE 55

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

CLAUSE 56

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

CLAUSE 58

THAT, Clause 58 of the Bill be amended—

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

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

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

CLAUSE 59

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

NEW CLAUSE 59A

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

Registration of medical devices establishment.

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

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

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

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

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

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

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

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

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

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

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

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

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

NEW PART

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

PART VIII-THE NATIONAL PHARMACOVIGILANCE SYSTEM

Pharmacovigilance.

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

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

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

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

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

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

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

PART XI

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

CLAUSE 60

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

Establishment of the National Quality Control Laboratory.

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

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

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

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

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

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

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

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

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

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

CLAUSE 61

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

PART XII

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

CLAUSE 63

THAT, Clause 63 of the Bill be amended—

(a) in sub-clause (1) by deleting the words "medicine, drug, appliance or article" wherever they appear and substituting therefor the words "health product or technology"; and
(b) in sub-clause (2) by inserting the words "or enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (d).

CLAUSE 64

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

CLAUSE 65

THAT, Clause 65 of the Bill be amended—

(a) in paragraph (a) by—
  (i) deleting the words " or similar article"; and
  (ii) deleting the word "extravagant,".
(b) in paragraph (b) by deleting the word " an article" and substituting therefor the words "health product or technology".

CLAUSE 66

THAT, Clause 66 of the Bill be amended—

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

(b) in sub-clause (3) by—
  (i) renumbering the provision as clause (2); and
  (ii) by inserting the words ", enrolled pharmaceutical technologists" immediately after the word "pharmacists" appearing in paragraph (ii).

CLAUSE 67

THAT, Clause 67 of the Bill be amended—

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

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

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

(c) in sub-clause (2) by deleting the word "article" wherever it appears in the definition of "appropriate quantitative particulars" and substituting therefor the words "health product or technology";
(d) in sub-clause (3) by—
(i) deleting the word " an article" appearing in sub-clause (3) and substituting therefor the words " a health product or technology";
(ii) deleting the words "two hundred thousand" appearing in paragraph (a) and substituting therefor the words "one million";
(iii) deleting the words "three hundred thousand" appearing in paragraph (b) and substituting therefor the words "two million".

CLAUSE 68

THAT, the Bill be amended by deleting Clause 68.

CLAUSE 69

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

PART XIII

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

CLAUSE 71

THAT, Clause 71 of the Bill be amended—

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

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

CLAUSE 72

THAT, Clause 72 of the Bill be amended—

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

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

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

CLAUSE 73

THAT, Clause 73 of the Bill be amended—

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

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

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

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

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

CLAUSE 78

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

CLAUSE 79

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

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

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

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

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

CLAUSE 80

THAT, Clause 80 of the Bill be amended—

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

(b) in sub-clause (1) by—

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

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

CLAUSE 81

THAT, the Bill be amended by deleting Clause 81.

CLAUSE 82

THAT, the Bill be amended by deleting Clause 82.

CLAUSE 83

THAT, the Bill be amended by deleting Clause 83.

CLAUSE 85

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

CLAUSE 86

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

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

CLAUSE 87

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

PART XIV

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

CLAUSE 88

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

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

CLAUSE 91

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

PART XV

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

CLAUSE 95

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—
  (i) deleting the word "drugs," in paragraph (a)(i);
  (ii) deleting the words "any drug" in paragraph (a)(ii);
  (iii) deleting the word "product" and substituting therefor the word "products" in paragraph (d);

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

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

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

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

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

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

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

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

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

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

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

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

(xiv) deleting paragraph (ii);

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

"(jj) on pharmacovigilance and post market surveillance;

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

(ll) pricing of health products and technologies;

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

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

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

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

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

(rr) to regulate parallel importation of medicines;"

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

CLAUSE 96

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

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

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

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

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

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

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

CLAUSE 97

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

SECOND SCHEDULE

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

THIRD SCHEDULE

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

FOURTH SCHEDULE

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

1. Biologics Committee.
2. Pharmacovigilance Committee.
3. Complementary, Alternative or Herbal Medicines Committee.
4. Radiopharmaceuticals Committee.

5. Cosmetics and Borderline Products Committee.
6. Clinical Trial Scientific Technical Advisory Committee.
7. Health Technology Assessment Committee.
8. Nutraceuticals and Dietary Supplements Committee.
9. Digital Health and Technologies Committee.
10. Medical Devices and Health Technologies Committee.
11. Veterinary Medicines Committee.

SEVENTH SCHEDULE

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

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

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

LONG TITLE

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

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

CLAUSE 2

THAT, the Clause 2 of the Bill be amended—

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

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

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

"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;

(d) 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 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 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 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 Seme (Hon. (Dr.) James Nyikal) 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 inserting the following new definitions in the proper alphabetic sequence—

No. 21 of 2017.

"Director-General for Health" has the meaning assigned to it under the Health Act;

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

CLAUSE 12

THAT, Clause 12 of the Bill be amended by deleting paragraph (t).

CLAUSE 21

THAT, Clause 21 of the Bill be amended—

(a) by deleting sub-clause (4); and

(b) in sub-clause (9) by deleting the words "Cabinet Secretary, with respect to its activities and the Cabinet Secretary shall lay a copy of each report before Parliament" and substituting therefor the following words "Board of the Authority which shall submit a copy of the report to the Cabinet Secretary who shall transmit the report to Parliament".

CLAUSE 22

THAT, Clause 22 of the Bill be amended in sub-clause (3) by deleting the words "sub-section (1)" and substituting therefor the words "The provisions of subsection(1)(a)".

CLAUSE 29

THAT, Clause 29 of the Bill be amended by deleting sub-clause (4) and substituting therefor the following new sub-clause (4)—

"(4) Where the Authority finds that an application for registration of a medicine or medical device does not satisfy the requirements provided in subsection (3), it shall notify the applicant in writing of the reasons why that medicine or medical device should not be registered and invite the applicant to make comments on its finding within a period of one month from the date of the notification."

CLAUSE 31

THAT, the Bill be amended by deleting clause 31.

CLAUSE 35

THAT, Clause 35 of the Bill be amended—

(a) in sub-clause (1) by inserting the words "upon consultation and concurrence with the person who prescribed the medicine," immediately after the word "shall";

(b) by deleting sub-clause (2);

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

(d) by deleting sub-clause (4).

CLAUSE 38

THAT, Clause 38 of the Bill be amended by deleting sub-clause (2) and substituting therefor the following new sub-clause (2)—

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

CLAUSE 39

THAT, Clause 39 of the Bill be amended in sub-clause (4) by inserting the word "and" immediately after the words "distribution of the Scheduled Substances".

CLAUSE 42

THAT, Clause 42 of the Bill be amended in sub-clause (3) by deleting the words "one hundred thousand shillings or to imprisonment for a term not exceeding three years" and substituting therefor the words "five hundred thousand shillings or to imprisonment for a term not exceeding one year".

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 79

THAT, the Bill be amended by deleting Clause 79.

CLAUSE 81

THAT, Clause 81 of the Bill be amended by deleting the words "Director of Medical Services" and substituting therefor the words "Director-General for Health".

CLAUSE 83

THAT, Clause 83 of the Bill be amended by deleting the words "Cabinet Secretary" wherever they appear and substituting therefor the words "the Authority".

CLAUSE 90

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

CLAUSE 92

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

FOURTH SCHEDULE

THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph (1) by deleting the word "Coordination" appearing in sub-paragraph (4);
(b) in paragraph (2) by inserting the following new sub-paragraphs immediately after sub-paragraph 2(e)—

"(f)a registered medical practitioner nominated by the Kenya Medical Association;
(g)the Director-General for Health or a representative designated in writing;"

(c) in paragraph (4) by deleting the words, "in consultation with the Cabinet Secretary responsible for health," appearing in sub-paragraph (2)(a).

4) Notice is given that the Nominated Member (Hon. Irene Mayaka) intends to move the following amendments to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

CLAUSE 37

THAT, Clause 37 of the Bill be amended —

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

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

(4)The list published under subsection (3) shall include narcotic substances, prescription-only medications, pharmacist-only medications, pharmacy-only medications, over-the-counter medicines, hazardous substances and prohibited substances".

(b) by renumbering sub-clause (3) as sub-clause (5); and
(c) by renumbering sub-clause (4) as sub-clause (6);

5) Notice is given that the Member for Ndhiwa (Hon. Martin Peters Owino) intends to move the following amendment to the Kenya Drugs Authority Bill, 2022 at the Committee Stage—

CLAUSE 72

THAT, clause 72 of the Bill be amended in subclause (1) by deleting the word "person" appearing immediately after the words "The Authority may authorise a" and substituting therefor the words "registered pharmacist".

…… ……/Notices(Cont'd)*

LIMITATION OF DEBATE

The House resolved on Wednesday, February 15, 2023 as follows—

Limitation of Debate on Reports of Audit Committees

II. **THAT,** each speech in debate on **Reports of Audit Committees shall** 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.

Limitation of Debate on Bills sponsored by Parties or Committees

III. **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 Other Committee Reports

IV. **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 Sessional Papers

V. **THAT**, pursuant to the provisions of Standing Order 97(1), this House orders that each speech in a debate on any **Sessional Paper** 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 Sessional Paper 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.

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*… ...../Notice Paper I**

NOTICE PAPER I

Tentative business for

Wednesday (Morning), October 25, 2023

(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 25, 2023–

A. MOTION – EXPANSION OF DRUG AND SUBSTANCE ABUSE REHABILITATION CENTRES
(The Hon. John Makali, M.P.)

(Question to be put)

B. MOTION – REGULATION OF THE SUGAR INDUSTRY TO DISCOURAGE BRANDING OF SUGAR BY NON-MILLERS
(The Hon. Peter Salasya, M.P.)

(Question to be put)

C. MOTION – ACTION TO ADDRESS THE RECENT SURGE IN ROAD ACCIDENTS IN THE COUNTRY
(The Hon. Naomi Waqo, M.P.)

(Question to be put)

D. COMMITTEE OF THE WHOLE HOUSE

(i) The Public Service (Values and Principles) (Amendment) Bill (National Assembly Bill No. 46 of 2022)
(The Hon. Abdul Dawood, M.P.)

(ii) The Penal Code (Amendment) Bill (National Assembly Bill No. 56 of 2022)
(The Hon. David Gikaria, M.P.)

E. THE CANCER PREVENTION AND CONTROL (AMENDMENT) (No. 2) BILL (NATIONAL ASSEMBLY BILL NO. 45 OF 2022)
(The Hon. Abdul Dawood, M.P.)

Second Reading

F. MOTION – BANNING THE GROWING OF EUCALYPTUS TREES IN THE COUNTRY
(The Hon. Moses Kirima M.P.)

G. MOTION – ESTABLISHMENT OF STRATEGIC GRAIN STORAGE RESERVES AND SILOS IN CLOSE PROXIMITY TO SMALLHOLDER FARMERS
(The Hon. Jessica Mbalu M.P.)

H. MOTION – POLICY ON INTEGRATING A CURRICULUM FOR ENVIRONMENTAL CONSERVATION IN PRIMARY AND SECONDARY SCHOOLS
(The Hon. Umul Ker Kassim, M.P.)

I. MOTION – POLICY FOR THE PROVISION OF MENTAL HEALTH SERVICES IN ALL HEALTHCARE FACILITIES
(The Hon. Mishi Mboko, M.P.)

J. MOTION – IMPLEMENTATION OF FIRST AID TRAINING AS A CORE SUBJECT IN SCHOOLS
(The Hon. Caleb Amisi, M.P.)

K. MOTION – ESTABLISHMENT OF A NATIONAL FUND TO SUPPORT VICTIMS OF GENDER-BASED VIOLENCE
(The Hon. Mary Emaase, M.P.)

L. MOTION – ADOPTION OF GOVERNMENT-TO-GOVERNMENT (G2G) MODEL TO ACQUIRE AND SUPPLY FERTILIZERS TO FARMERS AT SUBSIDISED COST
(The Hon. Geoffrey Ruku, M.P.)

M. MOTION – POLICY AND FUNDING FOR SUGARCANE FARMING IN THE COUNTRY
(The Hon. Peter Nabulindo, M.P.)

N. MOTION – PROVIDING A SAFETY NET FOR CAREGIVERS OF PERSONS WITH SEVERE DISABILITIES
(The Hon. Dorothy Ikiara, M.P.)

O. MOTION – NATIONAL SENSITIZATION AND SUPPORT FOR COMBATING SICKLE CELL AND HAEMOPHILIA DISEASES
(The Hon. Peter Nabulindo, M.P.)

P. MOTION – DEVELOPMENT OF A SATELLITE-BASED CLIMATE CHANGE MONITORING POLICY
(The Hon. Abdul Haro, M.P.)

Q. MOTION – ESTABLISHMENT OF A SCIENCE MUSEUM
(The Hon. John Kiarie, M.P.)

R. MOTION – AFFIRMATIVE ACTION PLAN FOR THE PROVISION OF WATER IN ARID AND SEMI-ARID AREAS
(The Hon. Mwengi Mutuse, M.P.)

S. MOTION – DEVELOPMENT OF A FRAMEWORK TO MITIGATE FLOOD HAZARDS
(The Hon. Umulkher Harun, M.P.)

T. MOTION – PROVISION OF APPROPRIATE ACCESS TO MARKETS IN THE COUNTRY
(The Hon. Beatrice Kemei, M.P.)

U. MOTION – SUPPORTING AND PROMOTING LOCAL FERTILIZER-MANUFACTURING INDUSTRIES
(The Hon. Samuel Atandi, M.P.)

V. MOTION – REGULATORY FRAMEWORK FOR THE MONEY LENDER INDUSTRY IN THE COUNTRY
(The Hon. Beatrice Kemei, M.P.)

W. MOTION – FORMULATION OF A GOVERNMENT-TO-GOVERNMENT FRAMEWORK FOR IMPORTATION AND DISTRIBUTION OF ESSENTIAL FOODSTUFF AND GOODS
(The Hon. Geoffrey Ruku, M.P.)

X. MOTION – POLICY FRAMEWORK FOR GOVERNMENT-TO-GOVERNMENT SOURCING OF ELECTRICITY EQUIPMENT AND ON CONNECTION AND BILLING OF ELECTRICITY INFRASTRUCTURE
(The Hon. Geoffrey Ruku, M.P.)

Y. MOTION – FORMULATION OF A REGULATORY FRAMEWORK ON ARTIFICIAL INTELLIGENCE IN THE COUNTRY
(The Hon. Marianne Kitany, M.P.)

Z. MOTION – DEVELOPMENT OF MEASURES TO MITIGATE DIGITAL EXCLUSION
(The Hon. Marianne Kitany, M.P.)

AA. MOTION – ESTABLISHMENT OF A NATIONAL POLICY TO COMBAT OBSTETRIC VIOLENCE IN KENYA
(The Hon. Gathoni Wamuchomba, M.P.)

BB. MOTION – ESTABLISHMENT OF A PRIORITY BOARDING PROTOCOL FOR KENYA DEFENCE FORCES AND KENYA SPECIAL FORCES PERSONNEL ON LOCAL AIRLINES
(The Hon. (Capt.) Ruweida Obo, M.P.)

CC. MOTION – ESTABLISHMENT OF A REGULATORY FRAMEWORK FOR CRYPTOCURRENCY
(The Hon. Irene Mayaka, M.P.)

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*……./Notice Paper II**

NOTICE PAPER II

Tentative business for

Wednesday (Afternoon), October 25, 2023

(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 25, 2023–

A. THE NATIONAL YOUTH COUNCIL (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 1 OF 2023)
(The Hon. Joshua Kandie, M.P.)
Second Reading
(Question to be put)

B. THE LAND (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 40 OF 2022)
(The Hon. Simon King'ara, M.P.)
Second Reading
(Question to be put)

C. THE ASSISTED REPRODUCTIVE TECHNOLOGY BILL (NATIONAL ASSEMBLY BILL NO. 61 OF 2022)
(The Hon. Millie Odhiambo, M.P.)
Second Reading

(Resumption of debate interrupted on Wednesday, October 18, 2023 – Afternoon Sitting)
(Balance of time – 3 hours 7 minutes)

D. THE GERIATRIC BILL (NATIONAL ASSEMBLY BILL NO. 50 OF 2022)
(The Hon. Gathoni Wamuchomba, M.P.)

Second Reading

E. THE PUBLIC SERVICE COMMISSION (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 6 OF 2023)
(The Hon. Benjamin Gathiru, M.P.)
Second Reading

F. THE PUBLIC PROCUREMENT AND ASSET DISPOSAL (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 62 OF 2022)
(The Hon. Benjamin Gathiru, M.P.)

Second Reading

G. THE ANTI-CORRUPTION AND ECONOMIC CRIMES (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 30 OF 2023)
(The Hon. Peter Kaluma, M.P.)

Second Reading

H. THE WILDLIFE CONSERVATION AND MANAGEMENT (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 3 OF 2023)
(The Hon. (Capt.) Ruweida Obo, M.P.)

Second Reading

I. MOTION – REPORTS OF THE AUDITOR-GENERAL ON THE FINANCIAL STATEMENTS FOR THE NATIONAL GOVERNMENT CONSTITUENCIES DEVELOPMENT FUND FOR TWELVE CONSTITUENCIES IN KAKAMEGA COUNTY
(The Chairperson, Decentralized Funds Accounts Committee)

(If not concluded on Tuesday, October 24, 2023)

J. MOTION – 1970 UNESCO CONVENTION ON THE MEANS OF PROHIBITING AND PREVENTING THE ILLICIT IMPORT, EXPORT AND TRANSFER OF OWNERSHIP OF CULTURAL PROPERTY
(The Chairperson, Departmental Committee on Sports and Culture)

(If not concluded on Tuesday, October 24, 2023)

K. MOTION – INSPECTION OF VARIOUS ONE-STOP BORDER POSTS IN THE NORTHERN CORRIDOR IN THE EAST AFRICAN COMMUNITY
(The Chairperson, Select Committee on Regional Integration)

(If not concluded on Tuesday, October 24, 2023)

L. MOTION - SESSIONAL PAPER NO. 1 OF 2023 ON KENYA NATIONAL POPULATION POLICY FOR SUSTAINABLE DEVELOPMENT
(The Chairperson, Departmental Committee on Finance and National Planning)

(If not concluded on Tuesday, October 24, 2023)

M. MOTION – THE 4TH GENERAL ASSEMBLY OF THE EASTERN AFRICA PARLIAMENTARY ALLIANCE ON FOOD SECURITY AND NUTRITION (EAPA-FSN) HELD IN KIGALI, RWANDA
(The Chairperson, EAPA-FSN Caucus)

(If not concluded on Tuesday, October 24, 2023)

N. MOTION – LOANS CONTRACTED BY THE NATIONAL GOVERNMENT BETWEEN MAY 2022 AND APRIL 2023

(The Chairperson, Public Debt and Privatization Committee)

(If not concluded on Tuesday, October 24, 2023)

O. MOTION – REPORTS OF THE AUDITOR-GENERAL ON TWENTY-THREE NON-COMPLIANT STATE CORPORATIONS

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

(If not concluded on Tuesday, October 24, 2023)

P. MOTION – PROCEEDINGS OF THE SECOND ORDINARY SESSION OF THE SIXTH PAN-AFRICAN PARLIAMENT (PAP)

(Member of the Pan-African Parliament)

(If not concluded on Tuesday, October 24, 2023)

Q. MOTION – PROCEEDINGS OF THE 2023 UNITED NATIONS HIGH LEVEL POLITICAL FORUM ON SUSTAINABLE DEVELOPMENT

(The Vice Chairperson, Parliamentary Caucus on Sustainable Development Goals (SDGs) and Business)

(If not concluded on Tuesday, October 24, 2023)

R. THE NATIONAL GOVERNMENT CONSTITUENCIES DEVELOPMENT FUND (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 13 OF 2023)

(The Leader of the Majority Party and the Leader of the Minority Party)

Second Reading

(If not concluded on Tuesday, October 24, 2023)

S. THE CONFLICT OF INTEREST BILL (NATIONAL ASSEMBLY BILL NO. 12 OF 2023)

(The Leader of the Majority Party)

Second Reading

(If not concluded on Tuesday, October 24, 2023)

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*……. /Notice of Questions**

NOTICE OF QUESTIONS

It is notified that, pursuant to the provisions of Standing Order 42A (6B), the **Cabinet Secretary for Interior and National Administration** will respond to Questions in plenary on Wednesday (Afternoon), October 25, 2023–

QUESTIONS BY PRIVATE NOTICE

Que. No.	Member	Subject
QPN 012/2023	Hon. (Dr.) Edwin Mugo, MP *(Mathioya Constituency)*	Status of investigations into the disappearance of *Ms. Esther Ruguru* of *ID No. 23800961*, aged 43, a resident of Mathioya Constituency
QPN 013/2023	Hon. David Gikaria, MP *(Nakuru Town East Constituency)*	Death and dumping of 12-year-old *Jasmine Njoki's* body at *Mbaruk* Center in Gilgil on 19th September 2023
QPN 014/2023	Hon. Gonzi Rai, MP *(Kinango Constituency)*	Status of investigations into the death of *Nyae Ngalaa Chamtu*, a minor who was allegedly killed by General Service Unit (GSU) officers on 15th September 2023 in Kinango
QPN 015/2023	Hon. Aduma Owuor, MP *(Nyakach Constituency)*	Investigation and Report on the security situation in Sondu within Nyakach Constituency
QPN 016/2023	Hon. Muthoni Marubu, MP *(Lamu County)*	Frequent killings in *Widho, Salama, Juhudi, Ziwa La Taa, Bobo, Maleli, Kakate*, and *Roka* villages in Lamu
QPN 017/2023	Hon. Gideon Mulyungi, MP *(Mwingi Central Constituency)*	Actions taken to apprehend suspected armed bandits traversing Mwingi Central Constituency, particularly in the *Ukasi* to *Waita* area

ORDINARY QUESTIONS

Que. No.	Member	Subject
Question No. **143/2023**	Hon. John Makali, MP *(Kanduyi Constituency)*	Operationalization of a national registration office in Bungoma
Question No. **197/2023**	Hon. Zamzam Mohammed, MP *(Mombasa County)*	Control, dismantle, and elimination of well-organized and vicious juvenile criminal gangs operating within Kisauni, Likoni and Old Town in Mombasa
Question No. **198/2023**	Hon. Paul Nzengu, MP *(Mwingi North Constituency)*	Status of investigations into the mysterious death of the *Mr. Muuo Muthengi*, a Prison Warden who was stationed at Thika Prisons
Question No. **201/2023**	Hon. Giseiro Ombane, MP *(Kitutu Masaba Constituency)*	Investigations into the gruesome murder of *Mr. Edward Morema Nyagechi* and *Mama Grace Morema* which occurred at their home in *Nyamakoroto*
Question No. **203/2023**	Hon. Martin Owino, MP *(Ndhiwa Constituency)*	Sub-dividing Ndhiwa Constituency into three (3) operational and adequately staffed administrative units
Question No. **264/2023**	Hon. Kwenya Thuku, MP *(Kinangop Constituency)*	Circumstances that led to the death of the following watchmen: *James Njoroge, Naftali Gathirwa, Peter Kinyanjui, Richard Kasuku, Papaiya Lokoringo, Joseph Kimani and George Muturi* who were killed by gangs in their respective schools
Question No. **265/2023**	Hon. Antony Kibagendi, MP *(Kitutu Chache South Constituency)*	Measures being taken to address the widespread abuse of drugs and banned substances

Question No. **266/2023**	Hon. (Dr.) Robert Pukose, MP *(Endebess Constituency)*	Status of investigations into the death of PC *Emmanuel Kiprop* from Endebess Kolongei who was killed by a mob in *Kathanje* Market
Question No. **270/2023**	Hon. Rael Kasiwai, MP *(West Pokot County)*	Efforts being undertaken to address incessant conflicts of boundaries between West Pokot & Turkana and West Pokot & Elgeyo Marakwet
Question No. **344/2023**	Hon. Yussuf Mohammed, MP *(Wajir West Constituency)*	Status of investigations into the circumstances that led to the death of two minors namely, *Abdisalan Hussein Issack* and *Munazil Adow* during peaceful demonstrations in Wajir Town
Question No. **345/2023**	Hon. Rozaah Buyu, MP *(Kisumu West Constituency)*	Status of investigations into the death of *Marion Atieno*, a minor who lost her life on her way home from *Kuoyo Secondary School*
Question No. **389/2023**	Hon. Martha Wangari, MP (*Gilgil Constituency*)	Changes made to the National Police Service Medical Insurance Scheme and reasons thereof
Question No. **454/2023**	Hon. (Capt.) Ruweida Obo, MP (*Lamu East Constituency*)	List of individuals affiliated with Al Shabaab militants and efforts made to apprehend the militants