REPUBLIC OF KENYA

THIRTEENTH PARLIAMENT – THIRD SESSION

THE NATIONAL ASSEMBLY

VOTES AND PROCEEDINGS

WEDNESDAY, NOVEMBER 06, 2024 AT 2.30 P.M.

1. The House assembled at Thirty Minutes past Two O'clock.

2. The Proceedings were opened with Prayer.

3. Presiding – the Deputy Speaker.

4. QUORUM AT COMMENCEMENT OF THE HOUSE

There being no Quorum present to commence business, the Deputy Speaker ordered that the Quorum Bell be rung for ten minutes;

And Quorum having been attained within the ten minutes, proceedings commenced.

5. RECOGNITION OF A DELEGATION

"Honourable Members,

I wish to introduce to you a delegation of 8 Members of staff from Suna West NGCDF Office, who are seated in the Public Gallery.

Honourable Members, on my own behalf and that of the National Assembly, I welcome them to Parliament and wish them fruitful deliberations. I thank you."

6. PAPERS

The following Papers were laid on the Table of the House-

(i) The Agreement for the Establishment of the Africa Finance Corporation and Explanatory Memorandum from the Ministry of Foreign & Diaspora Affairs;

(ii) Reports of the Auditor-General and Financial Statements for the year ended 30th June 2024 and the certificates therein in respect of: -
   a) Ethics and Anti–Corruption Commission;
   b) Kenya Youth Employment and Opportunities Project Credit No. IDA 5812-KE – Micro and Small Enterprises Authority;
   c) SC Reporting Toolkit Project – Ministry of Environment, Climate Change & Forestry;
   d) Multinational Lake Victoria Maritime Communications and Transport (MLVMCT) Project – Kenya Maritime Authority;
   e) Coordinate Implementation of Population Policy and ICPD25 Commitments Project;
   f) GOK/Unicef Education for Young People Programme – State Department for Basic Education; and
   g) Kenya Primary Education Equity in Learning Program Grant Number D991 – KE - Teachers Service Commission.

(Deputy Leader of the Majority Party)

(iii) Report of the Finance and National Planning on its consideration of the Equalisation Fund (Administration) Bill (Senate Bill No. 14 of 2023).

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

7. RE-ORGANIZATION OF BUSINESS PURSUANT TO STANDING ORDER 40

Pursuant to the provisions of Standing Order 40, the Deputy Speaker re-organized business to conclude with Order No. 8 and 9 prior to request for Statements.

[Change of Chair from the Deputy Speaker to the Fifth Chairperson of Committees]

8. MOTION – REPORT OF THE COMMITTEE OF THE WHOLE HOUSE ON THE KENYA DRUGS AUTHORITY BILL (NATIONAL ASSEMBLY BILL NO. 54 OF 2022)

Motion made and Question proposed –

THAT, this House do agree with the Report of the Committee of the Whole House on its consideration of the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022) up to Clause 79 and seek leave to sit again.

(Hon. Robert Pukose)

Question put and agreed to.

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

Motion made and Question proposed –

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

(Chairperson, Committee on Implementation)

Debate on the Motion having been concluded on Tuesday, November 5, 2024;

Mover replied;

Question put and agreed to.

10. TRIBUTE OF THE HOUSE PURSUANT TO STANDING ORDER 43

The Member for Suna West (Hon. Peter Masara) made a Statement on the demise of a veteran musician, Ms. Lilian Auma, popularly known as Princess Julie.

11. REQUEST FOR STATEMENT PURSUANT TO STANDING ORDER 44(2)(C)

The Member for Kilgoris (Hon. Julius Sunkuli) sought a Statement from the Chairperson of the Departmental Committee on Administration and Internal Security on two organizations operating in Kilgoris Constituency.

12. RESPONSES TO STATEMENTS PURSUANT TO STANDING ORDER 44(2)(C)

The Vice-Chairperson of the Departmental Committee on Agriculture and Livestock responded to Statements requested by-

(i) the Member for Wajir South (Mohammed Adow) on the status of strategic promotion and development of dry land agriculture in Kenya;
(ii) the Member for Gichugu (Hon. Robert Gichimu) on payment of tea bonuses for *Kimunye* and *Thumaita* tea factories for the financial year 2023/2024; and
(iii) the Member for Laikipia North (Hon. Sarah Korere) on the lease of Agricultural Development (ADC) land in *Rumuruti.*

13. COMMITTEE OF THE WHOLE HOUSE

The Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022)
Order for the Committee read;

IN THE COMMITTEE

In the Chair - The Fourth Chairperson of Committee

The Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022)

Clause 80 - amendment proposed

THAT, Clause 80 of the Bill be amended—
(a) in sub-clause (1) by—
  (i) deleting the word "article" wherever it appears and substituting therefor the words "health product or technology"; and
  (ii) inserting the words "or any other vessel" immediately after the word "vehicle" appearing in paragraph (b).
(b) in sub-clause (6) by deleting the word "article" and substituting therefor the words "health product or technology";
(c) in sub-clause (7) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";
(d) in sub-clause (8) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";
(e) in sub-clause (9) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";
(f) in sub-clause (10) by deleting the word "article" wherever it appears and substituting therefor the words "health product or technology";
(g) in sub-clause (11) by deleting the word "article" and substituting therefor the words "health product or technology";
(h) in sub-clause (12) by deleting the word "article" and substituting therefor the words "health product or technology".

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;

Question on the amendment put and agreed to;

Clause 80 - as amended agreed to.

Clause 81 - amendment proposed;

THAT, the Bill be amended by deleting Clause 81.

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;

Clause 81 - Further amendment proposed;

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

(Hon. Peter Kaluma)

Amendment withdrawn.

Clause 81 - as amended agreed to.

Clause 82 - amendment proposed

THAT, the Bill be amended by deleting Clause 82.

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 82 - deleted.

Clause 83 - amendment proposed

THAT, the Bill be amended by deleting Clause 83.

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;

Clause 83 - as amended agreed to.

Clause 84 - agreed to.

Clause 85 - amendment proposed;

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

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 85 - as amended agreed to.

Clause 86 - amendment proposed

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."

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 86 - as amended agreed to.

Clause 87 - amendment proposed

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

(The Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 87 - as amended agreed to.

PART XIV- amendment proposed

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

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
PART XIV- as amended agreed to.
Clause 88 - amendment proposed

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".

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 88- as amended agreed to.

Clause 89 - agreed to.

Clause 90 - amendment proposed

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

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 90- as amended agreed to.

Clause 91 - amendment proposed

THAT, Clause 91 of the Bill be amended—

(a) in sub clause (3) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General"; and
(b) in sub clause (4) by deleting the words "Kenya National Audit Office" and substituting therefor the words "Auditor-General".

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;
Clause 91- as amended agreed to.

Clause 92 - amendment proposed

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

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;

Clause 92- as amended agreed to.
Clauses 93 and 94 - agreed to.

PART XV - amendment proposed

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

PART XV- as amended agreed to.

Clause 95 - amendment proposed

THAT, Clause 95 of the Bill be amended—

(a) in sub-clause 2 by—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(jj) on pharmacovigilance and post market surveillance;

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

(ll)pricing of health products and technologies;

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

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

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

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

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

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

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

Debate arising;

Question on the amendment put and agreed to;

Clause 95 - amendment proposed

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

(Hon. Peter Kaluma)

Amendment dropped.

Clause 95 - amendment proposed

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

inserting the words "and herbal medicines" immediately after the word "medicines" appearing in paragraph (v);

inserting the words "herbal medicine" immediately after the word "medicine" appearing in paragraph (bb);

inserting the words "herbal medicines" immediately after the word "medicines" appearing in paragraph (bb);

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

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

(Hon. Millie Odhiambo)

Amendment dropped.

Clause 95 - as amended agreed to.

Clause 96 - amendment proposed

THAT, Clause 96 of the Bill be amended—

(a) in sub-clause (1) by—

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

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

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

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

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

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

(c) in sub-clause (3)—

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

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

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

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

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Clause 96- as amended agreed to.

Clause 97 - amendment proposed

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).

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Clause 97- as amended agreed to.

New Clause 27A proposed-

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

Application for product licence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) a copy of the certificate of registration;

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

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

(k) proof that the applicant holds—

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

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

(iii) a valid licence to sell poisons issued in accordance with this Act; or
(iv) a valid manufacturing licence issued in accordance with this Act; and
(v) proof of payment of the application fees as prescribed by the Authority.

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 27A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 27A be part of the Bill.

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to.

New Clause 27B proposed-

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

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.

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 27B be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;
Question put and agreed to;
Motion made and Question proposed-

THAT, New Clause 27B be part of the Bill

There being no debate arising;
Question put and agreed to;

New Clause 27C proposed-

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

Clause 27C

Registration during emergency.

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

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

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

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

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

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

(c) proof that the applicant holds—

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

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

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

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

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

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

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

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

(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.

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 27C be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;
Question put and agreed to;
Motion made and Question proposed-

THAT, New Clause 27C be part of the Bill

There being no debate arising;
Question put and agreed to;

New Clause 27D proposed-

THAT, the Bill be amended by inserting the following new clause immediately after clause 27C-

Clause 27D- Authorization of unregistered health product or technology.

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

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

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

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

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

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data related to the health product or technology for which authority is sought;
(b) written consent of the applicant, where applicable;
(c) details of registration or pending registration of the health product or technology with any other regulatory authority, where applicable;

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

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

(7) The Authority may, where it is of the opinion that the safety of any patient is compromised or where the scientific reasons for administering the unregistered health product or technology have changed—
(a) impose any additional conditions;
(b) request additional information;
(c) inspect the site where the unregistered health product or technology is manufactured, stored or administered; or
(d) withdraw the authorization to treat the patient.

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

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

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

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 27D be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;
Question put and agreed to;
Motion made and Question proposed-

THAT, New Clause 27D be part of the Bill

There being no debate arising;
Question put and agreed to;

New Clauses 29A proposed-

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

Authorization of health products and technologies.

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

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

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

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

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

(4) The manufacturer or marketing authorization holder of any registered biological therapeutic shall submit lot summary protocol for each lot that contains registered tests and results of tests performed and, such manufacturer or marketing authorization holder may be required to submit samples of product from the specified lot to the

Authority for official batch or lot release in accordance with the prescribed regulations.

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

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

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

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

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 29A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 29A be part of the Bill

There being no debate arising;

Question put and agreed to;

New Clause 29B proposed-

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

Parallel importation of health products and technologies. No. 17 of 2015.

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.

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 29B be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 29B be part of the Bill

There being no debate arising;
Question put and agreed to;

New Clause 36A proposed-

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

Clinical trials.

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

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

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

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

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

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

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

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 36A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 36A be part of the Bill

There being no debate arising;

Question put and agreed to;

New Clause 46A proposed-

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

Dietary supplements.

46A. (1) A dietary supplement shall—

(a) have a stated or implied therapeutic purpose; and

(b) not contain a scheduled substance.

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 46A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 46A be part of the Bill

There being no debate arising;
Question put and agreed to.

New Clause 50A proposed-

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

Information that is required to be displayed on the pack.

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

(a) the common name of the therapeutic cosmetic;

(b) the net weight of the theraupetic cosmetic;

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

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

(e) a warning statement; and

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

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

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

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

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 50A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 50A be part of the Bill

There being no debate arising;
Question put and agreed to.

New Clause 59A proposed-

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

Registration of medical devices establishment.

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

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

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

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

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

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

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

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

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

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

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

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

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

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 59A be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 59A be part of the Bill

There being no debate arising;

Question put and agreed to.

New Clause 59B proposed-

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

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.

(Chairperson, Committee on Health)

Motion made and Question proposed-

THAT, New Clause 59B be now read a Second Time;

(Chairperson, Committee on Health)

There being no debate arising;

Question put and agreed to;

Motion made and Question proposed-

THAT, New Clause 59B be part of the Bill

There being no debate arising;

Question put and agreed to.

First Schedule- agreed to.

Second Schedule- amendment proposed;

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Second Schedule- as amended agreed to.

Third Schedule- amendment proposed;

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Third Schedule- as amended agreed to.

Fourth Schedule- amendment proposed;

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

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

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Fourth Schedule- Further amendment proposed;

THAT, the Bill be amended by deleting the Fourth Schedule

(Hon. Peter Kaluma)

Amendment dropped.

Fourth Schedule- Further amendment proposed;

THAT, the Fourth Schedule of the Bill be amended—

(a) in paragraph 1(1) by deleting the words "Cabinet Secretary" and substituting therefor the word "Board"; and

(b) in paragraph 2(1) by inserting the words "and herbal medicines" immediately after the words "human medicinal products".

(Hon. Millie Odhiambo)

Amendment dropped.

Fourth Schedule- as amended agreed to.

Fifth Schedule- agreed to.

Sixth Schedule- agreed to.

Seventh Schedule- amendment proposed;

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.

(Chairperson, Committee on Health)

Question for the amendment proposed;
There being no debate arising;
Question on the amendment put and agreed to;

Seventh Schedule- amendment proposed;

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

(Hon. Peter Kaluma)

Amendment dropped.

Seventh Schedule- as amended agreed to.

Clause 2- amendment proposed;

THAT, Clause 2 of the Bill be amended—

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

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

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

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

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

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

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

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

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

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

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

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

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

"dietary supplement" means a product taken by mouth that is added to the diet to help meet daily requirements of essential nutrients, and which

usually contains one or more dietary ingredient and includes vitamins, minerals and herbs;

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

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

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

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

(b) device modification which may include—

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

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

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

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

(v) device exchange;

(vi) device destruction; or

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

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

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

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

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

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

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

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

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

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices;
(g) providing information by means of in vitro examination of specimens derived from the human body;
(h) disinfection substances;
(i) aids for persons with disabilities;
(j) devices incorporating animal or human tissues;
(k) devices for in-vitro fertilization or assisted reproduction technologies, and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

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

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

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

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

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under this Act;
"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;
"premise" includes any land, building, dwelling-place or any other place whatsoever; and includes stand-alone community retail pharmacy, private hospital pharmacy, public health facility pharmacy, wholesale pharmacy or distribution outlet, where health products and technologies are stored, handled or distributed;
"Registrar" means the Director-General of the Authority appointed under section 6;
"scheduling" means, in relation to a substance, the determination of the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included;
"therapeutic cosmetic" means a product with the ability to trigger biological actions on the dermis, skin, eyes or teeth, to prevent future damage and contains ingredients that are usually not found in regular cosmetics or at higher strengths than could be sold safely over the counter;
"traditional medicine" includes the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness;
"unregistered medical product" means a product that has not undergone evaluation and approval by the Authority subject to permitted conditions under the Act and the rules therein;
"vessel" means a truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat and other means that are used for purposes of conveying health products and technologies;
"wholesale dealer" means a person who is licensed to carry out a business where health products and technologies are stored, distributed or sold in bulk to persons other than individual consumers and includes registration, importation, warehousing, good distribution practices and pharmacovigilance;".

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Clause 2- Further amendment proposed;

THAT, Clause 2 of the Bill be amended by—

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

(b) deleting the definition of "enrolled pharmaceutical technologist" and substituting therefor the following new definition—
"enrolled pharmaceutical technologist" means a pharmaceutical technologist whose name appears on the Roll;"

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

(Hon. Peter Kaluma)

Amendment dropped.

Clause 2- Further amendment proposed;

THAT, the Clause 2 of the Bill be amended—

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

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

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

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

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

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

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

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

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

(h) deleting the definition of "chemical substance" and substituting therefor the following new definition—
"chemical substance" means any substance or mixture of substances prepared, sold or represented for use as a germicide, antiseptic, disinfectant, pesticide, insecticide, rodenticide, vermicide, detergent or any other substance or mixture of substances which the Authority may, declare to be a chemical substance;

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

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

(Hon. Antony Oluoch)

Amendment dropped.

Clause 2- Further amendment proposed.

THAT, Clause 2 of the Bill be amended—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Hon. Millie Odhiambo)

Amendment dropped.

Clause 2- as amended agreed to.

Title- amendment proposed;

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

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

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Title- Further amendment proposed;

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."

(Hon. Antony Oluoch)

Amendment dropped.

Title- as amended agreed to.

Clause 1- amendment proposed;

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.

(Chairperson, Committee on Health)

Question for the amendment proposed;

There being no debate arising;

Question on the amendment put and agreed to;

Clause 1- Further amendment proposed;

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

(Hon. Millie Odhiambo)

Amendment dropped.

Clause 1- as amended agreed to.

Bill to be reported with amendments.

14. HOUSE RESUMED - the Fifth Chairperson in the Chair

Bill reported with amendments;
Motion made and Question proposed;

THAT, the House do agree with the Report of the Committee of the Whole House on its consideration of the Kenya Drugs Authority Bill (National Assembly Bill No. 54 of 2022).

(Chairperson, Committee on Health)

Question proposed;

There being no debate arising;

Question for Agreement Deferred.

15. THE HIGHER EDUCATIONS LOANS BOARD (AMENDMENT) BILL (NATIONAL ASSEMBLY BILL NO. 58 OF 2022)

(The Hon. Joyce Kamene, M.P.)

Order read;

Order deferred.

16. THE LAND CONTROL BILL (NATIONAL ASSEMBLY BILL NO. 39 OF 2023)

Motion having been made and Question proposed-

THAT, the Land Control Bill (National Assembly Bill No. 39 of 2023) be read a Second Time.

(Hon. (Dr.) Wilberforce Oundo, M.P.- 18.10.2024)

Debate interrupted on Friday, October 18, 2024 resumed;

17. MOTION- SECOND REPORT ON EMPLOYMENT DIVERSITY AUDIT IN PUBLIC INSTITUTIONS

Motion having been made and Question proposed-

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

(Chairperson, Committee on National Cohesion and Equal Opportunity- 05.11.2024)

Debate interrupted on Tuesday, November 5, 2024 resumed;

There being no other Member wishing to contribute;

Mover replied.

Question deferred.

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

Motion made and Question proposed-

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

(a) deletion of paragraph 212 appearing on page 41 of the report and substituting therefor the following new paragraph –

"The Committee recommends that the irregular cash payments made for the casual works done amounting to Kshs. 2,308,996 be surcharged to the Governing Council of Kisumu National Polytechnic. The amount is to be paid within six months after the adoption of this report by the House;

(b) deletion of paragraph 216 appearing on page 41 of the report and substituting therefor the following new paragraph –

(c)

"The Committee recommends that the long outstanding imprest of Kshs. 37,800 be written off from the institution's books of accounts since no money was lost; it was as a result of demise of the employee"; and,

(d) effecting the consequential amendments in the report."

(Chairperson, Public Investments Committee on Governance and Education)

QUORUM OF THE HOUSE

Rising in his place on a Point of Order pursuant to the provisions of Standing Order 35, the Member for Buuri (Hon. Rindikiri Mugambi, MP) objected that there was no Quorum present in the House;

And the Fifth Chairperson having ascertained the claim, ordered that the Division Bell be rung for ten (10) minutes;

There being no Quorum attained at the expiry of the ten minutes;

And the time being Nine Minutes past Eight O'clock, the Fifth Chairperson interrupted proceedings and adjourned the House without Question put pursuant to Standing Order 35(2)(a).

19. HOUSE ROSE - at Nine Minutes past Eight O'clock

M E M O R A N D U M

The Speaker will take the Chair on,
Thursday, November 07, 2024 at 02.30 p.m.

--x--