Approved for tabling in the House.
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29/9/2021

REPUBLIC OF KENYA

THE NATIONAL ASSEMBLY

TWELFTH PARLIAMENT (FIFTH SESSION)

DEPARTMENTAL COMMITTEE ON HEALTH

.....

REPORT ON-

THE KENYA FOOD AND DRUGS AUTHORITY BILL (*NATIONAL ASSEMBY BILL NO 31 OF 2019*)

CLERKS CHAMBERS

DIRECTORATE OF DEPARTMENTAL COMMITTEES

PARLIAMENT BUILDINGS

NAIROBI

SEPTEMBER, 2021

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CHAIRPERSON'S FOREWORD

This report contains proceedings of the Departmental Committee on Health on its consideration of the Kenya Food and Drug Authority Bill *(National Assembly Bill No. 31 of 2019* which was published on 15th April 2019.

The Kenya Food and Drugs Authority Bill *(National Assembly Bill No. 31 of 2019)* underwent First Reading on 2nd May, 2019 and was thereafter committed to the Departmental Committee on Health pursuant to Standing Order 127 for consideration and reporting to the House.

The Bill is divided into fifteen parts and seeks to establish the Kenya Food and Drugs Authority. The Bill provides for the regulations and management of foods, drugs, chemical substances, medical devices and other health technologies. The Bill gives effect to devolved government principles and objects in food security regulation and food-connected purposes.

Following the placement of adverts in the print media on 30th of March, 2021 requesting for comments on the Bill from members of the public and relevant stakeholders pursuant to Article 118(1)(b) of the Constitution and Standing Order 127(3), the Committee received forty Seven (47) written memoranda from critical stakeholders and individuals who responded and their views are contained in this report.

In order to extensively carry out public participation on the Bill, the Committee invited stakeholders vide letter REF:NA/DCS/HEALTH/2021(31) REF: NA/DDC/F&NP/2021/35 dated 31st August, 2021 for a stakeholder engagement meeting which was held on Tuesday 7th September, 2021 at the Majlis Hotel in Lamu where the stakeholders attended the meeting.

The stakeholders welcomed the amendments proposed in the Bill. Most stakeholders were opposed to the Bill. The stakeholders' comments on the Bill are contained in the Report. All the stakeholders' comments were put into consideration while preparing the proposed Committee's amendments and some of the proposals were adopted forming part of the proposed Committee's amendments. To this end, the Committee made amendments to the Bill to remedy some of the issues raised above. Details of the Committee's proposed amendments are contained in the Report.

On behalf of the Departmental Committee on Health and pursuant to provisions of Standing Order 199(6), it is my pleasant privilege and honour to present to this House the Report of the Committee on its consideration of the Kenya Food and Drug Authority Bill, 2019. The Committee is grateful to the Offices of the Speaker and Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings. The Committee further wishes to thank all the stakeholders who participated in the consideration of the Bill. Finally, I wish to express my appreciation to the Honorable Members of the Committee and the Committee Secretariat who made useful contributions towards the preparation and production of this report.

It is my pleasure to report that the Committee has considered the Kenya Food and Drugs Authority Bill *(National Assembly Bill No. 31 of 2019)* and have the honour to table in the House the Committee's report on the Bill with recommendation that the Bill be **approved with amendments.**

Hon. Sabina Chege, MP
Chairperson, Departmental Committee on Health

PART I

1.0 PREFACE

1.1 ESTABLISHMENT OF THE COMMITTEE

The Departmental Committee on Health is established pursuant to the provisions of Standing Order No. 216 of the National Assembly and in line with Article 124 of the Constitution which provides for the establishment of the Committees by Parliament. The mandate and functions of the Committee are;

a) *Investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;*

b) *Study the programme and policy objectives of the Ministries and departments and the effectiveness of the implementation;*

c) *Study and review all legislation referred to it;*

d) *Study, assess and analyse the relative success of the Ministries and departments as measured by the results obtained as compared with its stated objectives;*

e) *Investigate and inquire into all matters relating to the assigned Ministries and departments as they may deem necessary, and as may be referred to them by the House;*

f) *Vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204;*

fa) *Examine treaties, agreements and conventions;*

g) *Make reports and recommendations to the House as often as possible, including recommendation of proposed legislation;*

h) *Consider reports of Commissions and Independent Offices submitted to the House pursuant to the provisions of Article 254 of the Constitution; and*

i) *Examine any questions raised by Members on a matter within its mandate*

1.2 COMMITTEE SUBJECTS

The Second Schedule of the Standing Orders on Departmental Committees outlines the subjects of the Committee's mandate as health, medical care and health insurance.

In executing its mandate, the Committee oversights the Ministry of Health, its Semi-Autonomous Government Agencies, Regulatory Bodies and Health Advisory Bodies as follows:

1. Kenyatta National Hospital (KNH)
2. Moi Teaching and Referral Hospital (MTRH)
3. Kenyatta University Teaching Referral and Research Hospital (KUTRRH)
4. Kenya Medical Training College (KMTC)
5. Kenya Medical Supplies Authority (KEMSA)
6. Kenya Medical Research Institute (KEMRI)
7. National Hospital Insurance Fund (NHIF)
8. Pharmacy and Poisons Board (PPB)
9. National AIDS Control Council (NACC)
10. National Cancer Institute (NCI)
11. Kenya Nuclear Regulatory Authority (KENRA)
12. The Mathari National Teaching and Referral Hospital (MNTRH)
13. Kenya Health Professionals Oversight Authority (KHPOA)
14. Kenya Health Human Resource Advisory Council (KHHRAC)

1.3 COMMITTEE MEMBERSHIP

1. The Departmental Committee on Health was re-constituted by the House in July, 2020 and comprises the following Members:

Chairperson
Hon. Sabina Chege, MP
Muranga County
Jubilee Party

Vice-Chairperson
Hon. Joshua Kutuny, MP
Cherengany Constituency
Jubilee Party

Hon. (Dr.) Eseli Simiyu, MP
Tongaren Constituency
Ford Kenya Party

Hon. Gideon Ochanda, MP
Bondo Constituency
ODM Party

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

Hon. Alfred Agoi Masadia, MP
Sabatia Constituency
ANC Party

Hon. (Dr.) James K, Murgor, MP
Keiyo North Constituency
Jubilee Party

Hon. Muriuki Njagagua, MP
Mbeere North Constituency
Jubilee Party

Hon. (Dr.) Mohamed D. Duale, MP
Daadab Constituency
KANU Party

Hon. Beatrice Adagala, MP
Vihiga County
ANC Party

Hon. James G Wamacukuru
Kabete Constituency
Jubilee Party

Hon. Prof. Mohamud Sheikh, MP
Wajir South
Jubilee Party

Hon. Sarah Puleta Korere, MP
Laikipia North Constituency
Jubilee Party

Hon. Capt. Ruweida Mohamed, MP
Lamu County
Jubilee Party

Hon. Kipsengeret Koros, MP
Sigowet-Soin Constituency
Independent Party

Hon. Martin Peters Owino, MP
Ndhiwa Constituency
ODM Party

Hon. Joyce Ekai Emanikor, MP
Turkana County
Jubilee Party

Hon. Said Hirabe, MP
Galole Constituency
Ford Kenya Party

Hon. Tongoyo Gabriel Koshal, MP
Narok West Constituency
CCM Party

1.4 COMMITTEE SECRETARIAT

2. The Committee is serviced by the following Secretariat staff:

Head of the Secretariat
Mr. Douglas Katho
Clerk Assistant II

Ms. Christine Odhiambo
Legal Counsel I

Mr. Muyodi Meldaki Emmanuel
Clerk Assistant II

Mr. Eric Kanyi
Fiscal Analyst II

Ms. Fiona Musili
Research Officer II

Mr. Ahmed Yakub
Media Relations Officer

Ms. Catherine Wangui
Serjeant-At-Arms

Mr. Nimrod Ochieng
Audio Officer

PART II

2.0 OVERVIEW OF THE KENYA FOOD AND DRUGS AUTHORITY BILL (NATIONAL ASSEMBY BILL NO 31 OF 2019)

2.1 SUMMARY OF LEGAL PROVISIONS

The Bill is divided into fifteen parts.

PART I provides for the short title and the commencement date of the Act. Also, it provides for interpretation of certain terms and the scope of application of the Act.

PART II establishes the Kenya Food and Drugs Authority as a body corporate able to sue and being sued, purchase property, entering into contracts and borrowing and lending money (Clause 4). It provides that the headquarters shall be in Nairobi and the Authority may establish branches anywhere in the country (Clause 5). The same part provides for the Director General of the Authority, his qualifications and his disqualifications (Clause 6 and 7). The Act provides for the Board that is to manage the authority, its members and their qualifications (Clause 8). It also provides for the oath of office, the vacation of office, removal from office and the functions and the powers of the authority (Clause 9 -13).

PART III provides for the functions of the Authority with respect to food (Clause 22). The Part provides for the prohibition against sale of unwholesome poisonous or adulterated food (Clause 23). It also provides that any person can initiate procedures to withdraw a certain food from the market if they have reasons to believe that the food is not manufactured or distributed in accordance with the Act. The person shall inform the Authority and the relevant food safety authority at the county level if he has reasons to believe that a food which he placed on the market may be unsafe for the consumers (Clause 24). Moreover, the part provides against deception (Clause 25). It goes on to provide for the prohibition against sale of food not of nature, substance or quality demanded (Clause 27). Further, it goes on to provide that any person who sells, prepares, packages, conveys, stores or displays for sale any food under insanitary conditions commits an offence (Clause 28). The Part also provides for the examination of food suspected to be unfit for human consumption by a regulatory officer (Clause 30). The Bill establishes the Therapeutic Foods Register that shall be under the care of The Registrar and shall be available for inspection by the public (Clause 32).

PART IV provides the prohibition of a number of medicines and declares the offence and punishment of any person who sells any medicine that is prohibited under this Act or any written law (Clause 34). This part also provides for various offences that can be committed in respect to the standard of medicines including their content, packaging and advertising (Clause 36). The Part ensures that the sale and preparation of medicines is up to standard by declaring it an offence to sell medicine that is not of the correct standard or preparing medicine that does not meet prescribed standards (Clause 37-38). Moreover, the Bill details the factors that the authority shall take into consideration before granting a product license (Clause 39). The bill also establishes the Medicines Register (Clause 40). The Bill under Clause 41-45 provides for the process of registration of medicines and medical devices, these clauses also detail the process of amendment, transfer and cancellation of registration. The Bill provides for measures that the Cabinet Secretary shall be able to pursue in order to ensure supply of more affordable medicines

(Clause 46). The Bill also provides for when and how a pharmacist can dispense interchangeable multi-source medicine instead of what was prescribed by a medical doctor (Clause 47).

PART V of the Bill regulates the sale, manufacture, exportation and importation of herbal medicines (Clause 48-57)

PART VI of the Bill provides for the formalities relating to licenses for the manufacture of medicinal substances (Clause 59-60)

PART VII of the Bill provides for the types of therapeutic cosmetics whose sale is prohibited and makes the sale of such therapeutic cosmetics an offence (Clause 61). Moreover, the bill provides for the sale of therapeutic cosmetics in such a manner as to make it likely for a therapeutic cosmetic that is not up to set standards to be confused for another therapeutic cosmetic that is up to the standards and makes it an offence to do so (Clause 62). The Bill prohibits the sale of therapeutic cosmetics under insanitary conditions and makes it an offence to do so (Clause 63). The Bill provides for the treatment of any therapeutic cosmetic which either contains a Scheduled Substance or claims to have a therapeutic effect as a medicine (Clause 64). Lastly, the part provides for the creation of a therapeutic cosmetics register (Clause 65).

PART VIII of the Bill provides for the prohibition of ingredients contained in therapeutic cosmetics by the Authority and makes the sale of any cosmetics containing these prohibited ingredients of an offence (Clause 66). The Bill provides for the creation of the a register containing duly registered medical devices and which shall include all the particulars of the devices and the holders of the devices that the Bill or any other law required to be contained in it (Clause 67). In addition the Bill provides for the types of medical devices whose sale is prohibited and makes the sale of any such medical devices an offence (Clause 68). Nevertheless, the Bill prohibits the sale of any medical device in a manner that is deceptive regarding any of the attributes of the medical device and makes it an offence to do so (Clause 69). The Bill also provides for the issuance of standards by the Authority to ensure that the exposure of patients to radiation is minimized and prohibits the sale of any medical advice that does not conform to these standards in such a manner that is likely to be confused for a medical device that does not conform to the standards (Clause 70).

PART IX of the Bill provides for certain offences relating to the sale of medical devices including sale of any medical device under insanitary conditions, sale of any medical device that has a measuring function that does not provide accurate measurements and sale of unapproved medical devices (Clause 71). The Bill also provides for the licensing of persons that deal in blood and blood products setting out the manner in which a license may be obtained, registered and revoked (Clause 72). Moreover the Bill provides for the collection of blood in exchange for payment and establishes a register for blood and blood products containing healthcare establishments that deal with blood and blood products and serious incidents associated with the collection and use of blood and blood components (Clause 73).

PART X provides for the manner in which the Authority shall handle serious and adverse incidents relating to blood and blood components (Clause 74). Moreover, the Bill provides for the manner in which the Authority shall regulate the manufacture of tobacco (Clause 75-77). Also, the Bill provides for the establishment of the National Quality Control Laboratory whose functions include examination and testing of drugs to ensure control drugs and medicinal substances, performing pharmaceutical evaluation, conducting research and training and testing the quality of locally manufactured and imported medicines, medical devices or therapeutic

foods on behalf of the Authority with a view to determining whether they comply with the set standards (Clause 78-79) (PART XI).

PART XII provides for the manner in which the Authority shall regulate the advertisement and labeling of health products and technologies (Clauses 80-87).

PART XIII provides the Cabinet Secretary with the authority to prohibit or control certain medicines and makes the contravention of any order of prohibition made by the Cabinet Secretary in exercise of this authority an offence (Clause 88). The Bill provides for the situations under which the Authority may permit persons to supply health products or technologies that are not registered (Clause 89). The Bill provides for the retention and disposal of any drugs seized under the Bill (Clause 90). The Bill also provides for the situations under which the Authority may compel a person handling health products to provide the Authority with information regarding the health products (Clause 91). The Bill nevertheless provides for the inspection of licenses and certificates of registration by regulatory officers and makes the obstruction of regulatory officers from exercising their powers an offence (Clause 92-95). Clause 96 provides for the criminal responsibility of directors, secretaries and managers where an act that is an offence under this Act is committed by a body corporate and applies the same to partners. Clause 97 provides for the inspection of animals and seizure of meat for human consumption that is deemed to be unfit for consumption in which they shall carry out their duties. The Bill provides for the powers of regulatory offices and prescribes the manner in which they shall carry out their duties (Clause 98). Clause 99 of the Bill provides for the powers of the Director of Medical Services, Director of Veterinary Services or the Director of Agriculture to order a public officer to have articles of food or health products analyzed. The Bill provides for the power of the Cabinet Secretary, the power of the court and the prosecution of any person for an offence under the Act (Clause 101-103).

PART XIV contains the financial provisions relating to the Authority including the funds of the authority, the financial year of the Authority, the preparation of the annual estimates of the Authority, the keeping of accounts and auditing of the Authority, the manner in which the Authority may invest its funds, the preparation of annual reports by the Authority and the submission of special reports to the National Assembly (Clause 106-112).

PART XV contains miscellaneous provisions relating to the functioning of the Authority including making of regulations for the effective enforcement **of the Act, transitional provisions and the laws or sections thereof repealed by the enactment of this Act (Clause 113-115).**

PART III

3.0 PUBLIC PARTICIPATION AND STAKEHOLDER ENGAGEMENT ON THE BILL

3. Article 118(1) (b) of the Constitution provides that, *"Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees".* Standing Order 127 (3) provides that *"the Departmental Committee to which a Bill is committed shall facilitate public participation and take into account the views and recommendations of the public when the Committee makes its report to the House"*

4. The Committee requested for comments on the Bill from members of the public and relevant stakeholders pursuant to the provisions of Article 118(1)(b) of the Constitution of Kenya and Standing Order 127(3), the Committee received memoranda from many critical stakeholders and individuals:

Long title And Short Title

5. Pharmaceutical Society of Kenya proposed THAT the Bill be amended by deleting the title and substituting therefor the following title "The Medicines and Health Products Bill, 2019"

Justification
There's need to establish the difference between the terms "medicine" and "drug" to avoid losing intent of the Bill.

6. PATH proposed that THAT the Bill be amended in the long title by deleting the long title and substituting therefor the following new long title—

AN ACT of Parliament to establish the Kenya Food and Drugs Authority; to provide for the regulation and management of food, drugs and scheduled substances, to provide for the regulation of medical devices and other health technologies; to guarantee the safety and quality of food and drugs and for connected purposes.

CLAUSE 2

7. The Ministry of Health noted as follows:

   i. That some definitions are insufficient and needed to be more comprehensive.

   ii. Some definitions are ambigious for example 'therapeutic cosmetics'. Any substance classified as 'therapeutic' is by nature considered a medicine.

   iii. medical device should include radiation emitting devices

   iv. There is need to define Additional definitions required such as, "antibiotic drug", "Codex Alimentarius Commission", "Codex Alimentarius Standard", "color additive", "food additive" "plasma-derived therapeutic product", "poison", "sponsor" and "standard"

Justification
Increase clarity

8. Pharmaceutical Society of Kenya proposed THAT Clause 2 of the Bill be amended (and consequently wherever the words appear in the Bill), as follows–

    a) By deleting the terms cigarette, food, insanitary conditions, tobacco, tobacco product

    b) In definition of the term "health products and technologies", by deleting the words "tobacco and tobacco products"

    c) By deleting the words "interchangeable multi-source medicine" and substituting therefor the word "generic medicine", and consequently amending the Bill where the term is applied

    d) By deleting the term "therapeutic" in the definition of the term "therapeutic cosmetics"

    e) By deleting the term "technologist" in the definition of the term "pharmaceutical technologist" and substituting therefor the term "technician"

9. Kenya Nutritionists & Dieticians Institute (KNDI) proposed definition of the following terms: Regulatory Officer, License and Therapeutic food.

    Justification
    The definitions provide the establishment of the provisions within the context of this Bill.

10. The Public Health Officers and Technicians Council, Kenya proposed definitions of the following terms as follows-

    i. 'Regulatory Officer' – Means officers appointed by the Authority under this Act for purposes of enforcement and shall include Authorized officers appointed or recognized under the Food Drugs and Chemical Substances Act Cap 254 and Public Health Act Cap 242

    ii. 'License' – Means a license issued by the authority under clause 12 (m) of this Act and shall not include or conflict licenses issued under Cap 254 or by the County governments to undertakings that sell food to the Public

11. Agrochemicals Association of Kenya was concerned with the definition of "chemical substance" in the Bill that includes pesticides, insecticides and rodenticides which are already regulated by the Pest Control Products Board and any other substance or mixture of substance that the Authority may declare. Pesticides are defined in the Pest Control Act as follows-

    "pest control product" means a product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, attracting or repelling any pest and includes—

    (a) any compound or substance that enhances or modifies or is intended to enhance or

modify the physical or chemical characteristics of a pest control product to which it is added; and

(b) any active ingredient used for the manufacture of a pest control product;

They further proposed that definition of chemical substance should be amended by deleting "pesticides, insecticide and rodenticide"

12. The Union of Veterinary Practitioners, Kenya proposed the following amendments on the definitions -

i. Include definition of "Feed" which includes any article manufactured, sold or represented for use as a therapeutic food or drink for animal consumption, and any ingredient of such therapeutic food or drink.

ii. "Veterinary pharmaceutical products" means a substance or a mixture of substances other than farm feed used or purporting to be suitable for use in connection with the diagnosis, treatment, prevention or cure of a disease, an infection or other unhealthy condition in animals;

(b) The maintenance or improvement of health, growth, production or working capacity in animals; or
(c) Restoring, correcting or modifying a somatic or organic function, or for correcting or modifying behavior in animals.

iii. Amend the definition of "blood products" as follows-

iv. Means any therapeutic substance derived from human or animal blood, including whole blood, blood component and plasma-derived medicinal substances.

v. Insert definition of "health and veterinary products and technologies" means blood and blood products- chemical substances, therapeutic cosmetics-food, herbal medicines and products, medical devices including radiation-emitting devices, medicines, scheduled substances, tobacco and tobacco products and substances.

vi. Amend definition of "veterinary surgeon" as follows means- A person registered as such under the Veterinary Surgeons and Veterinary Para-Professional Act

vii. "veterinary para-professional" means a person registered as such under veterinary Surgeons and Veterinary Para-Professional Act

13. Mr. Duncun Momanyi proposed insertion of the following terms –

a. Insert immediately after authority
"authorized officer" for the purposes of matters relating to sanitation and parts III and X of the Act, the public health officers shall be deemed to be authorized officers.

b. Insert immediately after Director General, the following paragraph;

"Director of Public Health" means the Director of Public Health appointed under Section 18(a)(iv) of the Health Act, No.21 of 2017.

c. Insert immediately after "medical practitioner" the following paragraphs:
"premises" includes any building or tent together with the land on which the same is situated and any adjoining land used in connection therewith and includes any vehicle, conveyance or vessel;

"public health officer" means a person registered as such under the Public Health Officers Act No. 12 of 2013.

14. Mr. Sospeter Otuya Katiechi, Ms. Faith Mumbua Kyalo and Mr. David Gichuka Ndichu proposed clarification of the definition of a pharmaceutical technologist as follows -

"pharmaceutical technologist" has the meaning assigned to it in the Pharmacy and Poisons Act;

15. Mr. Maxwell Banda, Mr. Samuel W.Kibe And Ms. Rose Kibuthu proposed definitions of the following terms as follows-

i. "pharmaceutical technologist" an enrolled pharmaceutical technologist is a person whose name has been entered in the roll to be established by this Board."

ii. "pharmacy" means
a) The profession as carried out by registered pharmacists or enrolled pharmaceutical technologists.
b) The duly licensed premises from which pharmacy services are provided by a registered pharmacists.

16. Mr. David Muthuri proposed definition of the following terms as follows-

"pharmacy" means

a) The professional of pharmacy as carried out by Registered Pharmacist or Pharmaceutical Technologist
b) The duly licensed premises from which pharmacy services are provided by a registered pharmacist or pharmaceutical technologist

17. Mr. Stephen Wachira proposed as follows-

i. Delete the "pharmaceutical" technologist and replace it with "diploma pharmacist"
ii. Delete the title "pharmacist" and replace it with "pharmacy specialist"
Therefore:
a) "pharmacy specialist" means a person duly registered as a degree pharmacist by the body responsible for the registration of pharmacy practitioners
b) "pharmacy practitioners" means an enrolled diploma pharmacist and a registered pharmacy specialist
c) "pharmacy"means
i. Profession of pharmacy as carried out by pharmacy practitioner's

ii. Duly licensed premises from which pharmacy services are provided by pharmacy practitioner's

18. Mr. John Kabui proposed definition of the following terms as follows-

"enrolled pharmaceutical technologist" means a holder of a diploma in pharmacy from a training institution recognized by the board and whose name appears on the roll
"pharmacy" means

a) The profession of pharmacy as carried out by enrolled by pharmaceutical technologist.
b) The duly licensed premise for which pharmacy services are provided by an enrolled pharmaceutical technologist.

19. Pest Control Products Board and Agrochemicals Association of Kenya noted that the definition of "chemical substance" includes pesticides, insecticides, rodenticides, which are already regulated by the Pest Control Products Board and by the Veterinary Medicines Directorate.

Justification
Will result in overlap of mandates.

20. Nzoia Sugar Company noted that definition of "food" would include sugar.

Justification
Would lead to clashing of roles with the Agriculture and Food Authority.

21. Agriculture and Food Authority noted that definition of food includes crops.

Justification
Crops are under the mandate of the Agriculture and Food Authority.

22. THAT the Bill be amended in clause 2 by—
a) deleting the definitions of the terms "cigarette" "tobacco" and "tobacco products";
b) deleting the words "including radiation-emitting devices" appearing in the definition of the term "health products and technologies";
c) deleting the words "whether radiation-emitting or not" appearing in the definition of the term "medical device" and
d) inserting the following new clauses immediately after clause 2—

Objects.

2A. The objects of this Act is to—

(a) establish a body corporate for the co-ordination and regulation of food, drugs and health products and technologies;

(b) promote standards of safety, efficacy and quality of food, drugs and health products and technologies and their products; and

(c) ensure an effective control and safety of food, drugs and health products and technologies.

Guiding principles.

2B. The Authority shall observe and uphold the national values and principles of governance set out in Article 10 of the Constitution and the values and principles set out in Article 232(1) of the Constitution, international best practices on food and drugs safety and quality, and for the avoidance of doubt, shall—

(a) ensure access to the highest attainable standard of health and health products;

(b) ensure that food, drugs and health products are handled and produced in accordance with the standards prescribed under this Act;

(c) strive to guarantee the highest degree of consumer confidence in the quality and safety of food, including exported and imported drugs and chemical substances;

(d) strive for the highest attainable standards of professionalism and discipline; and

(e) ensure reasonable access to its services in all parts of the Republic.

CLAUSE 3

23. The Pharmaceutical Society of Kenya proposed THAT Clause 3 (1) of the Bill be amended as follows –
(a) by deleting paragraphs (d) and (i)

(b) in Paragraph (c) by deleting the term "therapeutic"

24. Kenya Bureau of Standards (KEBS) noted that the Bill excludes the role currently played by other government institutions including-

i. Pharmacy and Poisons Board
ii. KEBS
iii. Kenya Plant and Health Inspectorate (KEPHIS)

This will create confusion in regulation of these products and as a result compromise quality of products. The Bill should recognize the roles currently undertaken by those institutions and specific obligation to those institutions to collaborate.

25. Public Health Officers and Technicians Council, Kenya proposed deletion of food and tobacco and tobacco products.

They noted that regulation of food, tobacco and medicines should not be done by the same regulator as both require distinct technical expertise in areas of medicine and tobacco. The regulatory officer defined under the proposed bill will therefore require different and distinct expertise to function competently.

In addition, Kenya's regulatory framework of medicine is currently defined as WEAK by the WHO, focus should therefore be on strengthening the regulatory framework of medicines and food separately and independently for better regulatory outcomes.

26. International Institute for Legislative Affairs noted that Tobacco and tobacco products are listed as health product/technology-Tobacco and tobacco products which are not health products /technologies.

    If tobacco products are retained in the list there is likely conflict with the authority assigned to regulate tobacco though the Tobacco Control Act.

27. The Union Of Veterinary Practitioners, Kenya proposed Insertion of a new paragraph3(1) (j) as follows-

    (j)Veterinary medicines

    Veterinary medicines needs to be covered here. There is need to have clear distinction between human and veterinary medicine.

28. Mr. Duncun Momanyi proposed that the Act be amended as follows-

    3(1) This Act applies to regulation of-

    a) Food
    b) Scheduled substances
    c) Tobacco and tobacco products
    d) Chemical substances; and
    e) Health products and technologies including-
        i. Blood and blood products;
        ii. Therapeutic cosmetics
        iii. Herbal medicines and products
        iv. Medical devices including radiation-emitting devices
        v. Medicines.

    B) Insert after the word constitution the following "or the Public Health Act Cap, 242 or Tobacco Control Act, No. 2 of 2007."

    The amended paragraph should read as follows –

    3(2) Unless otherwise provided in this Act or the Constitution or the Public Health Act Cap 242 or the Tobacco Control Act, No.4 of 2007, no other authority or law may regulate the items regulated under this law.

29. Kenya Tobacco Control Alliance proposed deletion of the following sections –
    i. 3(1)(i)
    ii. 3(2).

    Justification
    i. Tobacco and tobacco products are not health products or technologies, therefore outside the scope of the Bill.

    ii. Will lead to conflict with the authority assigned to regulate tobacco and tobacco products through the Tobacco Control.

30. Agriculture and Food Authority noted that food has been included as a health product and technology.

They noted that Health product is a terminology used in health sciences and not food related.

31. PATH proposed **THAT** the Bill be amended in clause 3 by deleting the clause and substituting therefor the following new clause;

3. This Act shall apply to the regulation of—

(a) therapeutic products Including
(i) Medicines for use in humans;
(ii) medical devices;
(iii) biological products for use in humans;
(iv) and the starting materials used in the manufacture of medicines, medical products and biological products;
(v) complementary medicinal products, including herbal medicinal products;

(b) food intended for human consumption, including food supplements;
(c) scheduled substances; and
(d) products containing scheduled substances and intended for use in humans, including;

(i) cosmetics; and
(ii) controlled substances.

CLAUSE 6

32. The Ministry of Health proposed that qualifications of the Director General should encompass the entire scope of the Authority's functions.

Justification
For inclusivity.

33. The Pharmaceutical Society of Kenya proposed THAT Clause 6 of the Bill be amended as follows–

In sub-clause (2), by deleting the words "appointed by Public Service Commission through a transparent and competitive process with the approval of Parliament" and substituting therefor the words "recruited by the Board through a transparent and competitive process and appointed by the Cabinet Secretary".

(b) In sub-clause (2), by deleting the word "four" and substituting the word "three"

(c) In sub-clause (3) (a), by deleting the words " in either pharmacy, food science, medicine or equivalent field" and substituting therefor the word "pharmacy"

(d) by deleting sub-clause (3) (d) and substituting therefor the words "is a member of the professional body regulating pharmacists and in good professional standing"

(e) by deleting sub-clause (5) and substituting therefor the words "The Director General shall be responsible for the day to day management of the Authority and accountable to the

Board"

(f) by deleting sub-clause (6)

34. The Union of Veterinary Practitioners, Kenya proposed that paragraph 6(3) be amended to incorporate veterinary medicine in qualifications as follows-

(3) A person shall be qualified for appointment as a Director General if such person—
(a) holds a masters' degree from a university recognized in Kenya in either pharmacy, food science, veterinary medicine, medicine or equivalent fields;
(b) has demonstrable experience in the regulation of health and veterinary products and technologies that affect human health;

35. Mr. Duncun Momanyi proposed THAT-

i. Paragraph 6(3a) should be amended by inserting "public health" immediately after medicine. The amended paragraph should read as follows-

6(3a) holds a masters' degree from a university recognized in Kenya in either pharmacy, food science, medicine, public health or equivalent fields;

ii. Paragraph 6(3b) should be amended by inserting "food, scheduled substances, chemical substances, and "immediately after regulation of. The amended paragraph should read as follows-

6(3b) has demonstrated experience in regulation of food, scheduled substances, chemical substances, and health products and technologies that affect human health.

36. The Agriculture and Food Authority noted that in paragraph 6(3)- Qualifications of Director General of the Authority states experience in health products and technologies. They proposed its deletion as it is discriminating against agriculture professionals.

37. PATH proposed THAT the Bill be amended in sub clause (1) by deleting the words "Public Service Commission" and substituting therefor the word "Board" appearing immediately after the words " appointed by the".

CLAUSE 8, 8(11) AND 3RD SCHEDULE

38. The Ministry of Health noted that Clause 8 provides for the establishment of the Board which will involve parliamentary vetting of members of the Board except for nominees from Council of Governors and Consumer Protection organization.

39. *The Ministry proposed that the Chairperson should not be competitively recruited; instead the Chair should be appointed by the President and not require parliamentary vetting. Further, Members of the Board should not undergo parliamentary vetting; instead they should be nominated by virtue of their positions in their Ministries/Agencies.*

40. Pharmaceutical Society Of Kenya proposed THAT Clause 8 of the Bill be amended as follows–

(a)in sub-clause (1) by deleting the words "Kenya Food and Drugs Board" and substituting therefor the words " Medicines and Health Products Authority

(b)in subclause (2) by deleting paragraphs(d),(f),(g),(h)and(i) and substituting therefor the following-

(d)the director responsible of pharmaeceutical services
(f)a registered pharmacist with knowledge and experience in regulation of medicines nominated by the Pharmaceutical Society of Kenya;
(g) a registered pharmacist with knowledge and experience in medicines research;
(h) a person qualified and experienced in biomedical engineering;
(i) a medical practitioner nominated by Kenya Medical Association.

(c) Insub-clause2(j),by inserting the words "and an ex-officio member of the Board" after the word "secretary"
(d) In sub-clause (3) by deleting the words " paragraph (h), and (i) of subsection (2) and substituting therefor the words "subsection (2) (d), (f), (g), (h) and (i)".
(e) In clause (5) (a) by deleting the word "science" and substituting the word "pharmacy"

41. Mr. Duncun Momanyi proposed an amendment to clause 8 as follows-

Replace, "person with special knowledge of food sciences" with "public health officer".

The amended section should read as follows;

8(2h) one public health nominated by the Council of Governors to represent the interests or counties

42. The Kenya Nutritionists & Dieticians Institute (KNDI) proposed amendments to the following paragraphs as follows-

(a) 8(h) to read as follows-

"one person with special knowledge of food and nutritional sciences nominated by the Kenya Nutritionists and Dieticians Institute"

Justification
The Institute is the custodian of all professionals with knowledge in food and nutritional sciences and would do proper justice to nominations.

(b) 8(i) to read as follows-

"a person with broad food safety knowledge nominated by the Council of governors"

Justification
All the Board of management members by default represent the consumers' interest and having an independent consumers representative is a duplication.

43. The Kenya Bureau of Standards (KEBS) pointed that section 8(2)(j) provides that the Director-General of the Authority shall be the Secretary of the Kenya Food and Drugs Board. They noted that it is contrary to government policy as captured under the Mwongozo Code of Conduct which provides for the office of the Corporation Secretary to act as Secretary to the Board.

44. Public Health Officers and Technicians Council, Kenya proposed amendments to Clause 8(2)(b) and Clause 8(2)(i) as follows -

i. Clause 8(2)(b)-

One member representing Public Health practitioners with special knowledge in food safety nominated by the Public Health Officers and Technicians Council.

ii. Clause 8(2)(i) -

A person with broad knowledge on food safety nominated by the Council of governors

45. Union of Veterinary Practitioners, Kenya proposed that the Board include the PS for livestock or a representative and the Director of Veterinary Services.

46. Agriculture and Food Authority proposed that paragraph 8(g)- which reads Director General of Agriculture, Fisheries and Food Authority be amended to read as follows –

-Director-General of Agriculture and Food Authority.

47. PATH proposed THAT the Bill be amended by inserting the following new sub clause immediately after sub clause (6)—

(6A) A person is disqualified from appointment as the Chairperson or member of the Board, if that person—
(a) is a member of Parliament;
(b) is a member of a county Assembly or executive;
(c) is a member of a governing body of a political party;
(d) is an undischarged bankrupt; or
(e) is convicted of an offence and sentenced to imprisonment for a term exceeding six months.

CLAUSE 9

48. The Agriculture and Food Authority proposed deletion of clause 9.

Justification

Oathing of chairman and members of the Board is not necessary

CLAUSE 12

49. The Ministry of Health noted that Clause 12 Provides for functions of the Authority. Functions of the Authority mainly focus on health technologies and products.

The Ministry recommended that Food related functions should be included in this section for consistency. In addition the section requires to be more comprehensive and explicit on the functions for example regulation of water.

Justification
Consolidate the functions in one section.

50. Pharmaceutical Society of Kenya THAT Clause 12 of the Bill be amended as follows –

(a) by deleting introductory sentence and substituting therefore the following –
"The function of the Authority shall be to regulate the research, production, manufacture, importation, distribution, marketing, sale and use of medicines and health products, and for that purpose, the Authority shall –

(b) In paragraph (c) by inserting the words "and economic value" after the word "efficacy"

(c)in paragraph (g) by inserting the words "regulating clinical trials" before the words "ensure that clinical trials"

(d)By deleting paragraph (p) and substituting therefor the following-

(p) providing medicines information and promoting rational use of medicines and health products.

(e)By inserting the following new paragraphs after paragraph (t) and renumbering the clause accordingly-

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

(v) schedule medicines and health products;

(w) carry out pharmacovigilance of medicines and health products;

(x) carryout and promote research related to medicines and health products;

(y) ensure quality control and quality assurance in medicines and health products;

(z) regulating disposal of medicines and health products; (aa) regulating complementary, alternative or herbal medicines.

51. The Kenya Bureau of Standards (KEBS) noted and recommended as follows-

The objectives, application and functions of the Bill are not cognizant of the existing regulatory framework where health and safety of the products covered is currently covered by different bodies established under various legal Acts within various ministries.The roles and functions already being carried out by these regulatory agencies.

Under section 12(q), the Authority assumes the function of Prescribing Standards. The role of prescribing Kenya Standards is the mandate of KEBS under the Standards Act (Cap 496)

Section 12(m), the Authority shall issue manufacturing licenses, revoke licenses and monitor compliance for the products covered under the Act.This will affect KEBS role in inspection, and monitoring of compliance functions of KEBS

If this role is assumed by the Kenya Foods and Drugs Authority this will adversely affect the mandatory standardization mark schemes as the bulk of permits fall under the Food, Agriculture, Water and Chemical sections. It will also adversely the standard levy.

KEBS is of the opinion that the Kenya Food and Drugs Authority role should be that of co-ordination and on the food and drug regulatory functions performed by different bodies mandated by existing National legislation.

52. The Agriculture and Food Authority proposed deletion of sub-clauses 12(g) and 12(q).

Justification
These are functions of the Kenya Bureau of Standards.

53. The New Kenya Co-operative Creameries Limited proposed deletion of sub-clauses 12(a), 12(m) and 12(q).

Justification

i. It creates duplicity of functions and mandate.

ii. The functions are currently being performed by the Kenya Bureau of Standards and Public Health.

54. Kenya Tobacco Control Alliance proposed deletion of sub-clause 12(q)

Justification
The functions are currently being performed by the Kenya Bureau of Standards.

55. PATH proposed THAT the Bill be amended in clause 12 by deleting the clause and substituting therefore the following new clause—

Functions of the Authority

12. (1) The functions of the Authority are to—

(a) be the lead agency in co-ordinating and harmonizing food and drugs safety control activities in Kenya at all stages of production, manufacture and distribution;

(b) provide for the regulation, investigation, inspection and approval of food, health products and technologies, and related matters in the public interest;

(c) ensure, in collaboration with the body responsible for standards, adequate and effective standards and guidelines for the regulation of health products and technologies;

(d) ensure the efficient, effective and ethical evaluation and registration of health products and technologies that meet defined standards of quality, safety and efficacy;

(e) ensure that clinical trial protocols required for registration of health products and technologies are assessed according to the prescribed ethical and professional criteria and standards;

(f) monitor the performance of enforcement authorities in enforcing the legislation for which they are responsible;

(g) formulate strategies and policies on food, nutrition and food security, including procedures for emergency response, and monitor their implementation;

(h) encourage and promote research on matters of food and drugs in Kenya;

(i) provide advice, information or assistance to any public authority in relation to food and drugs control, safety and trade;

(j) promote consumer education regarding food and drugs safety;
(k) foster co-operation between the Authority and other institutions or organizations and other stakeholders; and

(l) carry out any other matter in connection with or reasonably incidental to the performance of its functions under this Act

(2) The Authority shall in undertaking the functions under subsection (1) and pursuant to Article 189(1)(a) of the Constitution, collaborate the relevant department at the county level.

CLAUSE 17

56. The Council of Governors (CoG) proposed deletion of clause 17

Justification
It is the mandate of the County public service board to recruit the members of staff necessary to carry out County Government functions.

57. The Public Health Officers and Technicians Council, Kenya proposed definition of the appointing and qualifications of Regulatory Officer -

Justification
The Act should define persons who qualify as regulatory officers based on their areas of competence and expertise to conduct inspections. This will professionalize this position and give clarity.

58. Mr. Duncun Momanyi proposed insertion of the following new terms "and authorized officers" after officers.

The amended section should read;

17(1) The Authority may appoint such officers or staff including regulatory officers and authorized officers, as are necessary for the proper discharge of the functions of the Authority under this Act, upon such terms and conditions of service as the Authority may determine.

Justification
The authorized officers will be specifically dealing with food, food safety, sanitary inspection of premises, tobacco and tobacco products control.

Insert "and council of Governors" after Secretary.

17(3) The Cabinet Secretary and Council of Governors may upon request by the Authority second to the Authority such number of public officer as may be necessary for the purposes of the authority.

Justification
This is because majority of the Public Officers are employed by the Counties.

CLAUSE 19

59. The Public Health Officers And Technicians Council, Kenya noted that any lawful action taken by a member of the Board or any officer, employee or agent of the Authority shall, if the matter or thing is done in good faith for executing the functions, powers and duties of the Authority render the member, officer, employee or agent personally liable to any action, claim or demand whatsoever.

Justification
This protects the members of the board, staff or any agents of the Authority from personal liability but pegs the action undertaken on legality and/or professionalism in line with the leadership and integrity Act No. 19 of 2012. This is since personal liability is only viable if the action undertaken is lawful.

CLAUSE 20

60. The Pharmaceutical Society of Kenya proposed THAT Clause 20 of the Bill be deleted.

Justification
With the establishment of the Authority, there is no policy justification for creation or designation of the position of registrar in the Authority. The establishment and management of respective registers as well as issuance of licences is the responsibility of the Authority as a body corporate. In addition, the CEO is responsible for day to day management of the Authority. Consequently, it is inappropriate to assign the CEO the role of being the Registrar. This is tantamount to centering too much power and responsibility on a single office, which is contrary to management and corporate governance principles.

CLAUSE 21 AND FOURTH SCHEDULE

61. The Ministry of Health noted that the clause provides for establishment of Scientific advisory committees for the Board. These committees are mainly made up of desk officers from various Ministries and agencies as opposed to experts that would support evidence based decision making.

62. The Pharmaceutical Society of Kenya proposed THAT Clause 21 of the Bill be amended as follows–

2 (a) By deleting sub-clause (1) and substituting therefor the following– (1) There shall be established such Scientific Technical Committees of the Authority as shall be appropriate for purposes of ensuring effective performance and implementation of the functions of the Authority.

3 (b) By deleting the term "Scientific Advisory Committee" and substituting with the words "Scientific Technical Committee" wherever the term appears in the Bill.

4 (c) By deleting sub–clause (2) and substituting therefor the following– (2) Notwithstanding subsection (1), the following Scientific Technical Committees shall be established –

5 (a) Human Medicines Committee

6 (b) Veterinary Medicines Committee

7 (c) Medical Devices and Health Technologies Committee

8 (d) Biologics Committee

9 (e) Pharmacovigilance Committee

10 (f) Complementary, Alternative or Herbal Medicines and Dietary Supplements Committee

11 (g) Radiopharmaceuticals Committee

12 (h) Cosmetics and Borderline Products Committee

(e) By deleting sub-clause (5) and (6) and substituting therefor the following–

(5) A Committee shall consist of –

(a)a chairperson who shall be a person qualified and experienced on matters related to the Committee: provided that-

(i)for all Committees except the Veterinary Medicines Committee and Medical Devices

Committees, the chairperson shall be a registered pharmacist;

(ii)the chairperson of Veterinary Medicines Committee shall be a registered veterinary surgeon experienced in matters related to regulation of veterinary medicines;

(iii)the chairperson of Medical Devices and Health Technologies Committee shall be a qualified biomedical engineer;

(b)a secretary, who shall be the officer of the Authority who is incharge opf matters related to the Committee;

(c)two technical officers of the Authority qualified on matters related to the committee as may be designated by the Authority.

(d) one officer in the ministry of health who is qualified and experienced in matters related to the Committee: Provided that–

(i) for Human Medicines Committee, the Director of Pharmaceutical Services shall be a member;

(ii) for Veterinary Medicine Committee, a person designated by the Director of Veterinary Services shall be a member;

(e)four person, not being officers of Authority or employees of the ministry of health who are qualified, knowledgeable and experienced on matters related to the Committee: Provided that for the Veterinary Medicines Committee, two persons shall be registered pharmacist experienced on matters related to regulation of veterinary medicines.

(6) A person described under subsection (5) (a) and (e) shall be appointed by the Cabinet Secretary in consultation with the Authority: Provided that at least two persons described under sub-section (5) (e) shall be appointed from among the persons nominated by the Pharmaceutical Society of Kenya.

(f) By inserting new sub-clause (7), (8) and (9) and renumbering the clause respectively as follows–

(7) A member of the Committee appointed under subsection 5 (a) and (e) shall hold office for a term of three years, which may be renewed for a further term of three years.

(8) In appointing or constituting the Committee established under this section, the Cabinet Secretary and the Authority shall ensure that not more than two thirds of the members shall consist of persons of the same gender.

(9) The Cabinet Secretary shall prescribe procedures for operations of the Committees established under this section.

63. The Union of Veterinary Practitioners, Kenya proposed establishment of a Veterinary Pharmeutical Products Directorate and a Human Pharmaceutical Products Directorate.

Justification

The Bill should safeguard the functions of Veterinary Medicines Directorate created through the National Livestock Policy sessional paper No. 2 of 2008 and Veterinary Surgeons and Veterinary Paraprofessional Act, 2011 to help the authority regulate veterinary products.

The two directorates within the authority will create synergy between these two critical professions.

CLAUSE 22

64. The Ministry of Health noted that clauses 22-32 provides for regulation of food. It recommended tha the Bill requires a section outlining the process of registering food manufacturing facilities. These facilities should be defined as any factory, warehouse, or establishment (including a factory, warehouse, fishing vessel or establishment of an importer) that manufactures, processes, packs, or holds food; The section should include a clause on laboratory accreditation for analyses of foods.

65. Mr. Duncun Momanyi proposed deletion of section 22(2f).

Justification
The section is inconsistent with Article 186(1) of the Constitution as read with Part 2 of the Fourth Schedule. Part 2(2) provides county health services which include, in particular d)licensing and control of undertakings that sell food to the public.

66. The Pharmaceutical Society of Kenya proposed THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification
Food should not be regulated under the same legislation as medicines and health products.

67. The Public Health Officers and Technicians Council, Kenya proposed as follows –

i. Clarify which licenses are covered under this Act in 22(2)(f). This will be done through definition of a 'license' issued under this Act.

ii. Provide scientific and technical advice and assistance to the National Government and the county governments regard to consumer protection under 22(2)(g).

iii. 22(2)(h) draw up a general plan for regulation of food in collaboration with county-based units.

Justification

i. Licensing of food establishments and undertakings that sell food is a constitutional mandate of the County Government as outlined in schedule IV of 2010 constitution

ii. Crisis management regarding food does not make sense at the regulatory level since it is undertaken at the implementation level of food safety which is a devolved function.

iii. Crisis management regarding food safety does not make sense in the context of the regulation since it is undertaken at the implementation level which is a devolved function. Regulation is a national oversight function.

68. The Kenya Bureau Of Standards (KEBS) noted that the authority takes over the role of standards development for products covered under the Bill, thereby affecting the core mandate of KEBS under the Standards Act, Cap 496 Part III.

    It proposed that the Bill mandate the authority to refer to or adopt standards developed by KEBS as provided for under the Standards Act.

69. The Agriculture and Food Authority noted that section 22(1)- The Authority shall regulate and monitor the manufacture, processing, distribution, warehousing, wholesale and importation of food in Kenya.

    This contradicts the Crops Act which regulates and monitors crop products at manufacturing, distribution, warehousing and importation.

CLAUSE 23

70. The Public Health Officers and Technicians Council, Kenya proposed that clauses 23, 24, 25, 26, 27, 28, 29, 30 be deleted-

Justification

i. This Bill provides for the regulation of food safety, establishment of food standards and policy guidelines as functions of the national Government. However, the clauses 23 – 30 cover areas on service delivery which are devolved functions as enshrined in the constitution in fourth schedule.

ii. In addition, the clauses are adequately and comprehensively covered under Food, Drugs and Chemical Substances Act Cap 254 and the Public Health Act Cap 242.

iii. In lieu, where necessary, Food, Drugs and Chemical Substances Act Cap 254 should be amended to strengthen it as a service law rather than setting up a regulatory law that seeks to control matters of food safety.

iv. Currently, there is no gap on service delivery regarding food safety in the context of devolved health functions and repealing Cap 254 would create both legal and operational gap that will potentially create unprecedented public health crisis.

CLAUSE 25

71. The Council of Governors (CoG) proposed deletion of clause 25

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

72. The Pharmaceutical Society of Kenya proposed THAT Part III (Clause 22 – 32) of the Bill

be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

73. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses 23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments on clause 23.

CLAUSE 26

74. The Council of Governors (COG) proposed the deletion of clause 26.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

75. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

76. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses 23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments on clause 23.

CLAUSE 27

77. The Council of Governors (COG) proposed deletion clause 27.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

78. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

79. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses

23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments clause 23.

CLAUSE 28

80. The Council of Governors (COG) proposed deletion clause 27.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

81. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

82. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses 23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments clause 23.

CLAUSE 29

83. The Council of Governors (COG) proposed deletion clause 27.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

84. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

85. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses 23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments clause 23.

CLAUSE 30

86. The Council of Governors (COG) proposed deletion clause 27.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

87. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

88. The Public Health Officers and Technicians Council, Kenya proposed deletion of clauses 23, 24, 25, 26, 27, 28, 29, 30.

Justification

See earlier comments clause 23.

89. Mr. Duncun Momanyi proposed as follows-

Replace a regulatory officer with an authorized. The amended section should read as follows-

(1) An authorized may, examine any food intended for human consumption which has been distributed, sold, or is offered or exposed for sale or is in the possession of, or has been deposited with or consigned to, any person for the purpose of distribution or sale or manufacture for sale, if it appears to the regulatory officer to be unfit for human consumption, may seize it and remove it in order to have it dealt with in a manner provided for in this Act.
b)Section 30(1) is repeated. Therefore, the second section should be corrected 30(2). In in whose possession, section 30 and 6 subsections and not 5 as indicated.

Justification

The Authority will employ regulatory officers with different backgrounds. However, it is the authorized officer who is specialized in food and food safety.

90. Nzoia Sugar Company noted that in section 30(1)- functions of regulatory officer already being performed by Kenya Bureau of Standards and Public Health.

Comment

It will result in overlap of mandate

CLAUSE 31

91. The Council of Governors (COG) proposed deletion clause 27.

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

92. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

CLAUSE 32

93. The Pharmaceutical Society of Kenya THAT Part III (Clause 22 – 32) of the Bill be deleted.

Justification

Food should not be regulated under the same legislation as medicines and health products.

94. The Kenya Nutritionist and Dieticians Institute (KNDI) proposed the insertion of a new sub clause-

(5) Section 32 above shall not apply to therapeutic foods compounded by nutritionists and dieticians.

Justification

This section exempts the use administration and display of therapeutic foods and nutrition supplements under the custody of nutritionists and dieticians regulated under Cap 253 (B). KNDI has already developed regulations on food and nutritional supplements guided by section 36(2)

95. The Public Health Officers and Technicians Council, Kenya proposed the insertion of a new sub clause-

Clause 32 above shall not apply to therapeutic foods compounded by nutritionists and dieticians.

Justification

This clause exempts the use, administration and display of therapeutic foods and nutrition supplements under the custody of nutritionists and dieticians regulated under Cap 253 (B). KNDI has existing regulations on food and nutrition supplements established under Clause 36 (2) of Cap 253 (B) for the purposes of therapeutic foods. This is therefore an area under professional regulation.

CLAUSE 33

96. The Ministry of Health noted that Part IV that consists of Clauses 33-47 and provides for regulation of medicines including veterinary medicinal products -

i. Human and Vet medicine regulation should be separated because they do not

require the same stringent regulatory processes.

ii. Medical devises should be combined with the medicinal productions. Regulation of medicines and medical devises are combined in some areas (eg clause 40, 43) and not in others (Clauses 66-70). There needs to be consistency.

97. The Public Health Officers and Technicians Council, Kenya noted that there is need to clarify 33(3) to provide under which law the professionals will be regulated.

Justification

This section exempts pharmacists and pharmaceutical technologists. However, the Act that provides for their regulation and practice has been proposed for their regulation and practice has been proposed for repeal in the seventh schedule.

98. The Kenya Bureau of Standards (Kebs) noted that Authority takes over the role already vested in the Pharmacy and Poisons Board from section 33-47 under Pharmacy and Poisons Act (Cap 244)

99. The Kenya Nutritionist and Dieticians Institute (KNDI) noted that there is need to clarify 33(3) to provide under which law the professionals will be regulated.

Justification

This section exempts pharmacists and pharmaceutical technologists. However, the Act that provides for their regulation and practice has been proposed for their regulation and practice has been proposed for repeal in the seventh schedule.

CLAUSE 35

100. The Kenya Bureau of Standards (KEBS) noted that in clause 35 the Authority takes over the role already vested in the Pharmacy and Poisons Board from section 33-47 under Pharmacy and Poisons Act (Cap 244).

101. The Pharmaceutical Society of Kenya proposed THAT Clause 35 of the Bill be amended by inserting a new sub-clause (1) and renumbering the Clause accordingly as follows–

35 (1) The Cabinet Secretary shall prescribe the standards of medicines applicable in Kenya, which shall be in accordance with internationally acceptable standards prescribed under the Pharmacopoeia described under the Fifth Schedule.

Justification

As a matter of principle, clause 35 should commence with providing for the development of standards before providing for other consequential matters. In addition, the framing of Clause 35 (1) implies that the development of standards applicable in Kenya can be done without reference to the globally recognized standards which is inappropriate and irregular.

NEW CLAUSE

102. The Pharmaceutical Society of Kenya proposed THAT the Bill be amended by inserting a new Clause 45 and renumbering the Bill accordingly, as follows–

Scheduling medicines.

(1) All medicines shall be classified under the following schedules– (a) Schedule 1: General sales medicines which may be sold in any retail outlet, which shall consist of medicines that are widely used for frequently occurring symptoms, with proven safety record and the public is well aware of the dosage instructions and there is no risk of dependence;

(b) Schedule 2: Pharmacist only medicine, which shall only be sold in pharmacy and dispensed by pharmacist, which consists of medicines for symptoms that do not need medical test for diagnosis but requires a medical professional to advise on dosage instruction and safety information and carries no risk of dependence if used as advised. These medicines shall only be dispensed under direct supervision of a registered pharmacist;

(c) Schedule 3: Prescription only medicines which consists of medicines for disease only diagnosable with medical tests and whose dosage instructions and safety information are dependent on the diagnosis; and

(d) Schedule 4: Controlled medicines which shall consist of medicines for disease only diagnosable with medical tests and whose dosage instructions and safety information are dependent on the diagnosis and that cause dependence and carry risk of abuse.

(2) The Cabinet Secretary shall, in consultation with the technical committee on human medicines through the Authority and relevant professionals and stakeholders, prescribe the medicines that shall be classified under each schedule described under subsection (1).

(3) In prescribing the medicines to be classified under each schedule as described under subsection (2), the Cabinet Secretary shall be guided by–

(a) the medicine's innovator's classification and listing;

(b) the World Health Organization's guidelines on scheduling of medicines; and

(c) international formulary such as the British National Formulary.

CLAUSE 46

103. Mr. Maxwell Banda proposed that section 46(4) be amended to read as follows-

"A pharmaceutical technologist shall not substitute for prescribed medicine…"

104. Mr. Joel Nyumu Chege proposed that section 46(1) be amended as follows-

46. (1) A pharmacist and a pharmaceutical technologist shall dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical or dental p

ractitioner, nurse or other person registered under the relevant statutes regulating health professionals.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist or a pharmaceutical technologist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in

the prescription book.

CLAUSE 48

105. The Ministry of Health proposed that in Part V of the Bill that contains Clause 48-57 on Scheduled Substances.

i. The reason given for scheduling of substances is regulate the authorized seller and wholesalers. Other reasons should be included such as allowing restrictions to be placed on their supply to the public.

ii. Medicines and chemicals should be separated.

CLAUSE 52

106. Mr. Joel Nyumu Chege proposed that section clause 52 (1)(f) be amended as follows-

52 (1)(f) a hospital, dispensary or similar institution or a person or institution concerned with scientific education or research whether within or outside Kenya, where such hospital, dispensary, institution or person has been approved in that behalf by an order whether general or special, of the Cabinet Secretary: but it shall be an offence to sell Scheduled substances to any of the persons or institutions specified in paragraphs (d) and (f) unless a registered pharmacist or an enrolled Pharmaceutical Technologist is in direct control of the Scheduled Substances at the premises from which they are sold.

107. Mr. Sospeter Otuya Katiechi proposed that section 52(b) be amended as follows-

"(b) a person registered as lawfully carrying on the business of a pharmacist or pharmaceutical technologist in Kenya"

CLAUSE 58

108. The Ministry of Health noted as follows in clause 58-

i. The section fails to provide for licensing of manufacturing medical devises.

ii. The section needs to be more comprehensive and include provisions for issues related to licenses e.g. multi-site manufacturing licensing, publication of list of manufacturers, variation of licenses and transfer/ revocation and suspension of licenses.

109. The Kenya Bureau of Standards (KEBS) noted that in clause 58 the Authority takes over the role already vested in the Pharmacy and Poisons Board from section 58-59 under Pharmacy and Poisons Act (Cap 244).

CLAUSE 59

110. The Kenya Bureau of Standards (KEBS) noted that in clause 58 the Authority takes over the role already vested in the Pharmacy and Poisons Board from section 58-59 under Pharmacy and Poisons Act (Cap 244).

111. The Pharmaceutical Society of Kenya proposed THAT Clause 59 of the Bill be amended by inserting the words "in accordance with the most recent World Health Organization's prescribed guidelines on good manufacturing practice" after the word "Authority".

NEW CLAUSE 60

112. The Pharmaceutical Society of Kenya proposed THAT the Bill be amended by inserting new Clauses 60, 61 and 62 and renumbering the Bill accordingly as follows– Pharmacovigilance.

60.(1) The Authority shall, in coordination with relevant stakeholders establish, implement and ensure compliance with a national pharmacovigilance system.

(2) The system stipulated under subsection (1) shall provide for among others–

(a)medicines information system, which shall include collation and management of data and information;

(b) medicines reporting system;

(c)risk assessment and management;

(d) establishment of pharmacovigilance center;

(e)establishment of response system; and

(f) establishment of post-marketing surveillance.

(3) The Pharmacovigilance technical committee shall provide advice and support in the implementation of this section.

(4) The Authority shall prescribe guidelines for implementing the pharmacovigilance system established under this section.

(5) The Authority shall ensure that information collated and analyzed under the system established under this section informs decision making in respect to medicines quality assurance.

INSERTION OF NEW CLAUSE 61

113. Application for clinical trials authorization

62 (1) A person seeking to conduct clinical trials shall apply for authorization to the Authority in the prescribed form.

(2) A person making an application under subsection (1) shall – (a) meet all conditions stipulated under World Health Organization's or the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use's good clinical trial practice guidelines; and

(b) demonstrate that an ethical review board has approved the clinical trial to be undertaken.

(3) Where the Authority is satisfied that an applicant has met all the conditions stipulated under this section, it shall grant a written authorization to the applicant to conduct the clinical trials subject to appropriate conditions as may be imposed.

(4) A clinical trial shall be carried out in accordance with World Health Organization's or the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use's good clinical trial practice guidelines.

(5) An ethical review board shall carry out continuous monitoring and evaluation of clinical trials throughout the period and shall maintain a record or report of such monitoring and evaluation.

(6) The sponsor of the clinical trial shall submit the evaluation report to the ethical review board and to the Authority.

(7) The report described under subsection (6) shall be used by the authority to issue authorization of registration of new medicine or policy measures to be adopted on clinical trials and post marketing surveillance

(8) A product under clinical trial shall not be placed for sale, distribution of supply in the market.

(9) The Authority shall only issue market authorization on the product subject to the clinical trial, upon receiving satisfactory report of clinical trial's safety and efficacy

(10) The Clinical trials technical committee shall be responsible for managing the process described in this section.

CLAUSE 60

114. The Kenya Bureau of Standards (KEBS) noted that it had developed standards and regulatory framework that adequately covers cosmetic products provided in section 60-65 of the Bill. The existing Kenya Standards where in existence to be referenced.

CLAUSE 61

115. The Kenya Bureau of Standards (KEBS) noted that it had developed standards and regulatory framework that adequately covers cosmetic products provided in section 60-65 of the Bill. The existing Kenya Standards where in existence to be referenced.

The Act should clarify why only cosmetic products are covered in act while there are other chemical products that have substance that can affect health and safety.

CLAUSE 66

116. The Kenya Bureau of Standards (KEBS) noted that it had developed standards for some products covered under sections 66-70. The team proposes that the Act references existing Kenya standards.

They proposed recognition of other pharmacopeias eg Indian pharmacopeia as a

considerable bulk of products in market come from India.

CLAUSE 69

117. **THAT** the Bill be amended in sub clause (2) by deleting the words "radiation" and wherever it appears in the Bill.

CLAUSE 71

118. The Ministry of Health noted the following in clause 71-

i. Provides for licensing of collection and processing of blood

ii. Functions covered in this section need to be separated from those of the National Kenya Blood Transfusion services as provided for in the Health Act 2017. The Authority should focus on regulation of blood and production of blood products only.

iii. This bill should focus on prescribing a code on good manufacturing practices and standards for management of human blood and related components.

iv. Clause 72 should be deleted as it is not in line with current national and WHO policy. Blood donors should never be remunerated.

CLAUSE 74

119. The Ministry of Health noted the following in clause 74-

i. This section should limit itself to medicines used to treat individuals' dependent tobacco and identifying innovative products for tobacco control objects.

ii. Provisions in this section are better handled under the Tobacco Control Act

Justification

KFDA should be about regulating products that promote health.

120. The Public Health Officers and Technicians Council, Kenya proposed deletion of **the** entire part on Tobacco products.

Justification

This clause provides for the regulation of tobacco and tobacco products which are comprehensively regulated under the Tobacco Control Act No.4 of 2007. These roles are therefore a duplication of functions established under another written law which is not sought for repeal by this Act. Unless the mover demonstrates the existing gap and how the proposed bill will bridge the identified gap, then this part will conflict another written law which may result to confusion in the implementation of both Acts.

Moreover, the Tobacco Control Act No. 4 of 2007 and its subsequent Amendments/regulations provide for the establishment of a board, regulations and framework for tobacco control in a more comprehensive manner than the proposed clause. The board which has an exclusive mandate on the regulation of tobacco products is

therefore best suited to handle tobacco and its products in a more coordinated legal and regulatory framework. The deletion of this part X will therefore forestall duplication and overlap.

121. The Tobacco Control Board proposed deletion of PART X, Sections 74-76

Justification

i. The WHO-FCTC provides measures for tobacco control at the global level. Kenya is a party to the WHO-FCTC and pursuant to Article 2 of the Constitution of Kenya, 2010 all treaties signed and ratified are part of Kenyan Laws.
ii. The Tobacco Control Act was passed in 2007 and mirrors WHO-FCTC and is one of the strongest tobacco control legislations in the region.
iii. The CS for Health gazette Tobacco Control Regulations in 2014 via LN 169 dated 5th November, 2014 that were approved by Parliament
iv. Part III of the regulations provides for information to be provided by manufacturers and importers of tobacco products to the Cabinet Secretary.
v. Section 6(b) of the Tobacco Act mandates the Board to advise and make recommendations to the CS on the permissible levels of the constituents of tobacco products or their emissions required to be prescribed, the harmful constituents and ingredients of tobacco products required to be prohibited.
vi. Tobacco Control adopts a multi-sectoral approach which b rings all relevant stakeholders together. The Tobacco Control Board whose members are drawn from all relevant State and non-state actors has the mandate and capacity to perform the functions mandated.
vii. Kenya has signed and is in the process of concluding the Ratification of the Illicit Trade Protocol on Tobacco Products. The Protocol provides for a track and trace system to monitor tobacco products right from manufacturing to the point of sale.
viii. KRA further regulates and licenses all manufacturers and importers of tobacco products after they have complied with provisions of the Tobacco Control Act and subsidiary Regulations and also compliant with standards as set out buy KEBs.
ix. Tobacco and tobacco products do not fall under the definition of food or drugs as per the spirit and purpose of the KFDA Bill, hence need to leave under the Tobacco Control Act.
x. If section is approved will result in unnecessary confusion , duplication of functions and wastage of scarce resources.

122. The International Institute for Legislative Affairs proposed deletion of PART X, Sections 74-76

Justification

i. Tobacco and tobacco products do not fall under the definition of food or drugs as per the spirit and purpose of the KFDA Bill, hence need to leave under the Tobacco Control Act.
ii. Fails to include multi sector approach to the enforcement of the intended legislation as well as the interplay between the intended legislation to pre-existing policy and legislation framework.
iii. Part X is ultra vires as it oversteps the intended scope of legislation in contrary to the Framework Convention for Tobacco Control that was duly ratifies by Kenya.
iv. There is a potential for conflict of laws as there already exists an effective legislative and institutional framework for the manufacture of tobacco products in Kenya.

CLAUSE 75

123. The Ministry of Health noted the following in clause 75-

i. That this section should limit itself to medicines used to treat individuals' dependent tobacco and identifying innovative products for tobacco control objects.

ii. Provisions in this section are better handled under the Tobacco control Act.

Justification

KFDA should be about regulating products that promote health.

124. The Tobacco Control Board proposed deletion of PART X, Sections 74-76

Justification

(see justification clause 74)

CLAUSE 76

125. The Ministry of Health noted the following in clause 76-

i. This section should limit itself to medicines used to treat individuals' dependent tobacco and identifying innovative products for tobacco control objects.

ii. Provisions in this section are better handled under the Tobacco control Act

Justification

KFDA should be about regulating products that promote health

126. The Tobacco Control Board proposed deletion of PART X, Sections 74-76

Justification

(see justification clause 74)

127. PATH proposed deletion of Part X.

PART XI

128. PATH proposed THAT the Bill be amended as follows -

(a) in clause 77 sub clause (1) by inserting the following new paragraph immediately after paragraph (c) –

(cc) ensuring the quality control of drugs and medicinal substances;

(b) in clause 78 by deleting the clause and inserting the following new clauses immediately after clause 77.

Management of the laboratory.

78A. (1) The Laboratory shall be managed by a person, competitively recruited by the Authority, to be the Director of the Laboratory.

(2) A person is qualified for appointment as a Director under this section, if that person—

(a) holds a Bachelors degree in any of the following fields;

(i) health economics,

(ii) clinical engineering,

(iii) medical and surgical sciences,

(iv) laboratory diagnostic science, or

(v) pathology; and

(b) has at least ten years post qualifications experience in any of the fields listed under paragraph (a).

(3) The Director appointed under subsection (1), shall—

(a) hold office for a term of three years, renewable once, subject to satisfactory performance; and

(b) on such terms and conditions of service as the Authority, may specify in the instrument of appointment.

(4) The Director appointed under subsection (1), shall in addition to such functions set out in section 77—

(a) develop and administer a data bank on quality assurance on behalf of the Authority;

(b) offer advisory services to the Authority in regards to the management of the Laboratory under this Act; and

(c) submit after every three months, a report on the activities undertaken by

the Laboratory, to the Authority.

(5) The Director-General, shall second such qualified staff of the Authority to assist the Director, discharge the functions of the Laboratory under this Act.

Certificate of analysis.

78B. (1) The Director shall be responsible for the signing and issuance of a Certificate of Analysis for every analysis undertaken by the Laboratory.

(2) Despite subsection (1), the Director may in writing, delegate the power of signing and issuance of a certificate of analysis to any other staff of the Authority seconded to the Laboratory.

(3) The Certificate issued under subsection (1), shall be in the prescribed form, and shall be accepted as *prima facie* evidence of the facts stated, in any proceedings under this Act.

CLAUSE 77

129. The Ministry of Health noted provisions provided in this section must ensure that NQCL can provide results of product analysis independently without any influence.

CLAUSE 78

130. The Ministry of Health noted provisions provided in this section must ensure that NQCL can provide results of product analysis independently without any influence.

CLAUSE 79

131. The Ministry of Health noted that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 80

132. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

133. PATH proposed **THAT** the Bill be amended in sub clause (1) by deleting the words "specified in the Sixth Schedule under this Act" and substituting therefor the following words "as may from time to time be prescribed by the Cabinet Secretary on recommendation of the Authority".

CLAUSE 81

134. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 82

135. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 83

136. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

137. Mr. Sospeter Otuya Katiechi proposed amendment to clause 83 paragraph /(b) as follows-

(b) that the advertisement was published only in a -publication of a technical character intended for circulation only amongst persons of the following classes, or of one or some of them—
(i) qualified medical practitioners, dentists and veterinary surgeons;
(ii) registered pharmacists, pharmaceutical technologists and authorized sellers of Scheduled Substances;
(iii) persons undergoing training with a view to becoming qualified medical practitioners, dentists or veterinary surgeons, or registered pharmacists or pharmaceutical technologists; or
(i) persons carrying on business which includes the sale or supply of surgical appliances.

CLAUSE 84

138. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 85

139. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 86

140. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

CLAUSE 87

141. The Ministry of Health proposed that this section requires restrictions for advertisement on medical products that require prescription such as psychotropics and narcotics.

PART XIII

142. THAT the Bill be amended in Part XIII by deleting the Part and substituting therefor the following new Part—

Appointment of authorized officers.
87. (1) The Authority shall appoint such authorized officers for the purpose of undertaking inspections and enforcement under this Act.

(2) Without prejudice to the generality to subsection (1), the Authority may in consultation with the relevant county department, designate an authorized officer for the purpose of enforcement of this Act at the county level.

(3) An authorized officer under this Act, shall be issued with an identification document in the prescribed form, and shall on request, while undertaking inspections, produce such identification document.

Inspections.

88. An inspection carried out under this Act shall take into account—

(a) food and drug businesses and their surroundings and installations, as well as means of transportation, equipment and materials;
(b) food and drug ingredients, additives, disinfectants and any substances or processes used in the production, manufacturing or handling of food or drug;
(c) personnel employed at the food or drug business;
(d) packaging material;
(e) cleaning, disinfecting and maintenance at the food or drug business; and
(f) labelling.

Inspection of licenses and books.

90. (1) An authorized or licensed seller of any food, drug, scheduled substance health product or technology shall, on the demand of a regulatory officer, produce for inspection his certificate of registration or his license as the case may be.

(2) All books kept by any seller of a scheduled substance, food, drugs, health product or technology, or healthcare professional, or by a hospital, dispensary or similar institution, in accordance with the provisions of this Act, shall be open for inspection by a regulatory officer at all reasonable times.

(3) A person who obstructs or hinders a regulatory officer in the lawful exercise of the powers conferred under this Act, commits an offence.

Inspection of animals.

90. A regulatory officer may, in collaboration with the relevant government agency at the national and county level, and the for the purposes of this Act, inspect any animal intended for slaughter and may seize and examine any meat which the regulatory officer considers to be unfit for consumption.

Powers of an authorized officer.

91. An authorized officer for purposes of this Act, shall have the power generally to, enter any—

(a) premises which is on the register of premises;
(b) other premises in respect of any person who is licensed under this Act or any other written law;
(c) premises used in the
(d) manufacture, marketing, or distribution of a food or health product that is the subject of a marketing authorisation or licensing request;
premises suspected of or dealing in products regulated under this Act.

Search and seizure.

92. (1) Except for a dwelling place, an authorized officer may, without a warrant—

(a) enter any food or drug business or other premises in which any food or drug is being, or is suspected of being, produced, manufactured, treated, graded, packed, labelled, stored, handled, prepared, served or sold, or in which any other operation or activity in connection with food or drug is being, or suspected of being, carried out, and may, for the purpose of determining whether this Act is being violated;

(i) inspect or search such premises, and examine any food or drug, appliance, product, material, object or substance which is being, or is suspected of being, used or destined for use in connection with the production, manufacture, treatment, grading, packing, packaging, labelling, storage, handling, preparing, serving or sale of any food or drug;

(ii) demand any information regarding any such food or drug, appliance, product, material, object or substance from the owner or person in charge of such premises;

(iii) weigh, count, measure, mark, open and take samples in the prescribed manner of any food or drug, product, material, object or substance or its package or container, or lock, secure, seal or close any door giving access to it;

(iv) examine, make copies of or take extracts from any book, statement or other document found at such premises which refers to or is suspected of referring to such food or drug, and demand from the owner or any person in charge of the premises an explanation of any entry in it;

(v) inspect any operation or process carried out on such premises, and demand any information regarding such operation or process from the owner or person in charge of such premises or from any person carrying out such operation or process;

(vi) read any values recorded by measuring instruments installed on the premises or by instruments in the possession of the authorized officer;

(vii) take any photographs; or

(viii) seize any food or drug, appliance, product, material, object, substance, book, statement or document which appears to provide proof of a contravention of any provision of this Act, providing a signed receipt in the prescribed form which shall be countersigned immediately by the owner or other person in charge of such premises or object;

(b) stop and search any vehicle in which food or drug is being or is suspected of being transported, produced, manufactured, treated, graded, packed, packaged, stored, handled, prepared, served or sold or in which any other operation or activity in connection with food or drug is being or is suspected of being carried out; or

(c) stop, search and detain any person who is suspected of committing an offence under this Act.

(2) An authorized officer exercising the Authority vested under this section may request the presence and assistance of such law enforcement personnel as may considered necessary.

(3) An authorized officer shall exhibit his or her official identification card on demand by any person affected by the exercise or performance of any power, duty or function of such authorized officer under this Act.

(4) A person who obstructs or impedes a regulatory officer from exercising the powers of regulatory officer under this Act, commits of an offence.

(5) For purposes of this section, "premises" includes a street, open space, place of public resort, or bicycle or other vehicle utilized for the preparation, preservation, packaging, storage or conveyance of any article.

Retention and disposal of goods seized.

94. (1) A food, drug, article or document seized under this Act, may be retained for a period not exceeding thirty days, or if within that period proceedings are commenced before a court of law in respect of such drug, article or document, until the final determination of the proceedings.

(2) Where the court is satisfied that any such drug or article is of a perishable nature or that the market for the drug or article is seasonal, or a delay in disposing the drug or article would unduly prejudice the owner, the court may authorize the sale or other disposal of the drug or article.

(3) A court may where necessary, make an order as to the forfeiture or disposal of any drug or article in respect of which on offence is committed under this section.

Authority to be supplied with information.

95. The Authority may—

(a) by notice in writing, require a person, who manufactures, supplies, administers or is involved in the prescription of a health product or technology, or on whose direction a health product or technology is manufactured, supplied or administered, to furnish the Authority, within a period specified in that notice, with information, which is in that person's possession or which that person is in a position to obtain with respect to that health product or technology; or

(b) if requested by a person to whom a notice under this section is addressed, extend the period specified in that notice.

Food or drug unfit for consumption.

96. Where it appears that any food or drug at a business premises is unfit for human consumption or is likely to cause harm or danger to human health, an authorized officer shall—

(a) seize and seal such food or drug and issue a notice to the owner or the person in charge of the business premises that the food or drug or any specified portion of it is temporarily not to be sold, removed, manipulated, tampered with or otherwise altered without the authorization of the authorized officer; or

(b) issue a written notice temporarily ordering the food or drug removed to a specified place; or issue a written notice ordering the immediate destruction of the food or drug.

Prosecution.

94. A regulatory officer may undertake prosecutions, before a magistrate court having jurisdiction, for an offense committed under this Act, in the place where any article sold was actually delivered to the consumer or where the sample was taken.

CLAUSE 90

143. Mr. Duncan Momanyi proposed amendment to clause 90 as follows –

Inclusion of authorized officer

92. (1) An authorized or licenced seller of any food, scheduled substance health product or technology shall, on the demand of a regulatory officer, produce for inspection his certificate of registration or his licence as the case may be.

(2) All books kept by any seller of scheduled substance a food, health product or technology, medical practitioner, dentist or veterinary surgeon, or by a hospital, dispensary or similar institution, in accordance with the provisions of this Act or any rules there under, shall be open for inspection by a regulatory officer at all reasonable times.

93. A person who obstructs or hinders a regulatory officer in the lawful exercise of the powers conferred by this Act commits an offence.

97. A regulatory officer may, for the purposes of this Act, inspect any animal intended for slaughter and may seize and examine any meat which the regulatory officer considers to be unfit for consumption.

98. (1) A regulatory officer or an authorized officer may, at any hour reasonable for the proper performance of duty —

(a) enter any premises where the regulatory officer or authorized officer believes any article to which this Act or any regulations made thereunder apply is prepared, preserved, packaged, stored or conveyed, examine any such article and take samples, and examine anything that the regulatory officer or authorized officer believes is used or capable of being used for such preparation, preservation, packaging or storing or conveying;

(b) stop or search or detain any aircraft, ship or vehicle in which the regulatory officer or authorized officer believes that any article subject to the provisions of this Act is being conveyed and to examine any such article and take samples for the purposes of this Act;

(c) open and examine any receptacle or package which the regulatory officer or authorized officer believes contains any article to which this Act or any regulations made thereunder apply;

(d) examine any books, documents, or other records found in any place mentioned in paragraph

(a) of sub-Section (1) that the regulatory officer or authorized officer believes contain any information relevant to the enforcement of this Act with respect to any article to which this Act or any regulations made apply and make copies or take extracts;

(e) seize and detain for such time as may be necessary any article by means of or in relation to which he believes any provision of this Act or any regulations made thereunder has been contravened.

(2) A regulatory officer or an authorized officer acting under this Section shall, produce his authority.

(3) Any owner, occupier or person in charge of any premises entered by a regulatory officer pursuant to paragraph (a) of subsection (1), or any person found therein, who does not give to the regulatory office or authorized all reasonable assistance the person's power and furnish the regulatory officer with such information as the regulatory officer may reasonably require, shall be guilty of an offence.

(4) Any person who obstructs or impedes any regulatory officer or authorized officer in the course of the regulatory officer's duties or by any gratuity, bribe, promise, or other inducement prevents, or attempts to prevent the due execution by the regulatory officer or authorized officer of the regulatory officer's or authorized officer's duty under this Act or any regulations made thereunder commits of an offence.

(5) Any person who knowingly makes any false or misleading statement either verbally or in writing to any regulatory officer or authorized officer commits an offence.

(6) A regulatory officer or an authorized officer shall release any article seized by the regulatory officer under this Act when the regulatory officer or authorized officer is satisfied that all the provisions of this Act and any regulations made thereunder with respect thereto have been complied with.

(7) Where a regulatory officer or authorized officer has seized an article under this Act and the owner thereof or the person in whose possession the article was at the time of seizure consents to
the destruction thereof, the article may be destroyed or otherwise disposed of as the regulatory officer or authorized officer may direct.

(8) Where a person has been convicted of an offence under this Act or any regulations made thereunder, the court may order that any article by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the convicted person or found with such article, be forfeited, and upon such order being made such articles and things may be disposed of as the court may direct.

(9) Where any article has been seized under the provisions of paragraph (e) of subsection (1) and the owner thereof has been convicted of an offence under this Act, the article may be destroyed or otherwise disposed of as the regulatory officer or authorized officer may direct.

(10) Any article seized under this Act may at the option of a regulatory officer or authorized officer be kept or stored in the premises where it was seized or may at the direction of a regulatory officer or authorized officer be removed to any other proper place; and any person who removes, alters or interferes in any way with articles seized under this Act without the authority of a regulatory officer or authorized officer shall be guilty of an offence.

(11) A regulatory officer or an authorized officer may submit any seized article or any sample therefrom to the National Quality Control Laboratory for analysis or examination; and a public analyst shall as soon as practicable analyse or examine any sample sent to to the public analyst in pursuance of this Act and shall give the regulatory officer or authorized officer a certificate specifying the result of the analysis or examination, and such certificate shall be in such form as may be prescribed by the Authority.

(12) In this section, "premises" includes a street, open space, place of public resort, or bicycle or other vehicle utilized for the preparation, preservation, packaging, storage or conveyance of any article.

(13) In performing any of the functions under this Act, the regulatory officer or authorized officer, as the situation may require, may be accompanied and assisted by a Police Officer.

(14). The procedure to be followed by regulatory officer in obtaining, transmitting for analysis or examination or otherwise dealing with any sample, shall be prescribed by this Act or any other law

CLAUSE 96

144. The Council of Governors proposed deletion of Clause 96 –

Justification
The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

CLAUSE 97

145. The Council of Governors proposed deletion of Clause 97 –

Justification
This is the mandate of the County Governments as outlined in the Fourth Schedule of the Constitution.

146. The Public Health Officers and Technicians Council, Kenya proposed deletion of the clause 97.

Justification

The Meat Control Act, Cap 356 provides for the expanded role of both the County and the National Government in the interpretation roles in delivery.This clause is a duplication and may result in overlap in the mandate of Cap 356.

Both Veterinary and Health services are devolved functions as per the fourth schedule of the constitution. Since Cap 254, Cap 242 and Cap 356 are all laws which make provisions for service delivery, the inclusion of this clause will result in greater confusion and overlaps in the administration of these legislations particularly regarding the functions of Authorized officer under the Meat Control Act Cap 356, Cap 242 and Cap 254 viz a viz the role of a regulatory officer in the proposed bill.

147. The Council of Governors proposed deletion of Clause 97 –

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

148. The Public Health Officers and Technicians Council, Kenya proposed deletion of the entire clauses on food regarding service delivery.

Justification

The powers of a Regulatory officer as established in this bill conflicts the powers an Authorized of are established in the Food, Drugs and Chemical Substances Act Cap 254, The Public health Act Cap 242 and the Meat Control Act Cap 356 which are all service laws supporting the delivery of health and veterinary services as devolved functions. Moreover, these functions are currently adequately executed with no gaps or overlaps in service delivery.

The powers of a regulatory officer under the proposed bill should not conflict with the powers of authorized officers established under Cap 242, Cap 254 and Cap 356.

149. The Kenya Nutritionist and Dieticians Institute (KNDI) proposed deletion of the entire sections on food regarding service delivery

Justification

Constitutional roles of the devolved function will need a service law (Cap 254) to be properly executed.

CLAUSE 99

150. The Council of Governors proposed deletion of clause 99

Justification

The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

151. The Public Health Officers and Technicians Council, Kenya proposed as follows – Replace 'Director of Medical services' with 'Director General - Health'

Justification
The position was dropped with enactment of Health Act, 2017.

152. The Kenya Nutritionist and Dieticians Institute (KNDI) proposed as follows -

Replace "Director of Medical Services" with "Director General-Health"

Justification
The position was dropped with enactment of Health Act, 2017.

153. Mr. Duncun Momanyi proposed as follows –

Replace "Director of Medical Services" with "Director of Public Health" and replace "the Cabinet Secretary" with "any other written law".
99. The Director of Public Health, or , in relation to any matter appearing to affect the general interests of the consumer, the Director of Veterinary Services , in relation to any matter appearing to affect the general interests of animal husbandry in Kenya, and the Director of Agriculture in relation to any matter appearing to affect the general interests of agriculture in Kenya, and any other person authorized in writing by any other written law so to do, may direct a public officer to procure for analysis samples of any food, health product or technology, and thereupon that officer shall have all the powers of a regulatory officer under this Act and this Act shall apply as if the officer were a regulatory officer or

CLAUSE 100

154. The Council of Governors proposed deletion of clause 100

Justification
The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

CLAUSE 101

155. The Council of Governors proposed deletion of clause 101

Justification
The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

CLAUSE 102

156. The Council of Governors proposed deletion of clause 102

Justification
The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

CLAUSE 103

157. The Council of Governors proposed deletion of clause 103

Justification
The provisions are a replica of existing law , Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 and there is no need to repeat.

158. Mr. Duncun Momanyi proposed as follows –

Replace "A Regulatory Officer" with "An Authorized Officer"
103. (1) An Authorized Officer may take out proceedings for an offence under this Act or the regulations before any magistrate having jurisdiction in the place where any article sold was actually delivered to the purchaser or where the sample was taken

159. THAT the Bill be amended in paragraph (a) by deleting the paragraph and substituting therefor the following new paragraph—

(a) monies allocated by Parliament for the purposes of the Authority;

CLAUSE 113

160. Nzoia Sugar noted as follows –

113(2)(c)- This will have a direct impact on the operation of the entire food value chain

113(2)(e)- importation and exportation of sugar is a mandate of the Agriculture and Food Authority

CLAUSE 114

161. The Ministry of Health noted as follows in clause 114 -

Miscellaneous Provisions which includes regulations and transitional clauses

Provides that that all assets and liabilities of the former boards be transferred to KFDA.

Assets and liabilities pertaining to the regulation of health professionals currently regulated by the Pharmacy and Positions Board should not be assumed by the KFDA as regulation of professionals will continue under another agency.

Justification
Separation of assets and liabilities appropriately

162. The Public Health Officers and Technicians Council, Kenya proposed as follows-
114 (1)(2) Upon the date of the coming of this Act, the Cabinet Secretary for Health may, through a gazette notice, appoint such members engaged by the Authority under Clause 8 (1) for proper functioning of the Authority. Where necessary, as may be determined by the Authority and the Authority shall acquire such assets, liabilities, staff or any other resources from the former boards.

Justification
These clauses convert the Pharmacy and Poisons Board into the Authority with all staff and assets through this transition clause.

The bill should give the Cabinet Secretary for Health, the discretion to appoint the board members as per clause 8 (1) who shall engage the staff of the Authority.
This will allow the authority to recruit staff and acquire assets should the Pharmacy and Poisons Board be retained to regulate the practice of Pharmacists and Pharmaceutical Technologists in Kenya as a professional regulator.

163. The Pharmaceutical Society of Kenya proposed 114 THAT Clause 114 of the Bill be amended by inserting new sub-clauses (3), (4), (5) and (6) as follows– (3) A person who, upon this Act coming into force was a holder of a license issued under the Pharmacy and Poisons Act, Cap 244, shall be deemed to be a holder of the license under this Act under the same conditions applicable at the time the license was issued.

(4) Upon this Act coming into force, a license issued under the Pharmacy and Poisons Act, Cap 244 shall be deemed to be valid under this Act under the similar terms and conditions applicable under that Act.

(5) An application for registration or market authorization of a product or clinical trials that was being reviewed by the former board shall be deemed to valid and in process upon this Act coming into force.

(6) Upon this Act coming into force, any guidelines related to medicines and health products adopted under the Pharmacy and Poisons Act, Cap 244, shall be deemed to be guidelines adopted under this Act, subject to necessary modifications.

164. The Kenya Nutritionist and Dieticians Institute (KNDI) noted that this section converts the Pharmacy and Poison Board into the Authority with all staff and assets.

Justification
Set up authority established under 8 (1) for full functionality. The new authority has its own staff provisions and there is need to allow for competitiveness.

165. PATH proposed THAT the Bill be amended in sub clause (1) by inserting the following new paragraph immediately after paragraph (d).

(da) An officer working for a body established under the repealed Act, shall on the commencement of this Act be deemed to be an officer of the Authority.

(db) The Chairperson and members of the Pharmacy and Poisons Board appointed under the repealed Pharmacy and Poisons Act, shall continue to

serve during the remainder of their term until a new Board of the Authority is appointed.

(dc) Despite the repeal of the Pharmacy and Poisons Act, the Pharmacy and Poisons Board shall on the commencement of this Act, continue to enforce the provision relating to the regulation of the pharmacy profession under the repealed Pharmacy and Poisons Act.

CLAUSE 115

166. Mr. Duncun Momanyi noted as follows –

a) The section refers to Sixth Schedule but what it refers to is actually the Seventh Schedule
b) Include the Tobacco Control Act, No.4 of 2007 since this bill has not repealed or amended it.

It should be read:
115(1) The provisions of this Act shall be in addition to and not in derogation of the provisions of the Public Health Act and the Tobacco Control Act, No.4 of 2007 or their successors.

167. PATH proposed THAT the Bill be amended in sub clause (1) by deleting the words "Sixth Schedule" and substituting therefor the following words "Seventh Schedule".

FOURTH SCHEDULE - SCIENTIFIC ADVISORY COMMITTEES

168. The Pharmaceutical Society of Kenya proposed THAT the Fourth Schedule of the Bill be deleted.

Justification

The proposed amendments to Clause 21 imply that there is no need for the Fourth Schedule.

169. Mr. Duncun Momanyi proposed amendments as follows -

Insert the following phrase immediately after Public Health, 'who shall be the chairperson to the Committee"

21(2)(d) a representative of the Department of Public Health who shall be the chairperson to the Committee.

Replace the "Deputy Director General for Foods" with "Deputy Director for Public Health"
21(2)(j) the Deputy Director for Public Health or his or her designate.

Justification

The Fourth Schedule creates the National Food Safety Committee. It defines the composition of the committee. It also defines a secretary to the committee. However it has not defined the chairperson

Directorate for foods or food safety does not exist. Therefore, there is no office or position or position known as Deputy Director General for foods.

The Directorate of Public Health is the only one with the mandate of regulating and managing food and food safety. Therefore it implies that a representative from the directorate of public health is the most relevant.

170. PATH proposed THAT the Bill be amended in the Fourth Schedule by deleting the schedule and substituting therefore the following schedule—

FOURTH SCHEDULE **(s. 23(1)).**

National Food Safety Coordination Committee.

1. (1) There is established a Committee to be known as the National Food Safety Coordination Committee.

(2) The Committee, shall consist of the following members, appointed by the Authority—

(a) a representative of the Kenya Bureau of Standards;

(b) a representative of the Kenya Agricultural and Livestock Research Organization;

(c) a representative of the Kenya Plant Health Inspectorate Services;

(d) a representative of the Department of Public Health;

(e) a representative of the Department of Weights and Measures;

(f) a representative of the Department Government Chemist's;

(g) a representative of the National Biosafety Authority;

(h) a representative of the Kenya Dairy Board;

(i) a representative of the Horticultural Crops Development Authority; and

(j) a person, being an employee of the Authority, nominated by the Authority, who shall be the secretary to the Committee.

(3) The Committee shall, in addition to the functions set out in section 23(3) of this Act, be responsible for the offering of advisory services to the Authority on the formulation, implementation and monitoring of the food and drugs safety and quality.

(4) The members of the Committee, except for the person nominated under clause 1(2)(j), shall hold office for a term of three years and may be eligible for re-appointment, subject to satisfactory performance, for one single further term of three years.

(5) The quorum for the meetings of the Committee, shall be five members one of whom shall be nominated as the chairperson of the Committee, in the absence of the chairperson of the Committee.

(6) For purposes of this paragraph, "Committee", means National Food Safety Coordination Committee.

Human Medicines Committee.

2. (1) There is established a Committee to be known as the Human Medicines Committee.

(2) The Committee shall consist of the following members, competitively appointed by the Authority—

(a) a person with at least ten years, experience and expertise on matters relating to the regulation of human medicines, who shall be the Chairperson of the Committee;

(a) a person being a staff of the Authority nominated by the Authority, who shall be the Secretary to the Committee; and

(b) four other members who have knowledge and expertise and at least five years' experience on matters relating to human medicines, healthcare and public health.

(4) The members of the Committee, except for the Secretary of the Committee, shall hold office for a term of three years and may be eligible, subject to satisfactory performance, for re-appointment, for a single further term of three years.

(5) The quorum for the meetings of the Committee, shall be three members one of whom may be nominated to be the Chairperson of the Committee, in the absence of the Chairperson of the Committee.

(6) For purposes of this paragraph, "Committee", means Human Medicines Committee.

Veterinary Medicines Committee.

3. (1) There is established a Committee to be known as the Veterinary Medicines Committee.

(2) The Committee, shall consist of the following members, competitively appointed by the Authority—

(a) a person with knowledge and expertise, and at least ten years' experience on matters relating to veterinary services, and veterinary medicines regulation, who shall be the Chairperson of the Committee;

(b) a person, being a staff of the Authority, with knowledge, experience and expertise on veterinary services, and veterinary medicines regulation, who shall be the Secretary to the Committee; and

(c) four other members who have knowledge and expertise and at least five years' experience on matters relating to medicines regulation, veterinary services and veterinary public health.

(3) The Committee shall, in addition to the functions set out in section 23(3) of this Act, be responsible for the—

(a) offering of advisory services to the Authority on matters relating to veterinary medicinal products;

(b) giving of advice in relation to the safety, quality and efficacy of veterinary medicinal products; and

(c) promoting the collection and investigation of information relating to adverse reactions involving veterinary medicinal products.

(4) The members of the Committee, except for the Secretary of the Committee, shall hold office for a term of three years and may, subject to satisfactory performance, be eligible for re-appointment, for one single further term of three years.

(5) The quorum for the meetings of the Committee, shall be three members one of whom shall be nominated to be the Chairperson of the Committee, in the absence of the Chairperson of the Committee.

(6) For purposes of this paragraph, "Committee", means Veterinary Medicines Committee.

Medical Devices Committee.

4. (1) The is established a Committee to be known as the Medical Devices Committee.

(2) The Committee, shall consist of the following members, competitively appointed by the Authority—

(b) a person with knowledge and expertise on matters relating to the regulation of medical devices specifications and use, who shall be the chairperson of the Committee;

(c) a person, being members of the staff of the Authority, with knowledge, experience and expertise on expertise on matters relating to medical devices regulation, who shall be the secretary to the Committee; and

(d) four other members who shall have knowledge, experience and expertise on matters relating to medical devices regulation, nursing services and public health services.

(3) The Committee shall, in addition to the functions set out in section 23(3) of this Act, be responsible for the—

(a) offering of advisory services to the Authority, on matters relating to medical devices;

(b) giving of advice in relation to the safety, quality and efficacy of the medical devices; and

(c) promotion of the collection and investigation of information relating to any issues involving the use of medical devices.

(4) The quorum for the meetings of the Committee, shall be three members one of whom shall be nominated to be the chairperson of the Committee, in the absence of the Chairperson of the Committee.

(5) The members of the Committee, except for the Secretary of the Committee, shall hold office for a term of three years and may, subject to satisfactory performance, be eligible for re-appointment, for one single further term of three years.

(6) For purposes of this paragraph, "Committee", means Medical Devices Committee.

National Quality Control Committee.

5. (1) There is established a Committee to be known as the National Quality Control Committee.

(2) The Committee, shall consist of the following members, competitively appointed by the Authority—

(a) a person with knowledge and expertise and at least ten years experience, on matters relating to quality control, who shall be the chairperson of the Committee;

(b) a person, being a staff of the Authority, with knowledge, experience and expertise on matters relating to the regulation of health products, and quality control of medicines, therapeutic foods and therapeutic cosmetics, and medical devices medical devices, who shall be the Secretary of the Committee; and

(c) four other members who shall have knowledge and expertise, with at least five years' experience, on matters relating to the regulation of health products, and quality control of medicines, therapeutic foods and therapeutic cosmetics, and medical devices medical devices.

(3) The quorum for the meetings of the Committee, shall be three members one of whom shall be nominated to be the chairperson of the Committee, in the absence of the Chairperson of the Committee.

(4) The members of the Committee, except for a person appointed to represent the Authority, shall hold office for a term of three years and may be eligible for re-appointment, subject to satisfactory performance, for one single further term of three years.

(5) For purposes of this paragraph, "Committee", means National Quality Control Committee.

FIFTH SCHEDULE

171. The Pharmaceutical Society of Kenya THAT the Fifth Schedule of the Bill be amended –

(a) by inserting a new pharmacopoeia after the "British Pharmaceutical Codex" as follows– "The European Pharmacopoeia (Ph. Eur.)"

(b) by deleting reference to "S.36 (2) and substituting the reference "S. 36"

Justification The EU Pharmacopoeia is one of the most globally recognized and comprehensive Pharmacopoeias and should be included as a reference point for standards applicable to Kenya.

SIXTH SCHEDULE

172. The Pharmaceutical Society of Kenya THAT the Sixth Schedule of the Bill be amended as follows–

(a)in relation to the Pharmacy and Poisons Act, Cap 244, on the column titled "extent of repeal", insert the words "except matters related to regulation of pharmacy practice" after the words "whole Act"

(b) In relation to the Food, Drugs and Chemical Substances Act, Cap 254 on the column titled "extent of repeal", insert the words "except matters related to regulation of food" after the words "whole Act"

(c) By deleting reference to "S. 116" and renumbering it to "S. 115"

Justification
Clause 115 repeals Cap 244 in its entirety without providing for matters related to regulation of professional practice. This is inappropriate and dangerous too as the consequential effect will be to render pharmacy professional practice to be unregulated upon coming into force of this Act.

As proposed in this memorandum, Food should be regulated under Cap 254. Consequently, the whole Act should not be repealed.

The Bill does not have section 116.

173. PATH proposed THAT the Bill be amended in the Sixth Schedule by deleting the Schedule.

SEVENTH SCHEDULE

174. The Public Health Officers and Technicians Council, Kenya proposed as follows -

Retain the whole Cap 254 – Food Drugs and Chemical Substances Act.

Retain the whole Cap 244 – The Pharmacy and Poisons Board Act and amend propose amendments to exclusively regulate the practice of Pharmacists and pharmaceutical Technologists.

Justification
Schedule IV – Constitution of Kenya – Distribution of functions between National and County Government

Part 2 – County Governments

County Health Services, including, in particular
(d) Licensing and control of undertakings that sell food to the Public.

The Act should not be repealed for the following reasons:

i. Food, Drugs and Chemical Substances Act, Cap 254 is the only Act, other than the Public Health Act, Cap 242, that currently operationalizes schedule IV of the constitution within the context of health service provision in the County Governments.However, the Public Health Act, Cap 242 anchors Cap 254 within the context of service delivery.
ii. The Food, Drugs and Chemical substances Act acts a parent and/or anchor Act to other legislations including but not limited to the Meat Control Act, Cap 356, The Public Health Act and other laws. The deletion of Cap 254 will therefore affect the delivery of other subsequent laws as established.
iii. This clause of the Constitution of Kenya provides for the licensing and control of undertakings that sell food to the public Cap 254 provides for definition of food, standards of food, preparation of food under insanitary conditions and prohibition against sale of food not of nature, substance and quality.
iv. The Food, drugs and Chemical Substances Act, Cap 254 is the only law that makes provision for the inspection of food premises, issuance of food hygiene license, medical examination of food handlers and general maintenance of food quality and safety to give meaning to schedule IV of the constitutional function of licensing and control of undertakings that sell food as a County Government mandate.
v. The KFDA Bill does not make provisions for examination of food handlers as a basic requirement for food safety which Cap 254, the Act it seeks to repeal, comprehensively covers.
vi. KFDA Bill does not make provisions for food.
vii. The repeal of this Act therefore would result in a legal gap and overlap within the context of County Government in its function of control and licensing of food premises as devolved health function.
viii. The Act should however be amended should there be areas that affect its functionality in controlling food safety and quality value chain.
ix. This Act regulates the practice of Pharmacists and pharmaceutical Technologists in Kenya.The regulation of professionals should be discerned from the regulation of products and technologies for optimum outcomes.Cap 244 should therefore be retained, to let the proposed bill establish a new board of authority under (8) (1) and staff under 17 (1) for the efficient and effective regulation of medical.

175. National Biosafety Authority proposed that the National Food Safety Committee should be composed of experts on food safety.

176. PATH proposed THAT the Bill be amended in the Seventh Schedule by deleting the Schedule and substituting therefor the following new Schedule.

Written law	**Provision**	**Amendment**
Public Health Act, Cap. 242.	Section 2	The Public Health Act amended in section 2 by— (a) deleting the definition of the term "food" and substituting therefore the following new definition; "food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any

Written law	Provision	Amendment
		substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs;
	Section 131	Delete.
	Section 132	Delete.
	Section 133	Delete.
	Section 134.	Delete.
Use of Poisonous Substances Act, Cap. 247.	Whole Act.	Delete.
Food, Drugs and Chemical Substance Act, Cap. 254.	Whole Act.	Delete.
Dairy Industry Act, Cap. 336.	New insertion.	(a) The Dairy Industry Act, is amended by inserting the following new section immediately after section 36— Reports. **36A.** The Board shall after every thre months, report to the Kenya Food an Drugs Authority on the measures tak and progress achieved in the realizati of safety and quality of milk produce Kenya.
Meat Control Act, Cap. 356	Whole Act.	Delete.
Fertilizers and Animal Foodstuffs Act, Cap. 345.	New insertion.	The Fertilizer and Animal Foodstuff Act, is amended in section 2N by inserting the following new subsection immediately after subsection (1) — **2N. (1a)** The Chief Executive Officer shall, at least after every three months, submit a report to the Kenya Food and Drugs Authority on the measures taken and progress achieved towards the realization of food safety and quality as regards the importation, manufacture and sale of agricultural fertilizers.
Pest Control Products Act, Cap. 346.	New insertion.	The Pest Control Products Act is amended by inserting the following new section immediately after section 6—

Written law	Provision	Amendment
		Reports. **6A.** The Board shall after every three months, report to the Kenya Food and Drugs Authority on the measures taken and progress achieved in ensuring food safety and quality as regards the use and production of pest control product in Kenya.
Narcotic Drugs and Psychotropic Substances (Control) Act, No. 4 of 1994.	Section 16	Delete.
Nutritionists and Dieticians Act, No. 18 of 2007.	Section 2.	(a) The Nutritionists and Dieticians Act, is amended in section 2 by deleting the term "article". (b) The Nutritionists and Dieticians Act, is amended in section 6 by inserting the following new paragraph immediately after paragraph 6(a)— (aa) submit a report to the Kenya Food and Drugs Authority, at least every three months, on the measures taken and progress achieved in the realization of the safety and quality of food, food supplements and fortifiers with nutrient claims.
Breast Milk Substitutes (Regulation and Control) Act, No. 32 of 2012.	Section 2	(a) The Breast Milk Substitutes (Regulations and Control) Act, is amended by inserting the following new definitions in their proper alphabetical order— "Authority" means the Kenya Food and Drugs Authority established under section 6 of the Kenya Food and Drugs Authority Act; "food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs; (b) The Breast Milk Substitutes (Regulations and Control) Act, is amended by deleting section 7 and substituting therefore the following new section—

Written law	Provision	Amendment
		Power of to permit donation. **7.(1)** Donations or distributions of breast milk substitutes or complementary food products to charitable children institutions shall be in such manner as may be permitted by the Authority on the advice of the Committee. (2) The Authority shall not grant permission for the supply of any donation of any designated or complementary food product to an orphanage or social welfare institution unless the Authority is satisfied that— (a) the label on the package carrying a designated or complementary food product has been made in accordance with the shall be in accordance with the law relating to standards; and (b) the infant care providers have or shall receive appropriate training to prevent any health hazards occurring from improper use.
Agriculture and Food Authority Act, No. 13 of 2013.	Section 2.	The Agriculture and Food Authority Act is amended by inserting the following new definition in its proper alphabetical order— "food" means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs;

GENERAL STAKEHOLDERS COMMENTS

177. MINISTRY OF HEALTH

Other Areas that should be included in the Bill are as follows:-

i. Bottled drinking water. Standards and Regulation
ii. Regulation of Infant formula
iii. Biologicals and other innovator medicines
iv. Pharmaceutical Distribution Supply Chain
v. Wholesale Distribution of Therapeutic Products
vi. Post-market surveillance and Safety Risk Assessment
vii. Safety Reports
viii. Clinical Trials of therapeutic products
ix. Entry Searches and Warrants
x. Poison Control, Information and Prevention
xi. Combating anti-microbial resistance

178. MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND IRRIGATION

i. The Bill is timely however the scope of regulation covering food and medicine is extremely wide with massive impacts on human health, animal health and welfare, the environment, trade and the overall economy which require consideration by the executive.
ii. Observance of international treaties such as those under the World Trade Organization necessitates the country to engage trading partners through various agreed forums before altering a regulatory regime to avoid arbitrary bans to trade in animals and animal products.
iii. Good legislation is informed by policy and since we have robust livestock sector policies such as the Livestock Policy and the Veterinary Policy it is essential that related legislative interventions are based on the same.
iv. There is Joint Working Committee with the Ministry of Health working on a draft Bill to be submitted to Cabinet and subsequently tabled in Parliament during the second half of 2019. Therefore they request the withdrawal of the Bill in order for the Executive to be allowed to process the Bill.

179. COUNCIL OF GOVERNORS

i. The Food, drugs and Chemical Substance Act, Cap254 and the Public Health Act, Cap 242 has provisions on some of the issues raised in the introduced Kenya Foods and Drugs Authority Bill. The laws which existed before the promulgations of the Constitution and are still in force and effectively applicable at county level in line with the constitution .Further, the two laws cater for almost everything proposed in the bill and provide clear redress and penalties.
ii. The KFDA Bill attempts to repeal and replace theme refer to section 29, 30 and 31 of Cap 254 and clauses 25-31 and 96-103 of the Bill. This is in contravention of the sixth schedule (part 2 of transitional and consequential provisions)
iii. The COG welcomes the new provisions on the medical devices (sections 66-70) but proposes the National Assembly not to duplicate what already exists in law.

180. KENYA BUREAU OF STANDARDS (KEBS)

i. The proposed Kenya Food and Drug Authority should only perform oversight and coordination roles and limit its mandate to setting out policies and technical regulations on food, therapeutic products, cosmetics and veterinary products.
ii. The mandate of the authority should only be on issues of health and safety in the products covered by the /act and not on quality issues.
iii. The Authority should work within the existing regulatory framework and that agencies regulated under existing acts retain their functions for in order to enhance specialization and effectiveness.
iv. The Bill should work within existing standard and regulatory infrastructure already set up in various bodies and reference standards developed by body mandated under Kenya law with mandate of developing Kenya standards.
v. Product liability and traceability management and reference to Competition Act, 2012 should be referenced.

181. **THE PHARMACEUTICAL SOCIETY OF KENYA (PSK)**

The Pharmaceutical Society of Kenya (PSK) reckoned that should the KFDA Bill, 2019 be enacted in its current form, it would fundamentally alter and change in a negative way the effective regulation of research, production and manufacture, import, distribution, sale and use of medicines and health products. This would result in compromise of the medicines and health products value chain with the end result being placing public health in jeopardy. Whereas it is the right time to carryout policy and legal reforms in the pharmaceutical industry, in the Kenya Food and Drugs Authority Bill, 2019 PSK has observed that the Bill has fundamental policy and legislative gaps that if not changed, would result into an ineffective regulatory framework and non-realization of intended health outcomes.

PSK proposes to the Departmental Committee on Health that the Bill should not be enacted in its current form because it is:

i. Purporting to regulate food contrary to provisions of the Health Act 2017
ii. Lacking in policy and regulatory law provisions around the following substantive areas:
    a. Poisons Information Center
    b. Cost effectiveness analysis mechanisms for medicines and health products (health technology assessment)
    c. Clinical trials
    d. Biologic substances
    e. Scheduling of medicines and health products
    f. Practice including levels of practice in handling medicines and health products

Consequently, PSK proposes that the Departmental Committee on Health considers adopting the proposed amendments provided below, for the good of the pharmaceutical industry, pharmacy practice and protection of health and safety in Kenya.

182. **KENYA VETERINARY BOARD**

i. The Bill should focus only on human medicine and exclude veterinary medicine regulation which for the past one year is now effectively regulated as per international standards.
ii. International standards for regulating veterinary medicines are based on World Organization for Animal Health (OIE) and the current recommendation is that

veterinary medicines should be regulated by competent veterinary for purposes of better mitigation of animal diseases monitoring veterinary drug residue and antimicrobial resistance.

iii. Human medicine regulation in Kenya has proved a nightmare and adding on food regulation will only disadvantage further food safety guarantees. There should not be a mix in regulation of food and medicines in one agency and we need to benchmark on food regulation in Europe.

iv. Any aspect of practice in veterinary medicine to be regulated under any agency including food safety of animal origin needs expert input from Kenya Veterinary Board.

183. **KENYA VETERINARY ASSOCIATION**

i. Treaties ratified by Kenya such as World Trade Organization Agreement on Application of Sanitary and Phytosanitary Measures and International agreement are part of Kenya's Law. World Organization for Animal Health (OIE) and the current recommendation is that veterinary medicines should be regulated by competent veterinary for purposes of better mitigation of animal diseases monitoring veterinary drug residue and antimicrobial resistance.

ii. Aspects of practice in veterinary medicine to be regulated under any agency including food safety of animal origin needs should be left under mandate of the Kenya Veterinary Board and not KFDA.

iii. The Bill seeks to regulate products effectively regulated by other competent authorities.

184. **VETERINARY INPUT SUPPLIERS ASSOCIATION OF KENYA (VISAK)**

i. Current global practice is to segregate regulation and control of human medicine, veterinary medicine and food and pest control.

ii. International standards for regulating veterinary medicines are based on World Organization for Animal Health (OIE) and the current recommendation is that veterinary medicines should be regulated by competent veterinary for purposes of better mitigation of animal diseases monitoring veterinary drug residue and antimicrobial resistance.

iii. All veterinary medicine outlets countrywide are managed by Veterinary professional and therefore easy to monitor the movement and quality of veterinary medicines in the market.

iv. Veterinary medicine should regulated by the ministry that deals with livestock as veterinary professionals are registered and regulated by the Kenya Veterinary Board.

v. The Bill seeks to regulate products effectively regulated by other competent authorities without any public participation from the relevant affected agencies.

vi. Qualifications of Director General leaves out competencies regulated under the proposed Bill such as veterinary medicine.

vii. As the proposed Act seeks to regulate products that fall under the animal resource industry the PS in charge of livestock and animal health issues must be part of the Board.

185. **AGROCHEMICALS ASSOCIATION OF KENYA**

There will be duplication of regulation of Pesticides that will be encountered when the Food and Drug Authority Bill is passed with that of Pest Control Products Act, Cap 346 that regulates the importation and exportation, manufacture and distribution, sale, use and disposal of pest control products.

186. **TOXOCOLOGY SOCIETY OF KENYA**

A specialist in the field of toxicology should be included as key potential players to enhance the various functions mentioned in the Bill and to contribute to the safety of food and drugs with the country.

187. **ASSOCIATION OF PUBLIC HEALTH OFFICERS**

They do not support the Bill for the following reasons

i. The Bill is unconstitutional to the extent that it seeks to perform functions that are devolved to counties such as licensing and control of undertakings that sell food to the public.
ii. Through Clause 97(a) a regulatory officer may, for the purposes of the Act inspect any animal intended for slaughter and seize and examine any meat considered to be unfit. This a function devolved to counties to inspect animals that intended for slaughter.
iii. The Bill seeks to repeal the Food, Drugs and Chemical Substances Act that has been assisting the counties to operationalize schedule 4 of the Constitution.
iv. Section 23-30 of the Bill have been adequately covered in the Food, Drugs and Chemical Substances Act thus there is no need to repeal the present Act in order to create another Act.
v. The Bill leaves out Public Health Practitioners to ne members of the Board who should be part of the Board
vi. The Bill defines a regulatory officer as a person appointed by the Authority. The Bill being a multi sectoral Bill does not clearly define the role of the regulatory officer, qualifications technical know of the officer.

188. **OFFICE OF THE ATTORNEY-GENERAL**

i. The Bill is not informed by the Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization to which Kenya is a signatory.
ii. There is need for policy and operational coordination at the national level.
iii. Legislation should clearly set out the role of county governments.
iv. Currently food safety is collectively managed by three ministries- Agriculture, Health and Trade.
v. The Bill does not provide for an institutional framework for food control that features the elements that contribute towards an effective and efficient food control system
vi. The Bill will confuse the food control system.
vii. The Bill should be withdrawn to facilitate objective discussion on contentious issues.

189. **THE AGRICULTURE AND FOOD AUTHORITY**

i. A super-regulatory body for both food and drugs in one Act is ineffective
ii. The terminologies used in the Bill in reference to food are not related to commonly used terms for food.
iii. There is need to develop a separate legislation for food in order to harmonize and coordinate the different agencies regulating food.
iv. The production, harvest and post-harvest handling, mainly done by farmers, is the greatest risk to food safety and should be handled by the Ministry of Agriculture because that is where the competencies lie.

v. Clause 113 provides that the Authority shall develop Regulations, while there are already Regulations existing under The Crops Act. This is in conflict with the statutory mandate of the Agriculture and Food Authority.
vi. The Bill should take cognisance of other relevant laws where safety issues is guaranteed by other competent authorities at other levels of production.

190. **CEREAL MILLERS ASSOCIATION**

i. There are fundamental differences in the nature of hazards associated with food and drugs.
ii. The Bill will lead to duplicated roles and activities.
iii. Coordination and enforcement difficulties.
iv. Inconsistent and incoherent objective formatting .
v. Insufficient context.
vi. Increased cost of doing business.

191. **KENYA PHARMACEUTICAL ASSOCIATION**

i. Withdraw the Bill.
ii. The items under clause 3(1) are already currently regulated by other Boards in smaller units for effectiveness.
iii. Strengthen the Acts establishing the already existing Boards.

192. **KENYA VETERINARY BOARD**

i. Withdraw the Bill
ii. Regulation of food safety should be done separately from the regulation of medicines and medical devices.
iii. The Executive should develop an elaborate policy on Food Safety Policy to guide legislation.
iv. A Food Safety Bill should be developed to address the entire food chain continuum.
v. The Pharmacy and Poisons Act should be reviewed to provide for effective regulation of human medicines and devices in line with the standards set by the World Health Organisation.

193. **FRESH PRODUCE CONSORTIUM OF KENYA**

i. The Bill lacks alignment with international and regional food safety regulation frameworks.
ii. The Bill seeks to regulate an industry which is already being effectively regulated by other competent authorities.
iii. Combining human medicine, veterinary medicine, agrochemicals and food will lead to a bloated, inefficient and ineffective Authority.

194. **UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGA.NIZATION**

i. Expunge food products and safety from the scope of the Bill.
ii. A separate food safety Bill should be promulgated based on the principles of risk analysis.

195. **THE ASSOCIATION OF PUBLIC HEALTH OFFICERS (KENYA)**

i. The Bill is inconsistent with the Constitution.
ii. Unclear regulatory and enforcement mechanisms.
iii. The Bill proposes to repeal the Food, Drugs and Scheduled Substances Act, Cap. 254, and this will lead to inadequacies.

196. **VETERINARY INPUT SUPPLIERS ASSOCIATION OF KENYA**

i. The Bill seeks to regulate an industry which is already being effectively regulated by other competent authorities.
ii. Combining human medicine, veterinary medicine, agrochemicals and food will lead to a bloated, inefficient and ineffective Authority.

197. **KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)**

i. Separate legislation to regulate medicines, medical devices and therapeutics from the regulation of food.
ii. There is no provision for administration and enforcement.
iii. The Bill must respect and recognize the competencies of the existing institutions.
iv. There is need for development of a Food Control Policy based on inclusive consultations.

198. **JOHN O OCHOLA, ADVOCATE**

The Bill has far reaching implications as it seeks to repeal the Pharmacy and Poisons Act , the Food, Drugs and Scheduled Substances Act and the Narcotic Drugs and Psychotropic Substances Act (s. 16, 17 and 18). The Bill does not incorporate the recent amendments to the Pharmacy and Poisons Act despite it seeking to repeal the entire Act.

199. **DR. NAPHTAL MWANZIKI, AG. CEO , VETERINARY MEDICINES DIRECTORATE**

i. In the definitions, nay reference to humans or animals is dropped and a clear reference to either humans or animals adopted. The grouping together of either humans or animals is erroneous as neither veterinarians nor health professions as will have possess the relevant knowledge nor training to handle the two fields.
ii. Section 3(2) is erroneous as it does not take cognizance of other competent organizations regulating other services
iii. Section 6(3) is discriminative as it locks out other qualified cadres from being the director general of the authority.
iv. Section 46 veterinary professional should be allowed to dispense medicines intended to treat animals
v. There should be a distinct register for veterinary medicines (as required by the /world Animal Health Organization) difference from the register of human medicines.
vi. In section 50 (4) veterinary professionals registered by the Kenya Veterinary Board should also be licensed to have Whole Dealers Licenses

200. **CLETUS OTIENO**

i. The Bill seeks to repeal many acts and therefore will collate so many regulation roles that makes it riskier to the general public as it will be complex to regulate all these functions under one roof.
ii. In the Bill, a fine and a jail term imposed upon the importers of falsified medicines have been lowered three fold.
iii. This Bill also seeks lenient on the unqualified doctors against the recently assented Health Laws.

201. **JOEL NYUMU CHEGE**
The proposed Bill has assumed that pharmacy is a business and without a single mention of the work of the many pharmaceutical practitioners both pharmaceutical technologists and pharmacists who dedicate their time and resources to offering pharmaceutical care directly to the patients publicly and privately.

202. **VICTOR ARAP MAINA**
Anchor charges for registration of a drug in the bill and should be reasonable. The current fee of 2000 dollars per item is outrageous and is the cause of expensive medicines in this country Drugs only from Manufacturers approved by the FDA or equivalent certification bodies should be brought to Kenya.

203. **MAXWELL BANDAT**
i. The Bill in its functions has failed to capture some of vital functions that are currently carried out by the Pharmacy and Poisons Board like: Establishing criteria for registration of persons intending to become pharmacist and enrolled pharmaceutical technologists.
ii. Accreditation of institutions offering Bachelor degree in Pharmacy and Diploma in Pharmaceutical Technology in Kenya.
iii. Establishing a register for registered pharmacists and a roll for enrolled pharmaceutical technologists among other functions.

204. **VINCENT GATHUKIA**
i. Duplication of roles already performed by the Pharmacy and Poisons Board.
ii. Non-representation of all parties in the new proposed Board.
iii. Conflict with existing Acts.
iv. There is need to strengthen the existing Acts.

205. **DANIEL OTIENO**
The act is not one tailored or has not been developed based on the emerging trends in the healthcare sector in Kenya and in particular the pharmaceutical, medical equipment, food and veterinary products and tobacco.

206. **SHEILA CHELANGAT TERER**
There is need for clear distinction of pharmaceutical technologist

207. **ERIC GICHANE**
The roles and cadres have not been clearly defined that is pharmaceutical technologists. The scope of practice has been left out particularly pharmaceutical technologists, The Board should incorporate key players such as pharmaceutical technologists..

208. **PERPETUA MIRIKAU**
Supports the Bill without any amendments.

PART IV

4.0 COMMITTEE RECOMMENDATION

209. After considering the Kenya Food and Drugs Authority Bill *(National Assembly Bill No. 31 of 2019)*, the Committee recommends that the House approves the Bill with amendments as proposed in the schedule.

PART V

5.0 SCHEDULE OF PROPOSED AMENDMENTS

210. The Committee, having considered the Bill and the submissions from stakeholders, makes the following recommendations;

TITLE

THAT, the Title to the Bill be amended by deleting the words "Food And"

Justification

The amendment seeks to ensure that the Bill shall only provide for matters related to the regulation of drugs, so as to avoid conflicting and overlapping mandates with the Agriculture and Food Authority which regulates food.

LONG TITLE

THAT, the Bill be amended by deleting the Long Title and inserting the following Long Title—

"AN ACT of Parliament to establish the Kenya Drugs Authority; to provide for the regulation and management of drugs and chemical substances; to provide for the regulation of medical devices and other health technologies; to give effect to the principles and objects of devolved government in drug safety regulation and for connected purposes"

Justification

The amendment seeks to ensure that the Bill shall only provide for matters related to the regulation of drugs, so as to avoid conflicting and overlapping mandates with the Agriculture and Food Authority which regulates food.

CLAUSE 1

THAT, clause 1 of the Bill be amended by deleting the words "Food and"

Justification

The amendment seeks to ensure that the Bill shall only provide for matters related to the regulation of drugs, so as to avoid conflicting and overlapping mandates with the Agriculture and Food Authority which regulates food.

CLAUSE 2

THAT, clause 2 of the Bill be amended—

(a) in the definition of "article" by deleting the word "food";
(b) by deleting the definition of "cigarette";
(c) by deleting the definition of "food";
(d) by deleting the definition of "tobacco"; and
(e) by deleting the definition of "tobacco products".

Justification
The amendment seeks to remove any reference to food in the Bill, so as to avoid overlap of mandates in respect of the functions performed by the Agriculture and Food Authority.

The amendment also seeks to remove reference to tobacco products in the Bill, so as to avoid overlap of mandates in respect of the functions of the Tobacco Control Board.

CLAUSE 3
THAT, clause 3 of the Bill be amended in subclause (1)—
(a) by deleting paragraph (d); and
(b) by deleting paragraph (i).

Justification

The amendment seeks to ensure that the Bill shall not apply to the regulation of food or tobacco products, which are regulated by the Agriculture and Food Authority and the Tobacco Control Board respectively.

PART II
THAT, the Title to Part II of the Bill be amended by deleting the words "FOOD AND"

Justification

The amendment seeks to ensure that the Bill shall only provide for the regulation of drugs.

CLAUSE 4
THAT, clause 4 of the Bill be amended in subclause (1) by deleting the words "Food and".

Justification

The amendment seeks to ensure that the Bill shall only provide for the regulation of drugs.

PART III
THAT, the Bill be amended by deleting Part III.

Justification

The amendment seeks to ensure the deletion of all clauses providing for the regulation of food, that is clauses 22 up to clause 32. This is because the regulation of food is provided for in the Agriculture and Food Authority Act, No. 13 of 2013.

PART X
THAT, the Bill be amended by deleting Part X.

Justification

The amendment seeks to ensure the deletion of all clauses providing for the regulation of tobacco products, that is clauses 74 up to clause 76. This is because the regulation of tobacco is provided for in the Tobacco Control Act, No. 4 of 2007.

CLAUSE 114

THAT, clause 114 of the Bill be amended–

(a) in subclause (2) by deleting the words "Pharmacy and Poisons Board and the";

(b) by inserting the following new subsection immediately after subsection (2)–

"(3) Within a period of twelve months from the date of coming into operation of this Act–

(a) the Pharmacy and Poisons Board shall continue to exist for the purpose of the regulation of the profession of pharmacy, including the registration and licensing of pharmacists and pharmaceutical technologists; and

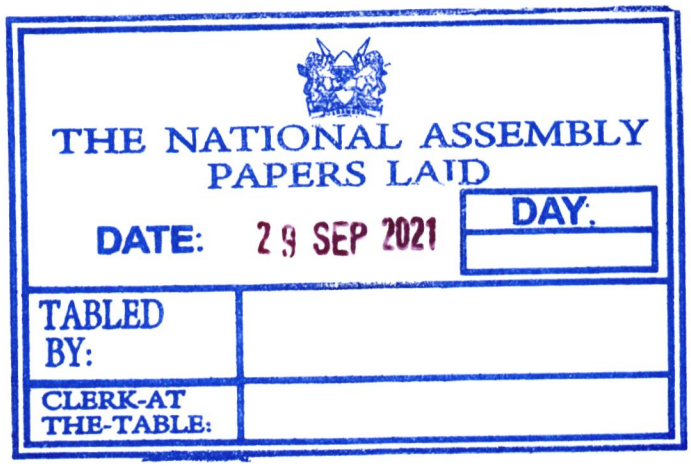
(b) Parliament shall enact legislation providing for the regulation of the pharmacy practice."

Justification

The amendment seeks to ensure that a vacuum shall not arise as a consequence of the repeal of the Pharmacy and Poisons Act. The amendment therefore provides that within one year from the enactment of the Act, the Pharmacy and Poisons Board shall continue to exist for purposes of regulation of the pharmacy profession, and also that there shall be subsequent legislation developed to provide for the regulation of the pharmacy profession.

SIGNED..... **DATE**.....27/9/2021.....

THE HON. SABINA CHEGE, MP
CHAIRPERSON
DEPARTMENTAL COMMITTEE ON HEALTH



THE NATIONAL ASSEMBLY
DEPARTMENTAL COMMITTEE ON HEALTH
ATTENDANCE SCHEDULE

ADOPTION SCHEDULE ON THE CONSIDERATION OF THE REPORT ON THE KENYA FOOD AND DRUGS AUTHORITY BILL (NA BILL NO. 31 OF 2019).

Tuesday 21st September, 2021

	NAME	SIGNATURE
1.	Hon. Sabina Chege, MP – **Chairperson**	Virtual
2.	The Hon. Joshua Kutuny, MP – **Vice-Chairperson**	Virtual
3.	Hon. Dr. Eseli Simiyu, MP	
4.	Hon. Dr. James Nyikal, MP	
5.	Hon. Dr. Mohamed Dahir Duale, MP	
6.	Hon. Dr. James Kipkosgei Murgor, MP	
7.	Hon. Alfred Agoi Masadia, MP	
8.	Hon. Muriuki Njagagua, MP	Virtual
9.	The Hon. Joyce Akai Emanikor, MP	Virtual
10.	Hon. Prof. Mohamud Sheikh Mohamed, MP	Virtual
11.	Hon. Martin Peters Owino, MP	
12.	Hon. Kipsengeret Koros, MP	Virtual
13.	Hon. Tongoyo Gabriel Koshal, MP	Virtual
14.	The Hon. Sarah Paulata Korere, MP	
15.	The Hon. Dr. Gideon Ochanda, MP	
16.	The Hon. Beatrice Adagala, MP	
17.	The Hon. Said Hiribae, MP	
18.	The Hon. (Capt.) Ruweida Mohammed, MP	
19.	The Hon. James Githua Kamau Wamacukuru, MP	Virtual

30/3/2021

REPUBLIC OF KENYA

TWELFTH PARLIAMENT (FIFTH SESSION)

THE NATIONAL ASSEMBLY

INVITATION FOR PUBLIC PARTICIPATION & SUBMISSION OF MEMORANDA

(Article 118 (1) (b) of the Constitution and Standing Order 127(3) of the National Assembly Standing Orders

In the Matter of consideration by the National Assembly: –
The Kenya Food and Drugs Authority Bill, (National Assembly Bill No. 31 2019)

SUBMISSION OF MEMORANDA

Article 118(1) (b) of the Constitution provides that, *"Parliament shall facilitate public participation and involvement in the legislative and other businesses of Parliament and its Committees"*. Standing Order (S.O.) 127(3) provides that *"the Departmental Committee to which a Bill is committed shall facilitate public participation and take into account the views and recommendations of the public in its report to the House"*.

The Kenya Food and Drugs Authority Bill (National Assembly Bill No. 31 2019) introduced by **Hon. Robert Pukose, MP,** seeks to establish the Kenya Food and Drugs Authority. The Bill provides for the regulation and management of foods, drugs, chemical substances, medical devices and other health technologies. The Bill gives effect to devolved government principles and objects in food security regulation and food-connected purposes.

The Bill has since been read a First Time pursuant to Standing Order 127(1) and stand committed to the Departmental Committee on Health for consideration and report to the House.

Pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3), the Committee invites interested members of the public to submit representations they may have on the said Bill. The Bill can be accessed from the parliamentary website at www.parliament.go.ke/the-national-assembly/house-business/bills.

The representations or written submissions may be forwarded to the Clerk of the National Assembly, **P.O. Box 41842-00100, Nairobi;** hand-delivered to the Office of the Clerk, **Main Parliament Buildings, Nairobi,** or emailed to **clerk@parliament.go.ke;** to be received on or before **Friday 9th April 2021, at 5.00 p.m.**

MICHAEL R. SIALAI, CBS
CLERK OF THE NATIONAL ASSEMBLY

MINUTES OF THE SIXTIETH (60TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN THE MAIN CHAMBER, PARLIAMENT ON TUESDAY 21ST SEPTEMBER, 2021 AT 10.00 AM

PRESENT

1. **The Hon. Sabina Chege, MP - Chairperson**
2. **The Hon. Joshua Kutuny, MP – Vice-Chairperson**
3. The Hon. Dr James Nyikal, MP
4. The Hon. Dr Eseli Simiyu, MP
5. The Hon. Dr James Kipkosgei Murgor, MP
6. The Hon. Dr Mohamed Dahir Duale, MP
7. The Hon. Muriuki Njagagua, MP
8. The Hon. Dr Gideon Ochanda, MP
9. The Hon. Joyce Akai Emanikor, MP
10. The Hon. Martin Peters Owino, MP
11. The Hon. Prof Mohamud Sheikh Mohamed, MP
12. The Hon. Kipsengeret Koros, MP
13. The Hon. Tongoyo Gabriel Koshal, MP
14. The Hon. (Cpt.) Ruweida Mohammed, MP
15. The Hon. Beatrice Adagala, MP
16. The Hon James Githua Kamau Wamacukuru, MP

ABSENT WITH APOLOGY

1. The Hon. Alfred Agoi Masadia, MP
2. The Hon. Sarah Paulata Korere, MP
3. The Hon. Said Hiribae, MP

IN ATTENDANCE

NATIONAL ASSEMBLY SECRETARIAT

1. Douglas Katho	–	Clerk Assistant II
2. Muyodi Emmanuel	–	Clerk Assistant II
3. Christine Odhiambo	–	Legal Counsel I
4. Nimrod Ochieng	–	Audio Officer

MIN. NO.NA/DC.H/2021/191: PRELIMINARIES

The Chairperson called the meeting to order at 10.14 am.

MIN.NO.NA/DC.H/2021/193: CONSIDERATION OF THE DRAFT REPORT OF THE KENYA FOOD AND DRUGS AUTHORITY BILL(NA BILL NO. 31 OF 2019)

The Committee considered the draft report and proposed amendments to the schedule of the *Kenya Food And Drugs Authority Bill (NA BILL NO. 31 OF 2019).*

(Details of the specific clauses and amendments are detailed in the report on the consideration of Kenya Food And Drugs Authority Bill (NA BILL NO. 31 OF 2019).

MIN.NO.NA/DC.H/2021/192: ADOPTION OF THE KENYA FOOD AND DRUGS AUTHORITY BILL(NA BILL NO. 31 OF 2019)

The Committee adopted the report of the ***Kenya Food And Drugs Authority Bill (NA BILL NO. 31 OF 2019)*** after being proposed by the Hon. Beatrice Adagala, MP and seconded by the Hon. (CAPT.) Ruweida Mohammed, MP ***(The Committee's proposed amendments are detailed in Part V of the report).***

MIN. NO.NA/DC.H/2021/195: ADJOURNMENT

There being no other business to deliberate on, the meeting was adjourned at 11:49 am.

HON. SABINA CHEGE, MP

(CHAIRPERSON)

Sign.....  **Date**.....27/9/2021.....

MINUTES OF THE FIFTY-FIRST (51ST) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN MAJLIS HOTEL, LAMU ON TUESDAY 7TH SEPTEMBER, 2021 AT 2.00 PM

PRESENT

1. **The Hon. Sabina Chege, MP - Chairperson**
2. The Hon. Dr James Nyikal, MP
3. The Hon. Martin Peters Owino, MP
4. The Hon. Kipsengeret Koros, MP
5. The Hon. (CAPT.) Ruweida Mohammed, MP
6. The Hon. Beatrice Adagala, MP

ABSENT WITH APOLOGY

1. **The Hon. Joshua Kutuny, MP – Vice-Chairperson**
2. The Hon. Dr Eseli Simiyu, MP
3. The Hon. Dr James Kipkosgei Murgor, MP
4. The Hon. Dr Mohamed Dahir Duale, MP
5. The Hon. Muriuki Njagagua, MP
6. The Hon. Joyce Akai Emanikor, MP
7. The Hon. Alfred Agoi Masadia, MP
8. The Hon. Dr Gideon Ochanda, MP
9. The Hon. Sarah Paulata Korere, MP
10. The Hon. Prof Mohamud Sheikh Mohamed, MP
11. The Hon. Tongoyo Gabriel Koshal, MP
12. The Hon. Said Hiribae, MP
13. The Hon James Githua Kamau Wamacukuru, MP

IN ATTENDANCE

NATIONAL ASSEMBLY SECRETARIAT

1. Douglas Katho	–	Clerk Assistant II
2. Muyodi Emmanuel	–	Clerk Assistant II
3. Christine Odhiambo	–	Legal Counsel I
4. Nimrod Ochieng	–	Audio Officer

MIN. NO.NA/DC.H/2021/164: PRELIMINARIES

The Chairperson called the meeting to order at 2.11 pm.

MIN.NO.NA/DC.H/2021/165: CLAUSE BY CLAUSE CONSIDERATION OF THE KENYA FOOD AND DRUGS AUTHORITY BILL(NA BILL NO. 31 OF 2019)

After lengthy deliberations, the Committee proposed amendments to the schedule of the ***Kenya Food And Drugs Authority Bill (NA BILL NO. 31 OF 2019)*** to be considered by the House in the Committee stage:

(Details of the specific clauses and amendments are contained in the report on the consideration of the Kenya Food And Drugs Authority Bill (NA BILL NO. 31 OF 2019).

MIN. NO.NA/DC.H/2021/166: ADJOURNMENT

There being no other business to deliberate on, the meeting was adjourned at 4:51 pm. The next meeting will be held on notice.

HON. SABINA CHEGE, MP

(CHAIRPERSON)

Sign..... **Date**27/9/2021.....

MINUTES OF THE TWENTY-NINTH (29TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD VIA ZOOM ON WEDNESDAY 14TH JULY, 2021 AT 10.00 AM

PRESENT

1. **The Hon. Sabina Chege, MP - Chairperson**
2. **The Hon. Joshua Kutuny, MP – Vice-Chairperson**
3. The Hon. Dr James Nyikal, MP
4. The Hon. Dr James Kipkosgei Murgor, MP
5. The Hon. Martin Peters Owino, MP
6. The Hon. Kipsengeret Koros, MP
7. The Hon. Beatrice Adagala, MP
8. The Hon. (Capt) Ruweida Mohammed, MP

ABSENT WITH APOLOGY

1. The Hon. Dr Eseli Simiyu, MP
2. The Hon. Dr Mohamed Dahir Duale, MP
3. The Hon. Alfred Agoi Masadia, MP
4. The Hon. Muriuki Njagagua, MP
5. The Hon. Dr Gideon Ochanda, MP
6. The Hon. Joyce Akai Emanikor, MP
7. The Hon. Prof Mohamud Sheikh Mohamed, MP
8. The Hon. The Hon. Tongoyo Gabriel Koshal, MP
9. The. Said Hiribae, MP
10. The Hon James Githua Kamau Wamacukuru, MP
11. The Hon. Sarah Paulata Korere, MP

IN ATTENDANCE

NATIONAL ASSEMBLY SECRETARIAT

1. Douglas Katho	–	Clerk Assistant II
2. Muyodi Emmanuel	–	Clerk Assistant II
3. Christine Odhiambo	–	Legal Counsel
4. Nimrod Ochieng	–	Audio Officer

MINISTRY OF HEALTH

Ms. Susan Mochache - Principal Secretary, Ministry of Health

MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND COOPERATIVES

Prof. Hamadi Iddi Boga, PhD, CBS – Principal Secretary for crops Development & Agricultural Research

MIN. NO.NA/DC.H/2021/100: PRELIMINARIES

The Chairperson called the meeting to order at 10.08 am.

MIN.NO.NA/DC.H/2021/101: MEETING WITH THE MINISTRY OF HEALTH AND AGRICULTURE, LIVESTOCK, FISHERIES AND COOPERATIVES ON THE HARMONIZATION AND CONSOLIDATION OF VIEWS ON THE KFDA BILL 2019

The Ministry of Health and the Ministry of Agriculture reported that they had considered the proposed law and concerns of other stakeholders and that they had agreed that:

i. Regulations of food will be separated from the regulation of human medicines and devices; and veterinary medicines and devices.
ii. The two Ministries will review the existing laws to accommodate the regulatory proposals in order to provide for enhancing the food safety system. The scope of Agriculture and Health Sector regulatory agencies will be clearly defined in their respective laws and in the proposed legislation for better coordination and effectiveness.
iii. The two Ministries will review the existing laws regulating human medicines and devices (Pharmacy and Poisons Act Cap 244), and veterinary medicines and devices (Veterinary Surgeons and Veterinary Paraprofessionals Act of 2011) to support the food safety system agenda.
iv. The two Ministries will review the draft National Food Safety Policy of 2013 and submit it to the Cabinet for consideration to inform the legislative proposals. The overall goal of the policy is to establish and maintain a rational, integrated farm-to-fork food safety system that harmonizes inter-agency efforts, minimizes inter-agency conflict and overlap, establish a coordination mechanism. This will ensure the protection of public safety and food trade consistent with the World Trade Organization (WTO) agreement on the Sanitary and Phytosanitary (SPS) Protocol measures and other international requirements.
v. To review Food, Drugs and Chemical Substances Act Chapter 254 to provide for an agency with oversight and coordinating role for all agencies involved in food safety including those that are currently unregulated. The review will establish a coordination mechanism with other regulatory agencies.
vi. The inter-ministerial TWG is on course to complete the consultative process for the Food Safety Policy and Bill before the same is presented to the Cabinet for approval and thereafter presentation to Parliament by the end of September 2021.
vii. The new legislative proposal to regulate food and safety will notify the WTO and its member countries to incorporate their feedback in the Bill to discourage disruption of our export earnings arising from arbitrary bans. Kenya's largest exports are agricultural food products.

MIN. NO.NA/DC.H/2021/102: ADJOURNMENT

There being no other business to deliberate on, the meeting was adjourned at 11:59 am.

HON. SABINA CHEGE, MP

(CHAIRPERSON)

Sign..... **Date**.....27/9/2024.....

MINUTES OF THE TWENTY-EIGHTH (28TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD VIA ZOOM ON TUESDAY 7TH JULY, 2021 AT 9.00 AM

PRESENT

1. **The Hon. Sabina Chege, MP - Chairperson**
2. **The Hon. Joshua Kutuny, MP – Vice-Chairperson**
3. The Hon. Dr James Nyikal, MP
4. The Hon. Dr James Kipkosgei Murgor, MP
5. The Hon. Muriuki Njagagua, MP
6. The Hon. Martin Peters Owino, MP
7. The Hon. Beatrice Adagala, MP
8. The Hon. (Capt) Ruweida Mohammed, MP

ABSENT WITH APOLOGY

1. The Hon. Dr Eseli Simiyu, MP
2. The Hon. Dr Mohamed Dahir Duale, MP
3. The Hon. Alfred Agoi Masadia, MP
4. The Hon. Dr Gideon Ochanda, MP
5. The Hon. Joyce Akai Emanikor, MP
6. The Hon. Prof Mohamud Sheikh Mohamed, MP
7. The Hon. Kipsengeret Koros, MP
8. The Hon. The Hon. Tongoyo Gabriel Koshal, MP
9. Said Hiribae, MP
10. The Hon James Githua Kamau Wamacukuru, MP
11. The Hon. Sarah Paulata Korere, MP

IN ATTENDANCE

NATIONAL ASSEMBLY SECRETARIAT

1. Douglas Katho	–	Clerk Assistant II
2. Muyodi Emmanuel	–	Clerk Assistant II
3. Christine Odhiambo	–	Legal Counsel
4. Nimrod Ochieng	–	Audio Officer

MIN. NO.NA/DC.H/2021/97: PRELIMINARIES

The Chairperson called the meeting to order at 9.18 am.

MIN.NO.NA/DC.H/2021/98: CONSIDERATION OF THE KENYA FOOD AND DRUGS AUTHORITY BILL(NA BILL NO. 31 OF 2019)

The Committee noted with concern that the regulatory provisions proposed in the Bill cut across the economy. It pointed out that this could bring challenges when it comes to implementing the law once enacted. Therefore, the Committee resolved to engage with the two critical stakeholders, i.e. the Ministry of Health and Agriculture, on Wednesday 14th July 2021 to provide a workable proposal.

MIN. NO.NA/DC.H/2021/99: ADJOURNMENT

There being no other business to deliberate on, the meeting was adjourned at 11:09 am.

HON. SABINA CHEGE, MP

(CHAIRPERSON)

Sign..... **Date**27/9/2021.....

MINUTES OF THE THIRTIETH (30TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON THURSDAY 27TH JUNE, 2019 AT 4TH FLOOR, COMMITTEE ROOM, CONTINENTAL HOUSE, PARLIAMENT BUILDINGS AT 11.00 A.M.

PRESENT

1. Hon. Sabina Chege , MP - **Chairperson**
2. Hon. (Dr.) Eseli Simiyu, MP
3. Hon. (Dr.) James Nyikal, MP
4. Hon. (Dr.) James Kipkosgei Murgor, MP
5. Hon. Muriuki Njagagua, MP
6. Hon. David Ochieng' MP
7. Hon. Martin Peters Owino, MP
8. Hon. Tongoyo Gabriel Koshal, MP

ABSENT WITH APOLOGY

1. Hon. (Dr.) Swarup Ranjan Mishra, MP – **Vice Chairperson**
2. Hon. Mercy Wanjiku Gakuya, MP
3. Hon. Alfred Agoi Masadia, MP
4. Hon. Patrick Munene Ntwiga, MP
5. Hon. Zachary Kwenya Thuku, MP
6. Hon. Prof. Mohamud Sheikh Mohamed, MP
7. Hon. Esther M. Passaris, MP
8. Hon. Gladwell Jesire Cheruiyot, MP
9. Hon. Stephen Mule, MP

ABSENT

1. Hon. (Dr.) Mohamed Dahir Duale, MP
2. Hon. Kipsengeret Koros, MP

IN ATTENDANCE

NATIONAL ASSEMBLY

1. Hon. Dr. Robert Pukose, M.P.	-	Sponsor of Bill
2. Mr. Muyodi M. Emmanuel	-	Clerk Assistant III
3. Mr. Lynette Otieno	-	Legal Counsel I

MINISTRY OF HEALTH

1. Ms. Susan Mochache	-	Principal Secretary
2. Dr. Simon Kibias	-	Deputy Director of Medical Services
3. Dr. Kepha Ombacho	-	Director of Public Health
4. Dr. Mary Wangai	-	Head, Legislation and Regulation

5. Dr. Fred Siyoi	-	CEO/Registrar, Pharmacy & Poisons Board
6. Dr. Josphat Mbiwa	-	Senior Deputy Director/Chief Pharmacist
7. Dr. Pius Wanjala	-	Senior Deputy Director/Chief Pharmacist NQCL
8. Mr. Ibrahim Abdi	-	Undersecretary/ Parliamentary Liaison
9. Mr. Nderi Ndiani	-	Legal Officer
10. Ms. Elizabeth Ochanda	-	Personal Assistant - Principal Secretary's Office

MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND IRRIGATION

Mr. Harry Kimtai	-	Principal Secretary, State Department for Livestock

MIN. NO.NA/C.H/2019/109: PRELIMINARIES

The Chairperson called the meeting to order at 11.13am and said a prayer. The agenda was adopted as proposed by Hon. (Dr.) James Kipkosgei Murgor, MP and seconded by Hon. (Dr.) James Nyikal, MP.

MIN. NO.NA/C.H/2019/110: CONFIRMATION OF MINUTES OF PREVIOUS SITTINGS

Minutes of the **26th sitting** held on 17th June, 2019 were confirmed as a true record of the proceedings as proposed by Hon. Martin Peters Owino, MP and seconded by Hon. (Dr.) James Nyikal, MP.

Minutes of the **27th sitting** held on 18th June, 2019 were confirmed as a true record of the proceedings as proposed by Hon. Tongoyo Gabriel Koshal, MP and seconded by Hon. David Ochieng', MP.

Minutes of the **28th sitting** held on 20th June, 2019 were confirmed as a true record of the proceedings as proposed by Hon. Martin Peters Owino, MP and seconded by Hon. David Ochieng', MP.

Minutes of the **29th sitting** held on 25th June, 2019 were confirmed as a true record of the proceedings as proposed by Hon. (Dr.) James Kipkosgei Murgor, MP and seconded by Hon. David Ochieng', MP.

MIN. NO.NA/C.H/2019/111: MATTERS ARISING

Under Minutes of the 26th sitting

The Committee was informed that the report on the National Hospital Insurance Fund (Amendment) Bill, 2019 had been tabled before the House on 26th June, 2019. The Bill now awaits second reading.

Under Minutes of the 27th sitting

It was resolved that the Committee should engage with all the relevant stakeholders when considering the Kenya Food and Drugs Authority Bill, 2019.

Under Minutes of the 28th sitting

The Committee resolved to engage with the Commission on University Education (CUE) and Universities offering medical courses with a view of having discussions on the ways of streamlining medical programmes offered in universities in the country.

MIN. NO.NA/C.H/2019/112: CONSIDERATION OF LEGISLATIVE PROPOSALS BEFORE THE COMMITTEE

The Committee was informed that Hon. Anthony Oluoch, MP and Hon. Gladys Wanga, MP, the sponsors of Access to Health Bill, 2019 and The Cancer Prevention and Control (Amendment) Bill, 2019 respectively had requested for rescheduling of their appearance before the Committee to Tuesday 2nd July, 2019.

Community Oral Health Officers Bill, 2019 - by Hon. Malulu Injendi, MP

The Committee recommended that the proposal be dropped and instead Kenya Medical Practitioners and Dentists Act be amended to accommodate the COHOs.

MIN. NO.NA/C.H/2019/113: MEETING WITH THE MINISTRY OF HEALTH AND THE MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND IRRIGATION ON THE KENYA FOOD AND DRUGS AUTHORITY BILL, 2019

The Committee considered views from both the Ministries of Health and Agriculture and the sponsor of the Bill, Hon. Dr. Robert Pukose, MP and noted that there was need for the three parties to build consensus on some of the contentious issues on the Bill and eventually front a joint position on the said legislation.

The Committee therefore resolved to write to the Speaker of the National Assembly with a view of seeking extension of 90 more days for these efforts.

MIN. NO.NA/C.H/2019/114: ANY OTHER BUSINESS

The Committee was informed of an Invitation by Kenya AIDS NGOs Consortium (KANCO) to a breakfast meeting on Wednesday 3rd July, 2019 at Intercontinental Hotel at 7.30 am. The agenda of the meeting being "vaccines immunization, nutrition and Universal Health Coverage, (UHC)".

MIN. NO.NA/C.H/2019/115: **ADJOURNMENT**

There being no other business, the meeting adjourned at 13.02pm. Next Sitting would be on Tuesday 2nd July, 2019.

Sign..... Date.....2/6/19.....

(Chairperson)

MINUTES OF THE TWENTY NINTH (29TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON TUESDAY 25TH JUNE, 2019 AT MEDIA CENTRE, PARLIAMENT BUILDINGS AT 10.00 A.M.

PRESENT

1. Hon. Sabina Chege , MP - **Chairperson**
2. Hon. (Dr.) James Nyikal, MP
3. Hon. (Dr.) James Kipkosgei Murgor, MP
4. Hon. Muriuki Njagagua, MP
5. Hon. Martin Peters Owino, MP
6. Hon. Mercy Wanjiku Gakuya, MP
7. Hon. Zachary Kwenya Thuku, MP
8. Hon. David Ochieng' MP

ABSENT

1. Hon. (Dr.) Swarup Ranjan Mishra, MP – **Vice Chairperson**
2. Hon. Prof. Mohamud Sheikh Mohamed, MP
3. Hon. Gladwell Jesire Cheruiyot, MP
4. Hon. Tongoyo Gabriel Koshal, MP
5. Hon. Stephen Mule, MP
6. Hon. Alfred Agoi Masadia, MP
7. Hon. Patrick Munene Ntwiga, MP
8. Hon. Kipsengeret Koros, MP
9. Hon. Esther M. Passaris, MP
10. Hon. (Dr.) Mohamed Dahir Duale, MP
11. Hon. Dr.) Eseli Simiyu, MP

IN ATTENDANCE

NATIONAL ASSEMBLY

1.	Mr. Victor Weke	-	Clerk Assistant I
2.	Mr. Muyodi M. Emmanuel	-	Clerk Assistant III
3.	Mr. Lynette Otieno	-	Legal Counsel I

MIN. NO.NA/C.H/2019/106: PRELIMINARIES

The Chairperson called the meeting to order at 10.05 am and said a prayer.

MIN. NO.NA/C.H/2019/107: CONSIDERATION OF THE KENYA FOOD AND DRUGS AUTHORITY BILL, 2019

The Committee resolved to defer the agenda, pending a meeting with the Ministry of Health, Ministry of Agriculture, Livestock, Fisheries and Irrigation and other relevant stakeholders to deliberate on some of the contentious clauses in the Bill.

MIN. NO.NA/C.H/2019/108: ADJOURNMENT

There being no other business, the meeting adjourned at 11.06am. Next Sitting would be on Thursday 27h June, 2019.

Sign..... **Date**27/06/19.....

(Chairperson)

MINUTES OF THE TWENTY SEVENTH (27TH) SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD ON TUESDAY 18TH JUNE, 2019 AT LAKE NAIVASHA RESORT AT 10.00 A.M.

PRESENT

1. Hon. Sabina Chege , MP - **Chairperson**
2. Hon. (Dr.) Swarup Ranjan Mishra, MP – **Vice Chairperson**
3. Hon. (Dr.) James Nyikal, MP
4. Hon. (Dr.) James Kipkosgei Murgor, MP
5. Hon. Muriuki Njagagua, MP
6. Hon. Esther M. Passaris, MP
7. Hon. David Ochieng' MP
8. Hon. Martin Peters Owino, MP
9. Hon. Gladwell Jesire Cheruiyot, MP
10. Hon. Tongoyo Gabriel Koshal, MP
11. Hon. Zachary Kwenya Thuku, MP

ABSENT WITH APOLOGY

1. Hon. (Dr.) Eseli Simiyu, MP
2. Hon. Stephen Mule, MP
3. Hon. (Dr.) Mohamed Dahir Duale, MP
4. Hon. Prof. Mohamud Sheikh Mohamed, MP
5. Hon. Alfred Agoi Masadia, MP

ABSENT

1. Hon. Kipsengeret Koros, MP
2. Hon. Patrick Munene Ntwiga, MP
3. Hon. Mercy Wanjiku Gakuya, MP

IN ATTENDANCE

NATIONAL ASSEMBLY

1.	Mr. Victor Weke	-	Clerk Assistant I
2.	Mr. Muyodi M. Emmanuel	-	Clerk Assistant III
3.	Mr. Lynette Otieno	-	Legal Counsel I

MIN. NO.NA/C.H/2019/98: PRELIMINARIES

The Chairperson called the meeting to order at 10.05 am and said a prayer.

MIN. NO.NA/C.H/2019/99: CONSIDERATION OF THE KENYA FOOD AND DRUGS AUTHORITY BILL, 2019

The Committee considered the proposed amendments on the Kenya Food and Drugs Bill, 2019 received from the Ministry of Health and other key stakeholders; clause by clause.

The Committee noted that the Bill was timely; however it would have far reaching effects if passed without further consultation with the aggrieved stakeholders. The Committee observed that a number of stakeholders had noted their reservation on some clauses in the Bill that were not in tandem with existing policies and standards.

Committee Resolutions

The Committee resolved to meet with all key stakeholders to seek clarifications on all the issues raised in their memoranda.

The secretariat was tasked to research on countries with proven track record of legislating on food, drugs and medical devices. Further, the Committee noted that it would be prudent to benchmark with countries with well established consumer protection agencies.

MIN. NO.NA/C.H/2019/100: ADJOURNMENT

There being no other business, the meeting adjourned at 3.51 pm.

Sign..... **Date**27/06/19.....

(Chairperson)