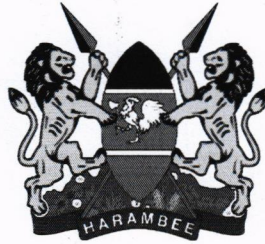


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REPUBLIC OF KENYA



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Recommended for approval for tabling.

28/03/22
Approved
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29/3/22

PARLIAMENT OF KENYA

THE SENATE

PAPERS LAID	
DATE	20/03/2022
TABLED BY	Chair
COMMITTEE	Hea Hh.
CLERK AT THE TABLE	Danny

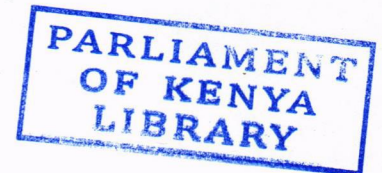
TWELFTH PARLIAMENT

SIXTH SESSION

THE STANDING COMMITTEE ON HEALTH

REPORT ON THE KENYA MEDICAL SUPPLIES AUTHORITY
(AMENDMENT) BILL, 2021

(SENATE BILLS NO. 53 OF 2021)



Clerk's Chambers,
First Floor,
Parliament Buildings,
NAIROBI.

MARCH, 2022

DC-EG

Recommended & Forwarded for Approval
28/03/22

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ABBREVIATIONS

KEMSA - Kenya Medical Supplies Authority

LIST OF ANNEXURES

1. *Annex 1* - Advertisement for public participation on the Bill
2. *Annex 2* - Matrix of submissions received on the KEMSA (Amendment) Bill, 2021
3. *Annex 3* - Minutes
4. *Annex 4* - Schedule for stakeholder engagement on the KEMSA (Amendment) Bill, 2021
5. Annex 5 - County Debt Ageing Analysis by KEMSA as of 20th May, 2020

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PREFACE

Mr. Speaker Sir,

The Senate Standing Committee on Health is established under standing order 218(3) of the Senate Standing Orders and is mandated to, “*consider all matters relating to medical services, public health and sanitation.*”

Committee Membership

The Membership of the Committee is composed of the following:

1. Sen. (Dr.) Michael Mbiti, MP. - Chairperson
2. Sen. Mary Seneta, MP. - Vice-Chairperson
3. Sen. Beth Mugo, EGH, MP.
4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeru, EGH, MP.
6. Sen. (Dr.) Abdullahi Ali Ibrahim, MP.
7. Sen. Fred Outa, MP.
8. Sen. Millicent Omanga, MP.
9. Sen. Ledama Olekina, MP.

Mr. Speaker,

The Kenya Medical Supplies Authority (Amendment) Bill (Senate Bills No. 53 of 2021) was read a First Time in the Senate on Wednesday, 3rd November, 2021 and thereafter stood committed to the Standing Committee on Health for consideration and facilitation of public participation in accordance with standing order 140(5) of the Senate Standing Orders.

Mr. Speaker,

The principal object of the Bill was to amend the Kenya Medical Supplies Act, 2013, by deleting section 4 of the Act which requires County Governments to procure drugs and medical supplies from the Authority as the first point of call. With the repeal of the provision, County Governments would be allowed to procure drugs and medical supplies from suppliers other than KEMSA.

Mr. Speaker,

Pursuant to the provisions of Article 118(1) (b) of the Constitution and standing order 140 (5), on Tuesday, 15th December, 2021, *vide* an advertisement that was placed in two newspapers with national circulation, as well as on the Parliament website and social media platforms, the Committee invited interested members of the public and key stakeholders to submit written memoranda on the Bill.

In response to the call for the submission of memoranda, the Committee received at least thirteen (13) written submissions from various stakeholders and concerned citizens with regards to the Bill.

Mr. Speaker,

Further to the above, between 2nd and 4th February, 2022, the Committee held a series of stakeholder engagement meetings with more than thirteen (13) key stakeholders, including, various government departments and agencies, universities, health regulatory bodies, unions, private sector groups, health professional groups and associations and civil society groups.

Mr. Speaker,

The Committee's observations and recommendations arising from this process are contained within this report. The Committee has further proposed amendments to the Bill that have been duly annexed to this report.

Mr. Speaker,

The Committee thanks the Offices of the Speaker and Clerk of the Senate for their support during the process of considering this matter.

The Committee also wishes to thank the members of the public, and the various stakeholders who participated in the stakeholder meetings.

Mr. Speaker Sir,

It is now my pleasant duty and privilege to present this report of the Standing Committee on Health, for consideration and approval by the House pursuant to Standing Order No. 226(2) of the Senate Standing Orders.

Signed..... 

Date.....24/3/2022.....

SEN. MBITO MICHAEL MALING'A, MP

CHAIRPERSON, STANDING COMMITTEE ON HEALTH

**ADOPTION OF THE REPORT OF THE STANDING COMMITTEE ON HEALTH OF
THE SENATE**

We, the undersigned Members of the Standing Committee on Health of the Senate, do hereby append our signatures to adopt the Report-


1. Sen. (Dr.) Michael Mbito, MP

..... 

2. Sen. Mary Seneta, MP

..... 


3. Sen. Beth Mugo, EGH, MP

..... 

4. Sen. Beatrice Kwamboka, MP

.....

5. Sen. (Prof) Samson Ongeru, EGH, MP

..... 

6. Sen. (Dr) Abdullahi Ali Ibrahim, MP

.....

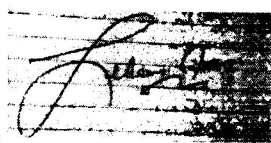
7. Sen. Fred Outa, MP

.....

8. Sen. Millicent Omanga, MP

.....

9. Sen. Ledama Olekina, MP

..... 

of public participation in accordance with standing order 140(5) of the Senate Standing Orders.

The principal object of the Bill was to amend the Kenya Medical Supplies Act, 2013, by deleting section 4 of the Act which requires County Governments to procure drugs and medical supplies from the Authority as the first point of call. With the repeal of the provision, County Governments would be allowed to procure drugs and medical supplies from suppliers other than KEMSA.

4. Overview of the Bill

The Bill proposed the following amendments to the Kenya Medical Supplies Authority Act:

(3) A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to—

(a) the drug being duly registered by the Board; and

(b) the drugs and medical supplies meet the standards of quality and are efficacious as authorized by the Board.

5. Consequences of the Bill

The Bill sought to ensure that Counties are able to guarantee the availability of medication and medical products in all county hospitals, and therefore guarantee the highest attainable standards of health as required under Article 43 of the Constitution.

CHAPTER TWO

PUBLIC PARTICIPATION AND STAKEHOLDER ENGAGEMENT

As indicated in the previous chapter, the Kenya Medical Supplies Authority (Amendment) Bill (Senate Bills No. 53 of 2021) was read a First Time in the Senate on Wednesday, 3rd November, 2021 and thereafter stood committed to the Standing Committee on Health for consideration and facilitation of public participation in accordance with standing order 140(5) of the Senate Standing Orders.

Accordingly, pursuant to the provisions of Article 118(1) (b) of the Constitution and standing order 140 (5) of the Senate Standing Orders, on Tuesday, 15th December, 2021, *vide* an advertisement that was placed in two newspapers with national circulation, as well as on the Parliament website and social media platforms, the Committee invited interested members of the public and key stakeholders to submit written memoranda on the Bill (*see Annex 1*).

In response to the call for the submission of memoranda, the Committee received at least **thirteen (13) written submissions** from various stakeholders and concerned citizens with regards to the Bill. A matrix with a summary of the submissions from the various stakeholders has been attached to this report as *Annex 2*.

Further to the above, between 2nd and 4th February, 2022, the Committee held a series of **stakeholder engagement meetings** with at least **thirteen (13) key stakeholders**, including, various government departments and agencies, universities, health regulatory bodies, unions, private sector groups, health professional groups and associations and civil society groups as indicated below:

a) Government Departments and Agencies

1. Ministry of Health (MOH)
2. Council of Governors (COG)
3. Kenya Medical Supplies Authority (KEMSA)
4. Pharmacy and Poisons Board

b) Private Sector Groups

5. Kenya Healthcare Federation (KHF)
6. Mission for Essential Drugs and Supplies (MEDS)

7. Kenya Association of Manufacturers (KAM)
8. Kenya Association of Pharmaceutical Industry (KAPH)
9. Federation of Kenya Pharmaceutical Manufacturers (FKPM)
10. Pharmaceutical Society of Kenya (PSK)

c) Non-State Actors and Civil Society Groups

11. Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)
12. NCD Alliance of Kenya (NCDAK)
13. Kenya Network for Cancer Organisations (KENCO)

The minutes of the above meetings have been attached to this report as *Annex 3*. In addition, a schedule of the meetings held with the aforementioned stakeholders has been attached to this report as *Annex 4*.

Further to the above, the Committee received written memoranda from thirteen (13) institutions and members of the public as per the schedule attached in *Annex 2*.

The Committee proceeded to consider the Bill and the submissions received thereon as set out in the matrix attached to this report as *Annex 2*.

CHAPTER THREE

COMMITTEE OBSERVATIONS

The Committee made the following observations:

1. 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.
2. Standing order 140(5) of the Senate Standing Orders provides that a Committee to which a Bill is committed shall facilitate public participation and shall take into account the views and recommendations of the public when it makes its report to the Senate.
3. Section 4 (1) (a) of the Kenya Medical Supplies Authority (KEMSA) Act, 2013 mandates the Authority to procure, warehouse and distribute drugs and medical supplies. .
4. The Health Laws (Amendment) Act, 2019, which became operational on 17th May, 2019, introduced sub-sections 4(3) and 4(4) to the KEMSA Act, 2013 to the effect that:
 - a) Section 4 (3) of the KEMSA Act, 2013, mandated all national and county public health facilities to obtain all their drugs and and medical supplies from the KEMSA;
 - b) Section 4 (4) of the Act prescribed a penalty of a fine not exceeding KShs. 2 Million or imprisonment for a term not exceeding five years, or both, for any person responsible for the procurement and distribution of drugs at a national or county public health facility who contravenes section 4(3) of the Act.

The above amendments effectively monopolized the procurement and distribution of drugs and medical supplies under KEMSA.

5. To note, the legality of the aforementioned amendments to the KEMSA Act, 2013 (amongst others) was challenged by the Senate and the Council of Governors in court *vide* Petitions No. 353 of 2019 and 284 of 2019, whereby the Senate sought their nullification on the basis that the National Assembly passed the Amendments

without reference to the Senate which is mandated to represent counties and protect their interests contrary to Article 96 of the Constitution.

6. The principal object of the KEMSA (Amendment) Bill, 2021, was to amend the Kenya Medical Supplies Act, 2013, by repealing sub-sections 4 (3) and (4) thereby breaking KEMSA's monopoly in respect to the supply of drugs and medical supplies to government hospitals, and allowing County Governments to procure drugs and medical supplies from suppliers other than KEMSA.
7. To note, as at 20th May 2020, the debt owed to KEMSA by the various County Governments amounted to KShs. 2,949,506,365.81, most of which remains unpaid to date (*see Annex 5*).
8. Drugs and medical supplies remain the key cost driver in the delivery of healthcare services. Through its bulk-pooled procurement system, Kenya benefits from the economies of scale brought about by competitive sourcing by KEMSA. This has in turn led to lower costs of medicine, and more affordable healthcare.
9. In addition, there is a need to put measures in place that ensure that essential drugs and medical supplies at all government health facilities are standard, safe, efficacious and of good quality countrywide.

CHAPTER FIVE

COMMITTEE RECOMMENDATIONS

The Committee therefore recommends that:

1. Clause 2 of the Bill be deleted and substituted to provide for KEMSA as the first point of call for the procurement, warehousing and distribution of health products and technologies listed in the Kenya Essential Medicines List and the Kenya Essential Health Products and Technologies List;
2. The Senate take legislative action to provide for the ring-fencing of County funds reserved for the purchase of drugs and medical supplies; and
3. The Senate take legislative action to ensure the recovery of old county debts arising from drugs and medical supplies supplied to Counties by KEMSA by way of a first charge.

REPUBLIC OF KENYA



TWELFTH PARLIAMENT | FIFTH SESSION

THE SENATE

INVITATION FOR SUBMISSION OF MEMORANDA

At the sittings of the Senate held on Tuesday, 2nd November, 2021 and Wednesday, 3rd November, 2021, the Bills listed at the second column below were introduced in the Senate by way of First Reading and thereafter stood committed to the respective Standing Committees indicated at the third column.

Pursuant to the provisions of Article 118 of the Constitution and Standing Order 140 (5) of the Standing Orders of the Senate, the Committees now invite interested members of the public to submit any representations that they may have on the Bills by way of written memoranda.

The Memoranda may be sent **by email** on the address: csenate@parliament.go.ke and copied to the email addresses of the respective Committee indicated at the fourth column below, to be received on or before **Friday, 19th November, 2021 at 5.00 p.m.**

	Bill	Committee Referred To	Email Address
a)	The Election Campaign Financing (Amendment) Bill (Senate Bills No. 51 of 2021)	Standing Committee on Justice, Legal Affairs and Human Rights	senatejlahrc@parliament.go.ke
b)	The Kenya Medical Supplies Authority (Amendment) Bill (Senate Bills No. 53 of 2021)	Standing Committee on Health	senatehealth@gmail.com
c)	The Irrigation (Amendment) Bill (National Assembly Bills No. 12 of 2021)	Standing Committee on Agriculture, Livestock and Fisheries	senatescalf@parliament.go.ke

The Bills may be found on the Parliament website at <http://www.parliament.go.ke/the-senate/senate-bills>.

**J.M. NYEGENYE, CBS,
CLERK OF THE SENATE.**

24th March, 2022,
The Clerk of the Senate,
Parliament Buildings,
NAIROBI.

**RE: COMMITTEE STAGE AMENDMENTS TO THE KENYA MEDICAL SUPPLIES
AUTHORITY (AMENDMENT) BILL, (SENATE BILLS NO. 53 OF 2021)**

NOTICE is given that the Chairperson of the Standing Committee on Health, Senator Michael Mbito intends to move the following amendments to the Kenya Medical Supplies Authority (Amendment) Bill, Senate Bills No. 53 of 2021, at the Committee Stage —

CLAUSE 2

THAT clause 2 of the Bill be deleted and substituted with the following new clause—

Amendment
of section 4 of
No. 20 of
2013.

2. The Kenya Medical Supplies Authority Act, 2013, hereinafter referred to as the principal Act is amended in section 4 by—

(a) deleting subsection (3) and substituting therefor the following new subsection—

No. 21 of
2017.

(3) A national and county public health facility shall, in the procurement of drugs and medical supplies listed in the national government guidelines for essential medicines under section 67(4) of the Health Act, obtain all drugs and medical supplies from the Authority subject to the —

(a) drug being registered by the Board; and

(b) drugs and medical supplies—

(i) meeting the standards of quality;

(ii) being efficacious as authorised by the Board.

Dated.....24th March, 2022.



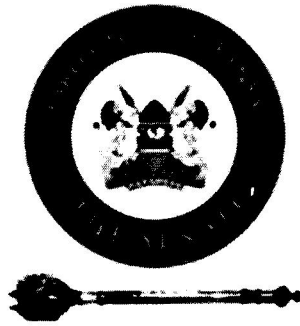
.....
Sen. Michael Mbito, MP
Chairperson, Standing Committee on Health.

		Kenya Association of Pharmaceutical Industry (KAPI)	
		Federation of Kenya Pharmaceutical Manufacturers (FKPM)	
		Pharmaceutical Society of Kenya (PSK)	
3.	<i>Civil Society Groups/NGOs</i>	KELIN	Friday, 4 th February, 2022
		HENNET	
		KENCO	
		NCD Alliance of Kenya	
B. Internal			
9.	<i>Consideration and adoption of:</i>	The KEMSA Amendment) Bill: a) The Committee Report on Public Participation b) Committee Stage Amendments	10 th to 13 th February, 2020
11.	<i>Tabling of Reports</i>	a) KEMSA (Amendment) Bill, 2021 - The Committee Report on Public Participation - Committee Stage Amendments	Tuesday, 16 th February, 2022

**SCHEDULE FOR STAKEHOLDER ENGAGEMENT ON THE KEMSA
(AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)**

No.	ACTIVITY	DESCRIPTION	TIMELINES
1.	Advertisement for submission of written memoranda	1. Publish on re-advertisement on: a) two newspapers with national distribution b) Parliament website c) Parliament social media pages d) Social media	a) Newspaper Adverts - Date of publication: Monday, 8 th November, 2021. - Deadline for submission of memoranda: Friday, 19 th November, 2021.
A. Structured Stakeholder Engagement on the KEMSA (Amendment) Bill, 2021			
3.	<i>Government Agencies and Departments</i>	<ul style="list-style-type: none"> ● Ministry of Health 	Thursday, 3 rd February, 2022
Council of Governors			
Nairobi Metropolitan Services			
Kenya Medical Supplies Authority (KEMSA)			
Pharmacy and Poisons Board (PPB)			
2.	<i>Private Sector</i>	Mission for the Essential Drugs and Supplies (MEDS)	Wednesday, 2 nd February, 2022
Kenya Healthcare Federation (KHF)			
Kenya Association of Manufacturers (KAM)			

TWELFTH PARLIAMENT | SIXTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON TUESDAY, 1ST FEBRUARY, 2022, AT 9:00 A.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

1. Sen. Mary Seneta, MP - Vice-Chairperson
2. Sen. Beth Mugo, EGH, MP
3. Sen. (Prof) Samson Ongeru, EGH, MP
4. Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
5. Sen. Millicent Omanga, MP
6. Sen. Fred Outa, MP
7. Sen. Ledama Olekina, MP

APOLOGY

1. Sen. Michael Mbiti, MP - Chairperson
2. Sen. Beatrice Kwamboka, MP

SECRETARIAT

1. Dr. Christine Sagini - Senior Clerk Assistant
2. Ms. Caroline Njue - Clerk Assistant
3. Ms. Sombe Toona - Legal Counsel
4. Mr. Robert Rop - Audio Officer
5. Mr. Frank Mutulu - Media Relations Officer
6. Mr. Hussein Salat - Fiscal Analyst

MIN. NO. SCH/01/02/2022: PRELIMINARIES

The Chairperson called the meeting to order at 9.15 a.m. and the meeting commenced with a word of prayer.

MIN. NO. SCH/02/02/2022: ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by **Sen. Fred Outa, MP** and seconded by **Sen. (Dr.) Abdullahi Ali, MP MP: -**

1. Preliminaries

a. Prayer

b. Adoption of the Agenda

2. Consideration of pending business before the Committee

3. Consideration and adoption of the proposed schedule for stakeholder engagement on the Kenya Medical Supplies Authority (KEMSA) Amendment Bill, 2021

4. Proposed visit to Rwanda by NHIF.

5. Any other business:

6. Date of the Next Meeting.

7. Adjournment.

MIN.NO.SCH/03/02/2022: CONSIDERATION OF PENDING BUSINESS BEFORE THE COMMITTEE

The Committee was informed of the pending business before the committee as follows:

BILLS

1. *The County E-Health System Bill*, sponsored by Sen. Judith Pareno. 2.

The Maternal, Newborn and Child Health Bill, sponsored by Sen. Rose Nyamunga, MP; and

3. *The Kenya Medical Supplies Authority (Amendment) Bill*, sponsored by Sen. Naomi Shiyonga, MP.

STATEMENTS

1. Construction of healthcare centers in Kajiado County funded by the African Development Bank (ADB) through the Ministry of Health by Sen. Mary Seneta, MP.

2. Statement regarding the delay in appointment of a substantive Director-General in the Ministry of Health by Sen. Samson Cherarkey, MP.

3. Operationalisation of the Counsellors and Psychologists Act, 2014, by Sen. Isaac Mwaura, MP.

4. Investing in mental health care post-COVID-19 pandemic by Sen. (Dr.) Michael Mbito, MP.

5. Mental health in Kenya in view of cessation of movement and curfew currently obtaining in the country by Sen. (Arch) Sylvia Kasanga, MP.
6. State of healthcare in public health facilities in Kitui County by Sen. Enoch Wambua, MP.
7. State of health care services to cancer patients in public health facilities in Counties by Sen. Getrude Musuruve, MP.
8. Delay in appointment of a substantive Director- General in the Ministry of Health by Sen. Samson Cherarkey, MP.
9. Efficacy of COVID – 19 vaccines by Sen. Petronilla Were, MP.
10. Status of operations of a public health clinic situated in Parklands, Nairobi city County on LR. No. 209/19441 by Sen. Millicent Omanga, MP.
11. Looming health crisis in Kakamega County exacerbated by the COVID 19 pandemic in the Country by Sen. Cleopas Malala, MP.
12. Medical negligence at health facilities in Bomet County by Sen. (Dr.) Christopher Langat.
13. Third wave of the COVID-19 pandemic and the COVID-19 Vaccine by Sen. George Khaniri, MP.

PETITIONS (*partially considered*)

1. Petition on the Closure of Kyuso Sub County Hospital, Kitui County by Hon. Stephen M. Musili and Hon. Johnson M. Kanandu.
2. Petition on NHIF cover for kidney post-transplant medication by Mr. Daniel Ngumi and others.
3. Petition on the Payment of Medical and Healthcare costs and provision of health cover for persons living with Autoimmune Diseases by the National Hospital Insurance Fund (NHIF) by Mikeson Mugo et al.
4. Petition on the alleged double taxation of pharmacies in Kenya by Mr. Collins A. Omollo.
5. Petition by Ms. Mario Juma and others on Challenges faced by patients suffering from Multiple Sclerosis (MS) and Neuromyelitis Optica (NMO).

With regards to the pending petitions, Members noted that most petitions had been partially considered, having already met with the Petitioners. With regard to the petition on the closure of Kyuso Sub County Hospital, Sen. Ali noted that it had been withdrawn and that the issue stood resolved.

MIN.NO.SCH/04/02/2022: CONSIDERATION AND ADOPTION OF THE PROPOSED SCHEDULE FOR STAKEHOLDER ENGAGEMENT ON THE KEMSA (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021) The Committee considered and adopted the proposed schedule for stakeholder engagement on the KEMSA Amendment Bill, 2021 as follows:

No.	ACTIVITY	DESCRIPTION TIMELINES
1.	Advertisement for submission of written memoranda	<p>1. Publish on re-advertisement on:</p> <p>a) two newspapers with national distribution</p> <p>b) Parliament website</p> <p>c) Parliament social media pages</p> <p>d) Social media</p> <p>a) Newspaper Adverts</p> <p>- Date of publication: Monday, 8th November, 2021.</p> <p>- Deadline for submission of memoranda: Friday, 19th November, 2021.</p>

A. Structured Stakeholder Engagement on the KEMSA (Amendment) Bill, 2021

● Ministry of Health Thursday, 3rd February,

3. Government

Agencies and Departments

Council of Governors

Nairobi Metropolitan Services

Kenya Medical Supplies Authority (KEMSA) 2022

		Pharmacy and Poisons Board (PPB)
2.	<i>Private Sector</i>	<p>Mission for the Essential Drugs and Supplies (MEDS) Wednesday, 2nd February, 2022</p> <p>Kenya Healthcare Federation (KHF)</p> <p>Kenya Association of Manufacturers (KAM)</p> <p>Kenya Association of Pharmaceutical Industry (KAPI)</p> <p>Federation of Kenya Pharmaceutical Manufacturers (FKPM)</p>
3.	<i>Civil Society Groups/NGOs</i>	<p>Pharmaceutical Society of Kenya (PSK)</p> <p>KELIN Friday, 4th February, 2022 HENNET</p> <p>KENCO</p> <p>NCD Alliance of Kenya</p>
B. Internal		

9.	Consideration and adoption of:	The KEMSA Amendment) 10 th to 13 th February, 2020 Bill: a) The Committee Report on Public Participation
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		b) Committee Stage Amendments
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11. **Tabling of Reports** a) KEMSA Participation
(Amendment) Bill, - Committee Stage
2021 Amendments
- The Committee Tuesday, 16th February, 2022
Report on Public

On the proposed report writing retreat on the KEMS Bill, the Committee was informed that the domestic budget had been exhausted. Following deliberations, in consideration of the crucial mandate of the committee, the Chairperson undertook to seek supplementary funding through the Offices of the Speaker and Clerk of the Senate.

MIN.NO.SCH/05/02/2022: PROPOSED BENCHMARKING VISIT TO RWANDA

The Committee deliberated on a proposed benchmarking visit to Rwanda on Health Financing Models for UHC as resolved at its joint retreat with NHIF that was held in November, 2022. Following deliberations, the Committee resolved to conduct the visit in the second half of February, 2022 for a tentative period of ten days. The secretariat was tasked with following up on the issue with NHIF and reporting to the Committee at the next meeting.

MIN. NO. SCH/06/02/2022: ANY OTHER BUSINESS

The Committee resolved to schedule its meetings every Tuesday and Thursday at 9.00 am, and to hold two meetings on each day.

Further, the secretariat was requested to come up with a schedule for conducting County visits as we await the domestic travel budget.

MIN. NO. SCH/06/02/2022: ADJOURNMENT

There being no other business, the meeting was adjourned at 9:49 a.m.



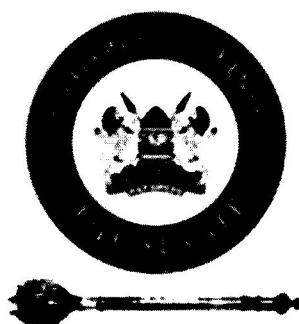
SIGNED:

(CHAIRPERSON)

09/02/22

DATE:

TWELFTH PARLIAMENT | SIXTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON WEDNESDAY, 2nd FEBRUARY, 2022, AT 9:00 A.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

1. Sen. Mary Seneta, MP - Vice-Chairperson
2. Sen. Beth Mugo, EGH, M
3. Sen. (Prof) Samson Ongeru, EGH, MP
4. Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
5. Sen. Millicent Omanga, MP
6. Sen. Fred Outa, MP
7. Sen. Ledama Olekina, MP
8. Sen. Beatrice Kwamboka, MP
9. Sen. Naomi Shiyonga, MP

APOLOGY

1. Sen. Michael Mbitu, MP - Chairperson

SECRETARIAT

1. Dr. Christine Sagini - Senior Clerk Assistant
2. Ms. Caroline Njue - Clerk Assistant
3. Mr. Malcolm Ngugi - Legal Counsel
4. Mr. Robert Rop - Audio Officer
5. Mr. Frank Mutulu - Media Relations Officer
6. Mr. Hussein Salat - Fiscal Analyst

IN ATTENDANCE

MISSION FOR THE ESSENTIAL DRUGS AND SUPPLIES (MEDS) 1.

Mr. Wycliffe Nandama - Chief Executive Officer

KENYA HEALTHCARE FEDERATION

1. Dr. Anastasia Nyalita - Chief Executive Officer
2. Dr. Kanyenje Gakombe - Chairperson
3. Mr. Patrick Wandere - Legal Representative

KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY (KAPI)

1. Dr. Winnie Mwangi - Chairperson
2. Evah Amwayi - Executive Secretary
3. Ms. Ann Dembah - Board Member
4. Dr. Esther Anyango - Administrative Manager

FEDERATION OF KENYA PHARMACEUTICAL MANUFACTURERS (FKPM)

1. Dr. Rohin Vora - Chairman
2. Dr. Simon Muigai - Chairman of technical committee
3. Ms. Loise Wanja - Executive Officer
4. Mr. Mwai Ngubuini - Member

PHARMACEUTICAL SOCIETY OF KENYA

1. Dr. Lucas Nyabero - Chief Executive Officer
2. Dr. Angelina Achoka - National Treasurer

MIN. NO. SCH/07/02/2022: PRELIMINARIES

The Chairperson called the meeting to order at 9.20 a.m. and the meeting commenced with a word of prayer.

MIN. NO. SCH/08/02/2022: ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by **Sen. Millicent Omanga, MP** and seconded by **Sen. Beatrice Kwamboka, MP**: -

1. Preliminaries

a. Prayer

b. Adoption of the Agenda

2. Submission of memoranda on the Kenya Medical Supplies Authority (KEMSA) Amendment Bill, 2021, by key stakeholders in the private sector:

- *Mission for Essential Drugs and Supplies (MEDS);*
- *Kenya Healthcare Federation (KHF);*
- *Kenya Association of Manufacturers (KAM);*
- *Kenya Association of Pharmaceutical Industries (KAPI);*
- *Federation of Kenya Pharmaceutical Manufacturers (FKPM); and -
Pharmaceutical Society of Kenya (PSK).*

3. Any other business

4. Date of the Next Meeting.

5. Adjournment.

MIN. NO. SCH/08/02/2022 CONFIRMATION OF MINUTES OF THE PREVIOUS SITTINGS

The Committee deferred the confirmation of minutes to a later date.

MIN.NO.SCH/09/02/2022: RECEIVING OF MEMORANDA FROM THE PRIVATE SECTOR ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021

The Committee received Stakeholder Submissions in the following order: 1. Mr. Wycliffe Nandama, Representative of the Mission for the Essential Drugs and Supplies (MEDS);

2. Dr. Anastasia Nyalita, Dr. Kanyenje Gakombe and Mr. Patrick Wandere, Representatives of the Kenya Healthcare Federation (KHF);

3. Dr. Winnie Mwangi, Dr. Evah Amwayi, Ms. Ann Dembah and Dr. Esther Anyango, Representatives of the Kenya Association of Pharmaceutical Industry (KAPI);

4. Dr. Rohin Vora, Dr. Simon Muigai, Ms. Loise Wanja, Mr. Mwai Ngubuini, Representatives of Federation of Kenya Pharmaceutical Manufacturers (FKPM); and

5. Dr. Lucas Nyabero and Dr. Angelina Achoka, Representatives of Pharmaceutical Society of Kenya.


6. The presentations were made in accordance with their written submissions, which they presented word for word. For more information, the matrix of public submissions on the Bill are annexed to these minutes.

MIN. NO. SCH/10/02/2022: ANY OTHER BUSINESS

1. The committee was advised that the balance for domestic travel was about Ksh. 1,000,000.
2. For purposes of the planned KEMSA Amendment Bill, 2021 Report-writing Retreat, in light of limited resources, the secretariat advised the Committee to consider retreating in a County that allowed for road travel. Options provided included Machakos, Kiambu and Naivasha. There being no quorum, the matter was deferred to the next meeting.

MIN. NO. SCH/11/02/2022: ADJOURNMENT

There being no other business, the meeting was adjourned at 10:28 a.m.

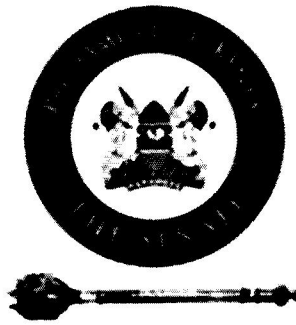


SIGNED:
(CHAIRPERSON)

09/02/22

DATE:

TWELFTH PARLIAMENT | SIXTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON THURSDAY, 3RD FEBRUARY, 2022, AT 9:00 A.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

1. Sen. Michael Mbiti, MP - Chairperson
2. Sen. Mary Seneta, MP - Vice-Chairperson
3. Sen. (Prof) Samson Ongeru, EGH, MP
4. Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
5. Sen. Millicent Omanga, MP
6. Sen. Fred Outa, MP
7. Sen. Ledama Olekina, MP
8. Sen. Beatrice Kwamboka, MP
9. Sen. Naomi Shiyonga, MP

APOLOGY

1. Sen. Beth Mugo, EGH, MP

SECRETARIAT

1. Ms. Mary Chesire - Deputy Director
2. Dr. Christine Sagini - Senior Clerk Assistant
3. Ms. Caroline Njue - Clerk Assistant
4. Mr. Mitchell Otoro - Legal Counsel
5. Mr. Robert Rop - Audio Officer
6. Mr. Frank Mutulu - Media Relations Officer
7. Mr. Hussein Salat - Fiscal Analyst

8. Ms. Angela Gumato - Legal Pupil
9. Mr. Daniel Onyango - Legal Pupil
10. Mr. Titus Michubu - Legal Pupil
11. Ndindi Kibathi - Legal Pupil

IN ATTENDANCE

MINISTRY OF HEALTH (MOH)

1. Ms. Susan Mochache - Principal Secretary
2. Mr. Benard Kuria - State Council
3. Mr. Fred Omiah - Parliamentary Business

KENYA MEDICAL SUPPLIES AUTHORITY (KEMSA)

1. Dr. John Kabuchi - Ag. Chief Executive Officer
2. Mr. Frederick Wanyonyi - Director Legal Services
3. Ms. Beatrice Kariuki - Legal Officer

PHARMACY AND POISONS BOARD (PPB)

1. Dr. Fred Siyoi - Chief Executive Officer
2. Dr. Jacinta Wasike -
3. Dr. Dominic Kariuki - Head of Inspectorate

MIN. NO. SCH/12/02/2022: PRELIMINARIES

The Chairperson called the meeting to order at 9.20 a.m. and the meeting commenced with a word of prayer.

MIN. NO. SCH/13/02/2022: ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by **Sen. Mary Seneta, MP** and seconded by **Sen. Millicent Omanga, MP**: -

1. Preliminaries
 - a. *Prayer*
 - b. *Adoption of the Agenda*
2. ***Submission of memoranda on the Kenya Medical Supplies Authority (KEMSA) Amendment Bill, 2021, by key stakeholders in the Government:***
- Ministry of Health (MOH)

MIN. NO. SCH/20/02/2022: CONFIRMATION OF MINUTES OF THE PREVIOUS SITTINGS

The Committee deferred the confirmation of minutes to a later date.

MIN.NO.SCH/21/02/2022: RECEIVING OF MEMORANDA FROM THE CIVIL SOCIETIES ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021

The Committee received Stakeholder Submissions in the following order:

1. Mr. Timothy Wafula and Mr. Allan Maleche, Representatives of the Kenya Legal & Ethics Issues Network on HIV and AIDS (KELIN);
2. Mr. Gideon Ayodo and Mr. Harrison Andeko, Representatives of the Non-Communicable Diseases Alliance Kenya (NCDAK);
3. Ms. Catherine Wachira and Mr. Charles Muya, Representatives of the Kenyan Network for Cancer Organizations (KENCO).

The presentations were made in accordance with their written submissions, which they presented word for word. For more information, the matrix of public submissions on the Bill are annexed to these minutes.

MIN. NO. SCH/22/02/2022: ANY OTHER BUSINESS

1. The committee was informed that there would be a Housekeeping Meeting on Tuesday 8th February, 2022 to confirm minutes as well as to consider and adopt the Committee Feb/Mar 2022 Work Plan.
2. The Committee was notified of an invitation by MOH to attend a follow up meeting on the Mental Health Bill at Radisson Blu Hotel.

MIN. NO. SCH/23/02/2022: ADJOURNMENT

There being no other business, the meeting was adjourned at 10:08 a.m.

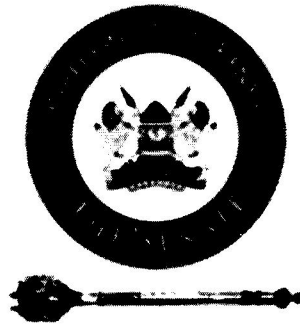


SIGNED:
(CHAIRPERSON)

09/02/22

DATE:

TWELFTH PARLIAMENT | SIXTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON WEDNESDAY, 9TH FEBRUARY, 2022, AT 9:00 A.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

1. Sen. Michael Mbiti, MP - Chairperson
2. Sen. Mary Seneta, MP - Vice-Chairperson
3. Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
4. Sen. Beatrice Kwamboka, MP
5. Sen. Fred Outa, MP

APOLOGY

1. Sen. Ledama Olekina, MP
2. Sen. Beth Mugo, EGH, MP
3. Sen. (Prof) Samson Ongeru, EGH, MP
4. Sen. Millicent Omanga, MP

SECRETARIAT

1. Dr. Christine Sagini - Senior Clerk Assistant
2. Ms. Caroline Njue - Clerk Assistant
3. Ms. Sombe Toona - Legal Counsel
4. Mr. Robert Rop - Audio Officer
5. Mr. Hussein Salat - Fiscal Analyst
6. Mr. Frank Mutulu - Media Relations Officer

MIN. NO. SCH/24/02/2022: PRELIMINARIES

The Chairperson called the meeting to order at 9.20 a.m. and the meeting commenced with a word of prayer.

MIN. NO. SCH/25/02/2022: ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by **Sen. (Dr.) Abdullahi Ali, MP** and seconded by **Sen. Mary Seneta, MP**: -

1. Preliminaries

a. Prayer

b. Adoption of the Agenda

2. *Confirmation of minutes for the sittings held on:*

• *Tuesday 1st February, 2022*

• *Wednesday 2nd February, 2022*

• *Thursday 3rd February, 2022*

• *Friday 4th February, 2022*

3. *Consideration and adoption of the proposed committee schedule for the quarter*

4. Any other business.

5. Date of the Next Meeting

6. Adjournment.

MIN. NO. SCH/26/02/2022 : CONFIRMATION OF MINUTES OF THE PREVIOUS SITTINGS

The Minutes of the Sitting held on Tuesday, 1st February, 2022 were confirmed as a true record having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP.

The Minutes of the Sitting held on Wednesday, 2nd February, 2022 were confirmed as a true record having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP.

The Minutes of the Sitting held on Thursday, 3rd February, 2022 were confirmed as a true record having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP.

The Minutes of the Sitting held on Thursday, 3rd February, 2022 were confirmed as a true record having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP.

The Minutes of the Sitting held on Friday, 4th February, 2022 were confirmed as a true record having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP.

MIN. NO. SCH/27/02/2022: CONSIDERATION AND ADOPTION OF THE PROPOSED COMMITTEE SCHEDULE FOR FEB/MARCH

**PROPOSED COMMITTEE SCHEDULE
FEBRUARY/MARCH 2022**

Proposed key focus areas:

1. Pending legislative business as follows:
 - a) Pending Bills
 - b) Pending Statements
 - c) Pending Petitions
2. County visits
3. Capacity-building and training

No.	ion Sponsor / Petition	Date Tabled / Appro ved	Proposed Stakehol ders Proposed Date	Time Remarks
		the review and harmonization of the curriculum and training of health professionals conference (Mombasa) – Ongoing	KMPDC – Various 7 th to 9 th , February, 2022	
	Hybrid conference on MOH/		UHC Scale-up MOH – Monday, 7/2/2022 – Concluded	
	Official Launch of the National Confirmation of minutes & adoption of proposed work plan.	Health Amendment Bill, 2020. (Radisson Blu Hotel, Nairobi)	SCH -- -- Wednesday, 8/02/2022	MOH – MOH Thursday, 9/2/2022 9.00 am 8.00 am
	Follow up consultative meeting on the Mental			

Thursday, 10th to Monday, 14th February, 2022 - Proposed Committee Retreat to consider and adopt the report and Committee Stage Amendments on the KEMSA (Amendment) Bill, 2021

Site visit to the public health clinic	situated in Parklands, Nairobi city County on	LR. No. 209/19441 Sen.	Omanga , MP of Lands - NCC - Tuesday,	15/2/2022 9.00 am
Pending Statements and Petitions in relation to MOH as follows:	healthcare centers in Kajiado County funded by the African Development Bank (ADB) through the Ministry of Health by Sen. Mary	Seneta, MP. b) Statement regarding the delay in appointment of a substantive Director-General in the Ministry of Health by Sen.	Samson Various Divers e dates MOH Thursday, 17/02/2022 9.00 am	
a) Construction of	Cherarkey, MP.			
c) Operationalisation of the Counselors and Psychologists Act, 2014, by Sen. Isaac Mwaura, MP.				
d) Investing in mental health care post-COVID-19 pandemic by Sen. (Dr.) Michael Mbiti, MP.				
e) Mental health in Kenya in view of cessation of movement and curfew currently obtaining in the country by Sen. (Arch) Sylvia Kasanga, MP.				
f) State of health care services to cancer patients in public health facilities in Counties by Sen. Getrude	Musuruve, MP.			
g) Efficacy of COVID				

– 19 vaccines by
Sen. Petronilla
Were, MP.

- h) Third wave of the
COVID-19
pandemic and the
COVID-19
Vaccine by Sen.
George Khaniri,
MP.
- i) Petition by Ms.
Mario Juma and
others on the
challenges faced
by patients
suffering from
Multiple Sclerosis
(MS) and
Neuromyelitis
Optica (NMO).
- j) Petition raised by
Mr. Daniel Ngumi
and others in the
petition on NHIF
cover for kidney
post-transplant
medication.
- k) Petition by Mr.
Mikeson Mugo
and other patients
living with
Autoimmune
Diseases
concerning
payment of
medical and
healthcare costs
and provision of
health cover for
persons living with
Autoimmune
Diseases by the
National Hospital
Insurance Fund.

1) Status update on the implementation of NHIF benefit packages for indigents across the country 209/19441 9.00 am 9.00
by county.

Statement State of
regarding the healthcare in
status of a public health Sen.
public health facilities in Enoch
clinic situated Kitui County Wambua ,
in MP
Parklands, 9/11/20 21
Nairobi city
County on Sen.
LR. No. Omanga , MP

- NCC - Tuesday,
NMS - Min. 22/2/2022
of
Lands
- Devel opers
- ????

am
Kitui
County
Executive Thursday,
24/2/2022

Sunday, 27th February, 2022 to 9th March, 2022- Proposed visit to Rwanda with NHIF to benchmark on Health Financing Models

17th to 21st March, 2022 - Committee Retreat for the consideration and adoption of Petition Reports.

Proposed venue: Nairobi, Kiambu, Machakos or Naivasha.

(Dates to be determined)- Proposed County visits (based on previously approved schedules by the Committee):

- a) Option 1:*** Narok, Bomet, Kericho; or
- b) Option 2:*** Uasin Gishu, Nandi, Trans Nzoia, Elgeyo Marakwet and West Pokot; or
- c) Option 3:*** Wajir, Marsabit and Isiolo; or
- d) Option 4:*** Kwale, Kilifi and Lamu

MIN. NO. SCH/28/02/2022: MATTERS ARISING

Under MIN. NO. SCH/26/02/2022, the committee was informed that the pending petitions and statements in relation to MOH would be considered on Thursday 17th February by the Cabinet Secretary.

On the County E-Health System Bill and the Maternal, Newborn and Child Health Bill, the legal counsel reported that the advert did not receive any responses and the committee resolved that the legal counsel should go with the targeted approach on the interested parties to get submissions on the same.

The report writing retreat on the KEMSA Amendment Bill was rescheduled to be discussed on Tuesday 15th February, 2022.

On the Rwanda visit, the committee was informed that a resolution was received from NHIF and the dates would be ten (10) days from 27th February-9th February, 2022.

The chairperson proposed that the members should visit Sen. Beth Mugo to condole with her on the bereavement of her husband. It was resolved that the visit should be on Wednesday 16th February, 2022 in the morning.

MIN. NO. SCH/29/02/2022: ANY OTHER BUSINESS

1. The committee was informed that there would be a Housekeeping Meeting on Tuesday 8th February, 2022 to confirm minutes as well as to consider and adopt the Committee Feb/Mar 2022 Work Plan.
2. The Committee was notified of an invitation by MOH to attend a follow up meeting on the Mental Health Bill at Radisson Blu Hotel.

MIN. NO. SCH/30/02/2022: ADJOURNMENT

There being no other business, the meeting was adjourned at 9:52 a.m.



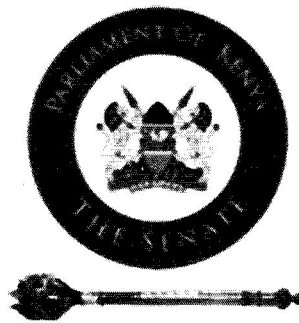
SIGNED:

(CHAIRPERSON)

17/3/2022

DATE:

TWELFTH PARLIAMENT | SIXTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON THURSDAY, 24TH MARCH, 2022 AT 11:00 A.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

- 1) Sen. (Dr.) Michael Mbito, MP - Chairperson
- 2) Sen. Mary Seneta, MP - Vice Chairperson
- 3) Sen. Beth Mugo, EGH, MP
- 4) Sen. Ledama Olekina, MP
- 5) Sen. (Prof) Samson Ongeru, EGH, MP

SECRETARIAT

- 1) Dr. Christine Sagini - Clerk Assistant
- 2) Ms. Caroline Njue - Clerk Assistant
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Frank Mutulu - Media Relations Officer
- 5) Mr. Robert Rop - Audio

MIN. NO. SCH/86/11/2021: PRELIMINARIES

The Meeting commenced at 11:15 a.m. with a word of prayer from the Chairperson.

MIN. NO. SCH/87/2021; ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by Sen. Beth Mugo, EGH, MP and seconded by Sen. Mary Seneta, MP: -

1. Preliminaries

- a) *Prayer*
- b) *Adoption of Agenda*

2. *Adoption of Committee Stage Amendments.*
3. *Adoption of the Committee Report on the KEMSA (Amendment) Bill, 2021, Report.*
4. Any other business
5. Date of Next Meeting
6. Adjournment

MIN. NO. SCH/82/11/2021: CONSIDERATION AND ADOPTION OF COMMITTEE STAGE AMENDMENTS ON THE KEMSA (AMENDMENT) BILL, 2021

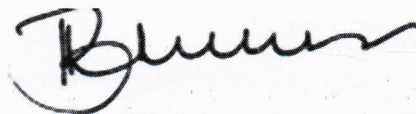
The Committee considered and adopted the Committee Stage Amendments on the KEMSA (Amendment) Bill, 2021, having been proposed by Sen. Ledama Olekina, MP, and seconded by Sen. (Prof) Samson Ongeru, EGH, MP.

MIN. NO. SCH/83/11/2021: CONSIDERATION AND ADOPTION OF THE COMMITTEE REPORT ON THE KEMSA (AMENDMENT) BILL, 2021

The Committee considered and adopted the Committee Report on the NHIF(Amendment) Bill, 2021, having been proposed by Sen. Mary Seneta, MP, and seconded by Sen. Beth Mugo, EGH, MP.

MIN. NO. SCH/84/11/2021: ADJOURNMENT

There being no other business the meeting was adjourned at 12.00 p.m



SIGNED:

(CHAIRPERSON)

DATE:24/4/2022.....



4th February, 2022

To the Chairperson,

The Senate Committee on Health,

Nairobi, Kenya.

Dear Sen Dr. Ali Abdullahi Ibrahim,

RE: KAPI POSITION ON THE KEMSA AMENDMENT BILL 2021

Kenya Association of Pharmaceutical Industry (KAPI) is a membership organization established in the late 1960's, representing biopharmaceutical manufacturers (or their local representatives) that through research invent and develop medicines and technologies (e.g., Biopharmaceuticals, Vaccine Healthcare, Medical devices & Diagnostics) that significantly improve people's lives. KAPI represents the industry voice and promotes efficiency in the pharmaceutical industry to ensure that medical products and healthcare technologies of the highest quality can be readily available for diagnosis, prevention and treatment of diseases. Kenya Association of Pharmaceutical Industry (KAPI) is anchored on our commitment to improve access to safe, quality and affordable medicines for the Kenyan people.

Following the Stakeholders' Consultative Meeting which was held on the 2nd of February, 2022 to discuss the amendments made to the KEMSA BILL 2021, KAPI, having reviewed the document, would like to register its support to the proposed amendments. We believe that the proposed changes will provide public facilities with the freedom to source health products competitively and allow KEMSA to focus on essential supplies and emergency supplies.

We believe that some of the advantages of the proposed amendments are as follows:

1. The amendments address the risks that come with a monopoly market such as: Non-competitive pricing, and Supply disruptions
2. Increased diversity
3. Promotion of Private Public Partnerships that will promote achievement of UHC

As the representative of the biopharmaceutical manufacturers in Kenya, and their local representatives, that through research invent and develop medicines and technologies, KAPI would like to table the following proposals to the existing challenges at KEMSA:

1. We suggest that treasury re-direct some funds to help pay off the current KEMSA debt of about KShs. 6 Billion.
2. Since counties have already been financed by the Central Government to fund health, a more stern approach to collection needs to be applied.

Chairperson:	Winnie Ng'ang'a	Tel: +254 721 606 733	Email: winnie.w.nganga@gsk.com
Vice-Chairperson:	Vinod Guptan	Tel: +254 722 795 021	Email: guptanvinod@gmail.com
Secretary:	Evah Amwayi	Tel: +254 727 221 260	Email: evah.n.amwayi@gsk.com
Treasurer:	David Odhiambo	Tel: +254 711 592 940	Email: david.odhiambo@novartis.com



3. There is a need to ensure that solid standard operating procurement procedures are in place to control the process with:
 - a. Pre-approved accreditation of suppliers,
 - b. Pooled procurement to consolidate volumes.
4. Health Tech Assessment (HTAs) tools should be adopted to leverage on evidence based policy making on procurement. These tools will assist in creating systems that are clear and legally binding between all the parties involved.
5. Strengthening the regulation and enforcement agency such as PPB to ensure that the quality efficacy and safety remains uncompromised.
6. KEMSA should consider awarding tender products at competitive market rates rather than considering some the new entities that get awarded based on completeness of their documents.
7. Supply chain/suppliers will provide better than the current 20% fill rate at KEMSA. Suppliers will continue supplies and avoid stock-outs at the government hospitals and hence better patient outcomes.

Your consideration of this matter will be highly appreciated.

Yours faithfully,

Dr Winnie Ng'ang'a
KAPI Chairperson



Your Ref: SEN/DCO/CORR/SCH/009/01/2022(1)

31st January 2022

Our Ref: KAM/10/27/mb/jw/PW/2022

**J.M Nyegenye, CBS
Clerk of The Senate,
Clerk's Chambers,
Parliament Buildings,
P.O Box 41842 - 00100
NAIROBI.**

Dear Mr. Nyegenye,

RE: REQUEST FOR EXTENSION OF TIME FOR KAM SUBMISSIONS ON THE KENYA MEDICAL SUPPLIES (AMENDMENT) BILL, 2021

Kenya Association of Manufacturers (KAM) presents her compliments on behalf of its members and appreciates your continued support.

KAM is a business membership organization, in the value-add industry. Our membership comprises of industries in manufacturing and value add in manufacturing sector, with our members operating not only in Kenya, but also in the EAC Region.

We are in receipt of your letter with thanks (Ref: SEN/DCO/CORR/SCH/009/01/2022(1)) dated 27th January 2022 to formally make our submissions on the Kenya Medical Supplies (Amendment) Bill 2021. The submission date is indicated as Wednesday, 2nd February 2022 at 9.00 am. We wish to request for an extension of one week from the indicated submission date to Wednesday 9th February 2022 at 9.00 am. This will allow us sufficient time to gather and consolidate our members' views.

This purpose of this letter is to therefore request for an extension of one week to Wednesday, 2nd February 2022 at 9.00 am for our formal submissions on the Kenya Medical Supplies (Amendment) Bill 2021.

We look forward to your favorable response and consideration, advance feedback can be sent through ceo@kam.co.ke or call +254 20 2324817/8.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Phyllis Wakiaga'.

**Phyllis Wakiaga
CHIEF EXECUTIVE**



FEDERATION OF KENYA PHARMACEUTICAL MANUFACTURERS

P.O. Box 53362-00200 NAIROBI. KENYA

Panesar Center, Mombasa Road after Airtel, Opposite Auto Express, 2nd Floor room 206

Tel: +254 723916980

E-mail: info@fkpm.co.ke/fkpm.ke@gmail.com Website www.fkpm.co.ke

2nd February 2022

**FEDERATION OF KENYA PHARMACEUTICAL (FKPM) SUBMISSION ON THE KENYA MEDICAL SUPPLIES
AUTHORITY (KEMSA) AMMENDMENT BILL (SENATE BILLS NO. 53 OF 2021)**

1. First, we need to understand why the responsibility to procure medicines is being given to the counties. The root cause of deficit of drugs and medical supplies has to be established first before the responsibility is shifted otherwise the actual problem is not sorted.
2. What is the guarantee that once counties have the responsibility to procure medicines there will be no shortage? There is a risk for both stock outs and expiries as forecasting is not coordinated between counties, thus both wastage and insufficiency.
3. As per section 4 (3) (b), the authority i.e. KEMSA ensures that the drugs and medical supplies meet the standards of quality and are efficacious as authorized by the Board. How will the quality of drugs and medicines supplies be assured when procured by the county governments? (Counties may not have the infrastructure to sufficiently verify the quality of the products).
4. The following factors have to be taken into consideration before counties are given the authorization to procure medicine.
 - Whether the Drugs have been manufactured in compliance with cGMP as per WHO standards.
 - Who will carry out tests to ensure the product quality since KEMSA carry out QC Tests?
 - Who will be checking for substandard and counterfeit products being supplied in every county?
5. Decentralisation of the supply chain will throw into question implementation of national health programmes such as those of HIV/AIDS, Tuberculosis, vaccine programs etc.
6. Removal of subsection 4- then what is the penalty for non-compliance.
7. Safeguards for quality, safety and efficacy are being removed since counties do not have the capacity to ensure these.

Sec. 4.3.a requires that medicines procured, be registered by Pharmacy & Poisons Board (PPB) and is critical in safeguarding public health. It should therefore NOT be deleted. There will be high chances of a breach in supply chain integrity since counties have no supply chain QA systems.

8. Overall cost of procurement will increase if there is no centralized procurement. Economies of scale achieved by KEMSA will be reduced drastically. Duplication of existing KEMSA distribution infrastructure by the counties will also lead to additional costs. Result will be higher cost of healthcare.
9. Ability of KEMSA to perform functions 4(1)c,d,e of the Act will be adversely affected if the counties are not obliged by law to procure from KEMSA.
10. Few distributors or manufacturers have the nationwide reach that KEMSA has in terms of logistics. KEMSA might be left with only the difficult to reach facilities where other players are not willing to deliver, further lowering the incentives to ensure access to medicines.

Through KEMSA patients are able to access affordable and quality health products, this is largely due to a centralised procurement system. Within the system there is an efficient bidding process which ensures quality healthcare products are available to government healthcare centers at affordable prices, in addition this is central to achieving UFC.

FKPM believes that decentralising the procurement process will lead to negative impact on the patient due to the points mentioned above:

It is therefore our belief that KEMSA should be allowed to remain as the central procuring center and we would also support initiatives that would lead to systematic improvement to the institution.



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

**SUBMISSIONS TO THE SENATE DEPARTMENTAL COMMITTEE ON
HEALTH ON KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT)
BILL (SENATE BILLS NO. 53 OF 2021)**

We refer to your letter dated 27th January, 2022 addressed to us under reference SEN/DCO/CORR/SCH/001/01/2022(1).

The Pharmacy and Poisons Board (“the Board”) has taken note of the proposal by the Senate to allow the county governments to procure medical products from other distributors in addition to Kenya Medical Supplies Authority (KEMSA) and the request for submissions. The Board thus wishes to respond as below:

1. The Board is the national regulatory authority established under the Pharmacy and Poisons Act (Cap 244) to regulate the profession of pharmacy and ensure access to medical products and health technologies that conform to prescribed standards of safety, quality and efficacy.
2. Currently, in facilitating access by the public to medical products that are of good quality, safety and efficacy, the Board has granted KEMSA access to its register of medical products and technologies. This facilitates the procurement of only authorized medical products.
3. It is therefore our proposal to the Committee that in considering this amendment Bill, to ensure the protection of the “*Wanjiku*” by mandating:
 - a. the procurement of only medical products registered or approved for use by the Board. This will ensure enforcement of the prescribed standards of quality, safety and efficacy of all medical products manufactured, imported into or exported out of the country in line with the Pharmacy and Poisons Act;
 - b. Procurement from only authorized sellers of medical products licensed by the Board under the Pharmacy and Poisons Act. This will

ensure that the personnel, premises and practices employed in the storage, marketing, distribution and sale of medical products comply with the defined codes of practice and other prescribed requirements.

Prepared By:



Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER

The Chairperson,
Senate Standing Committee on Health,
The Senate,
Parliament Buildings,
P. O. Box 41842 –00100,
Nairobi, Kenya

**RE: KELIN SUBMISSIONS TO THE SENATE STANDING COMMITTEE
ON HEALTH ON THE KENYA MEDICAL SUPPLIES AUTHORITY
(AMENDMENT) BILL (SENATE BILLS NO. 53 OF 2021)**

KELIN makes these submissions pursuant to your invitation dated 27th January 2022 *Re: Stakeholder Engagement on the Kenya Medical Supplies Authority (Amendment) Bill (Senate Bills No. 53 Of 2021) (Ref: SEN/DCO/CORR/SCH/013/01/2022 (1))*.

The Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) is an organization that advocates for a holistic and rights-based system of service delivery in health and for the full enjoyment of the right to health by all, including the vulnerable, marginalized and excluded populations.

We make these submissions in support of the Kenya Medical Supplies Authority (Amendment) Bill, specifically that Section 4(3) and 4(4) of the Kenya Medical Supplies Authority Act, 2013 be deleted.

Our support of this amendment is based on the following reasons:

1. As a matter of context:

(i) First, Article 43(1)(a) guarantees every person the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. Therefore, availability, accessibility, acceptability and quality of health services, including medical supplies, are some of the core components to realise this right.

(ii) Second, noting that health is a devolved function, county governments are as per the Fourth Schedule to the Constitution responsible for the bulk of county health services, including county health facilities and pharmacies; ambulance services; promotion of primary health care; among others. Section 20 of the Health Act, 2017 further unpacks this function to include that counties are responsible for procuring and managing health supplies.

2. Sections 4(3) and 4(4) of the KEMSA Act 2013 limits the ability of counties to procure and manage health supplies from any other entity other than KEMSA, and makes it a criminal offence to do so.

3. The challenge with this is that in instances where KEMSA is facing stock outs, or is unable to discharge its functions fully, the law limits the ability of counties to source the supplies from elsewhere. County health facilities then experience stock outs of medical supplies.

4. We appreciate the thinking behind having KEMSA as the main agency for procurement and distribution of drugs and medical supplies to county government, especially when it was working well due to positive reforms. However, when it is not working a challenge is created. As such, the amendment gives a chance for counties to seek supplies elsewhere.
5. When this happens, and it has happened numerous times, it is the *common mwananchi* that suffers. People, especially vulnerable and marginalized communities, are denied their right to health – which leads to serious illness and deaths that could have been avoided.
6. An example: early last year, when KEMSA faced allegations of corruption and mismanagement of COVID-19 funds, USAID decided not to use the state corporation for distribution of HIV commodities. This led to a stalemate that threatened the lives of over 1.3 million people living with HIV.

For the entire year, Kenya faced chronic shortage of very important HIV-related commodities including but not limited to ARVs, viral load testing reagents, HIV test kits, including for early infant diagnostics (EID), shortage of condoms, laboratory and diagnostic supplies, among others.

Facilities had no ARVs, and those with limited stocks started dispensing the ARVs for shorter durations (down from 3 months, to one month, to two weeks).

Shorter durations mean extra burden of extra regular visits to health facilities (extra burden of travelling and searching for health facilities with stocks; risk of crowding health facilities in wake of increased COVID-19 infections).

Lack of access to the commodities also meant that the standard of care for people living with HIV was compromised since important monitoring tests including the viral load was not being done contrary to the set Ministry of Health Guidelines on HIV care and management.

We also saw instances where people living with HIV were provided with drugs on the verge of expiry, phased out drugs and unlabelled plastic bags which is purely against the requisite consumer quality assurance standards.¹

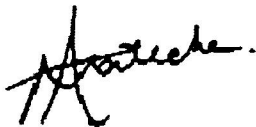
Children born of HIV positive mothers failed to get timely diagnosis and prophylaxis to prevent HIV infection and/or even get life-saving medication for HIV.

Expectant mothers living with HIV in Kenya faced the risk of giving birth to HIV positive babies because of missed HIV testing and/or prophylaxis during the much-needed ante-natal care.

¹ See Angela Oketch "Health ministry probes toxic ARVs released by Kemsas to Kenyans," <https://nairobineews.nation.co.ke/health-ministry-probes-toxic-arvs-released-by-kemsas-to-kenyans/>

7. As the stalemate persisted, counties could not procure from elsewhere with the ripple effect experienced by over 1.3 million people living with HIV across the country.
8. It is therefore our submission that the law should allow counties to procure medical supplies from other entities. This would enable them take full responsibility for provision of health services at the county level – without the troubles of KEMSA creating a barrier to access. This will also prevent instances where county governments use KEMSA as a scape goat anytime they experience stock out of commodities (even in instances where the blame would right fall back to the said county governments)
9. In conclusion, the Ministry of Health through the Pharmacy and Poisons Board should ensure strict implementation of the existing regulations, standards and guidelines to ensure the quality of medical supplies procured from other sources meets the threshold and does not endanger the lives of people

Yours faithfully,



Allan Maleche

Executive Director

Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)

Karen C, Kuwinda Lane, Off Langata Road.

P O Box 112 - 00202 KNH Nrb,



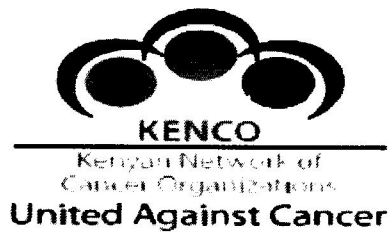
Reclaiming Rights, Rebuilding Lives
Tel: 020, 2515790 | Mobile: +254708389870

E-mail: amaleche@kelinkenya.org

Website: www.kelinkenya.org

Enclosed:

- (a) National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK) Letter to Cabinet Secretary for Health dated 5th May 2021
- (b) Communities of people living with HIV and CSOs Petition to the National Assembly 8th November 2021
- (c) Communities of people living with HIV and CSOs appeal to President Uhuru Kenyatta dated 9th November 2021



3RD FEBRUARY 2022.

TO:
THE CHAIRPERSON,
THE SENATE,
STANDING COMMITTEE ON HEALTH.

Dear Sir/Madam,

**SUBMISSION ON THE KENYA MEDICAL SUPPLIES AUTHORITY (KEMSA)
(AMENDMENT) BILL, 2021.**

The Kenyan Network of Cancer Organizations (KENCO) is the national umbrella body of registered cancer civil society organizations with a current membership of over 37 organizations which are active in various aspects of cancer control throughout the country, and committed to a united response against cancer.

We hold cancer matters close to heart given that every hour, six (6) people are diagnosed with cancer in Kenya. The scourge of cancer has impact that transcends beyond spiritual, economic, socio-cultural and political beliefs thus calling for a unified multi-sectoral approach which can only be achieved when different sectors of the society come together, to form a common force in the fight against this disease. Losing one patient every 15 minutes is simply unacceptable and we need to urgently address factors that unfairly stand between Kenyans and cancer prevention, diagnosis and treatment.

This submission is in line with the Senate call requesting for submissions on the above subject which seeks to amend the KEMSA ACT, 2013 by deleting subsection (3) and deleting subsection (4).

We appreciate that Health is a devolved function and county governments are mandated to ensure delivery of health services under the county health system, which includes provision of drugs and medical supplies, but we also recognise that KEMSA is a state corporation with a mandate to fulfil which includes procuring, warehousing and distributing drugs to public health facilities.

SUBMISSION:

We are calling on the Senate to not accept the amendment and instead use the legislative process to oblige all public facilities more so public cancer centres to procure cancer drugs from KEMSA. The benefit of economies of scale through bulk procurement will pass to cancer patients; which will be a relieve bearing in mind that they already have very high out of pocket spending. As a matter of policy then the National Hospital Insurance Fund should only pay for cancer drugs procured through KEMSA for public hospitals.

KEMSA is now stocking some of the cancer medicines. This should be expanded to all anti-cancer medicines based on the National Treatment Guidelines to avoid lack or stock out of drugs.

Kenya has not fully utilized various mechanisms of availing cancer drugs that are still in patent like the Trade Related Intellectual Property Flexibilities (TRIPS). The Pharmacy and Poisons board should activate these mechanisms to ensure Kenyans benefit from quality brands.

We recommend there be chosen an oversight institution to strengthen the systems at KEMSA to ensure clear and accountable procurement processes and regulation of prices for cancer supplies. Regulation of prices of cancer drugs in the private sector should be pegged on the KEMSA prices and monitored by the oversight body.

CONCLUSION:

Allowing counties to separately procure drugs looks like a quick fix-it solution but issues of quality and regulation of pricing will come up and the cancer patient will pay heavily for this. We recommend that the suggested amendments do not take place.

Regards,

CM

Christine Mugo-Sitati,

Executive Director.

Kenyan Network of Cancer Organizations.

Customer	Invoiced Amount	Current 0-30 Days	31-60 Days	61-90 Days
BARINGO COUNTY	48,943,515.39	6,284,194.60	600,520.00	4,858,769.00
BOMET COUNTY	14,420,025.71	19,500.00	22,120.00	0.00
BUNGOMA COUNTY	0.00	0.00	0.00	0.00
BUSIA COUNTY	107,920,366.75	0.00	-5,600.00	0.00
ELGEYO MARAKWET COUNTY	-506,984.01	0.00	0.00	126,400.00
EMBU COUNTY	27,355,928.49	0.00	1,063,000.00	11,861,996.00
GARISSA COUNTY	52,221,546.10	0.00	42,150.00	11,559,789.00
HOMA BAY COUNTY	104,372,357.46	0.00	11,818,692.90	490,970.00
ISIOLO COUNTY	0.38	0.00	0.00	0.00
KAJIADO COUNTY	94,380,936.01	60,995,104.12	26,730.00	870,500.00
KAKAMEGA COUNTY	133,539,174.97	3,747,125.00	64,702,599.80	60,167,896.76
KERICHO COUNTY	40,806,780.12	1,540.00	0.00	40,805,240.12
KIAMBU COUNTY	69,278,944.17	148,490.00	-18.00	4,082,420.00
KILIFI COUNTY	209,218,088.06	0.00	0.00	244,920.00
KIRINYAGA COUNTY	29,911,489.56	0.00	0.00	0.00
KISII COUNTY	11,387,553.82	-176,000.00	11,563,553.82	0.00
KISUMU COUNTY	49,185,227.98	7,747,500.00	0.00	0.00
KITUI COUNTY	90,905,737.94	-50,716.00	0.00	6,078,381.00
KWALE COUNTY	61,551,324.36	800,090.00	423,681.00	58,916,635.65
LAIKIPIA COUNTY	16,391,833.68	0.00	0.00	1,364,885.00
LAMU COUNTY	41,928,140.14	795,363.00	3,119,283.00	32,078,814.16
MACHAKOS COUNTY	86,341,157.22	26,061,360.62	58,434,516.60	1,670,480.00
MAKUENI COUNTY	48,180,678.81	0.00	1,273,960.00	37,969,030.80
MANDERA COUNTY	-7,500.00	0.00	-7,500.00	0.00
MARSABIT COUNTY	63,525,867.21	2,765,700.00	25,103,307.80	2,311,805.00
MERU COUNTY	63,369,564.95	1,039,851.20	1,400,600.00	3,815,316.00
MIGORI COUNTY	61,016,368.03	0.00	17,664,756.20	0.00
MOMBASA COUNTY	14,629,988.16	0.00	0.00	0.00
MURANG'A COUNTY	81,576,878.50	0.00	0.00	0.00
NAIROBI METROPOLITAN SERVICES(NMS)	394,290,036.10	26,406,465.00	137,301,437.34	44,415,195.70
NAKURU COUNTY	1,400,908.91	0.00	0.00	0.00
NANDI COUNTY	84,421,790.86	0.00	0.00	5,229,728.00
NAROK COUNTY	17,605,346.18	0.00	0.00	0.00
NYAMIRA COUNTY	41,123,296.20	6,708,114.00	3,291,526.00	11,619,975.90
NYANDARUA COUNTY	27,027,809.01	5,346,508.00	21,751,251.01	0.00
NYERI COUNTY	49,664,381.70	8,868,910.00	25,711,732.70	15,083,739.00
SAMBURU COUNTY	39,094,296.15	-194,400.00	0.00	3,854,914.00

Customer	Invoiced Amount	Current 0-30 Days	31-60 Days	61-90 Days
SIAYA COUNTY	51,021,885.59	38,065.00	30,000.00	7,264,206.00
TAITA TAVETA COUNTY	70,749,253.67	0.00	0.00	0.00
TANA RIVER COUNTY	445,000.00	445,000.00	0.00	0.00
THARAKA NITHI COUNTY	64,406,584.06	4,701,490.00	3,090,035.00	30,714,006.38
TRANS NZOIA COUNTY	61,842,219.57	0.00	5,398,883.00	41,747,565.78
TURKANA COUNTY	167,476,490.03	59,758,467.56	1,296,000.00	0.00
UASIN GISHU COUNTY	41,985,900.80	41,985,900.80	0.00	0.00
VIHIGA COUNTY	114,434,728.22	0.00	0.00	0.00
WAJIR COUNTY	64,258,426.51	356,015.00	2,384,262.00	0.00
WEST POKOT COUNTY	36,413,022.29	15,360,278.20	0.00	2,628,915.00
Σ	2,949,506,365.81	279,959,916.10	397,501,480.17	441,832,494.25

Customer	91-180 Days	181-270 Days	271-360 Days	Over 360 Days
BARINGO COUNTY	36,046,675.79	1,153,356.00	0.00	0.00
BOMET COUNTY	2,579,290.00	11,799,115.71	0.00	0.00
BUNGOMA COUNTY	0.00	0.00	0.00	0.00
BUSIA COUNTY	4,379,153.00	52,564,806.90	0.00	50,982.00
ELGEYO MARAKWET COUNTY	-633,384.01	0.00	0.00	0.00
EMBU COUNTY	14,430,932.49	0.00	0.00	0.00
GARISSA COUNTY	16,964,693.00	22,580,069.66	1,075,504.44	-660.00
HOMA BAY COUNTY	90,999,027.36	0.00	1,065,764.18	-2,096.98
ISIOLO COUNTY	0.00	0.00	0.00	0.38
KAJIADO COUNTY	16,319,783.00	16,168,818.87	0.00	0.02
KAKAMEGA COUNTY	4,867,479.00	54,186.45	0.00	-112.04
KERICHO COUNTY	0.00	0.00	0.00	0.00
KIAMBU COUNTY	65,048,652.17	0.00	0.00	-600.00
KILIFI COUNTY	146,499,573.56	62,208,514.60	0.00	265,079.9
KIRINYAGA COUNTY	0.00	29,911,489.56	0.00	0.00
KISII COUNTY	0.00	0.00	0.00	0.00
KISUMU COUNTY	0.00	0.00	0.00	41,437.72
KITUI COUNTY	84,878,072.94	0.00	0.00	0.00
KWALE COUNTY	0.00	0.00	1,410,917.70	0.01
LAIKPIA COUNTY	14,885,466.68	141,482.00	0.00	0.00
LAMU COUNTY	252,090.00	4,962,754.32	722,335.66	-2,500.00
MACHAKOS COUNTY	174,800.00	0.00	0.00	0.00
MAKUJENI COUNTY	8,842,610.01	95,078.00	0.00	0.00
MANDERA COUNTY	0.00	0.00	0.00	0.00
MARSABIT COUNTY	33,345,054.41	0.00	0.00	0.00
MERU COUNTY	57,113,797.75	0.00	0.00	0.00
MIGORI COUNTY	43,351,611.83	0.00	0.00	0.00
MOMBASA COUNTY	0.00	0.00	0.00	14,629.98
MURANG'A COUNTY	57,089,120.00	24,487,758.50	0.00	0.00
NAIROBI METROPOLITAN SERVICES(NMS)	0.00	66,927,266.78	0.00	119,239.6
NAKURU COUNTY	0.00	0.00	0.00	1,400,908.
NANDI COUNTY	48,818,973.48	29,828,716.00	544,373.38	0.00
NAROK COUNTY	0.00	0.00	0.00	17,605.34
NYAMIRA COUNTY	14,942,589.68	4,557,190.62	0.00	3,900.00
NYANDARUA COUNTY	-69,950.00	0.00	0.00	0.00
NYERI COUNTY	0.00	0.00	0.00	0.00
SAMBURU COUNTY	32,690,608.40	0.00	2,805,235.13	-62,061.38

Customer	91-180 Days	181-270 Days	271-360 Days	Over 360 Days
SIAYA COUNTY	42,458,998.18	1,166,195.34	64,421.07	0.00
TAITA TAVETA COUNTY	67,246,478.54	0.00	0.00	3,502,775
TANA RIVER COUNTY	0.00	0.00	0.00	0.00
THARAKA NITHI COUNTY	3,541,100.00	22,359,952.68	0.00	0.00
TRANS NZOIA COUNTY	1,317,839.00	0.00	13,548,051.20	-170,119.4
TURKANA COUNTY	25,342,459.80	81,079,562.67	0.00	0.00
UASIN GISHU COUNTY	0.00	0.00	0.00	0.00
VIHIGA COUNTY	0.00	9,272,624.00	53,569,598.00	51,592,50
WAJIR COUNTY	61,091,669.46	426,480.05	0.00	0.00
WEST POKOT COUNTY	16,137,802.00	1,018,600.00	1,267,427.09	0.00
Σ	1,010,953,067.52	442,764,018.71	76,073,627.85	300,421,7

STANDING COMMITTEE ON HEALTH

**STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE)
BILLS NO. 53 of 2021)**

No.	CLAUSE	STAKEHOLDER	PROPOSED AMENDMENT	COMMITTEE RESOLUTION
1.	4 Functions of the Authority	Ministry of Health	<p>MOH proposes that KEMSA remains the point of first call for all Health Products and Technologies (HPTs) listed in the Kenya Essential Medicines List, Medical Equipment and Supplies List registered by the Pharmacy and Poisons Board.</p> <p>JUSTIFICATIONS</p> <p>The applicable procurement is only of medical products registered by the Pharmacy and Poisons Board. This will ensure enforcement of the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country.</p> <p>In addition, KEMSA implements a bulk pooled procurement system therefore benefiting from the economies of scale due to competitive sourcing which should eventually lead to lower cost of medicines-thus affordability</p>	Adopted only in respect to the Kenya Essential Medicines List, Medical Equipment and Supplies List.

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

2.		<p>KENCO (Kenyan Network of Cancer Organisations)</p>	<ul style="list-style-type: none"> • KENCO opposes the proposed amendments <p>JUSTIFICATION KENCO of the view that the current procurement method is efficient and sufficiently functional as it helps cancer patients benefit from economies of scale during procurement of cancer medication</p> <p>Additionally, KENCO is satisfied with the quality safeguards the current regime assures cancer patients in Kenya.</p>	<p>Adopted only in respect to the Kenya Essential Medicines List, Medical Equipment and Supplies List.</p>
3.		<p>FKPM (Federation of Kenya Pharmaceutical Manufacturers)</p>	<p>FKPM opposes the proposed amendments and is satisfied with the current status quo.</p> <p>JUSTIFICATIONS Affordable medicines are central to achieving Universal Health Coverage and the current system ensures the quality of drugs and medicines supplies procured by the county governments. KEMSA carries out quality control tests and therefore safe guards against substandard and counterfeit products being supplied in every county. In addition, decentralisation of the supply chain will throw</p>	<p>Adopted only in respect to the Kenya Essential Medicines List, Medical Equipment and Supplies List.</p>

(STANDING COMMITTEE ON HEALTH)

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 of 2021)

		<p>into question implementation of national health programmes such as those of HIV/AIDS, Tuberculosis, vaccine programs etc. Furthermore, the overall cost of procurement will increase if there is no centralized procurement since economies of scale achieved by KEMSA will be reduced drastically and the cost of distribution will increase therefore increasing the cost of healthcare. KEMSA might be left with only the difficult to reach facilities where other players are not willing to deliver, further lowering the incentives to ensure access to medicines.</p>	
4.	<p>Pharmaceutical Society of Kenya</p>	<p>PSK is in support of the proposed amendments in the Bill.</p> <ul style="list-style-type: none"> ● In addition, PSK proposes— <ul style="list-style-type: none"> (i) KEMSA functions be devolved to counties or regional blocks (ii) Subject KEMSA to periodic (at least once every 3 years) quality management system audits including good distribution practice (GDP) audits. (iii) Subject county procurement 	Rejected

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

			<p>practices to audit even when they buy from KEMSA. They should demonstrate among other criteria that they procured the most responsive items at the most competitive price and from qualified suppliers.</p> <p>(iv) Counties expeditiously and efficiently pay what is owed by counties to KEMSA.</p> <p>(v) Restructure KEMSA Human resources to ensure professionals are driving KEMSA business. For instance, technical departments such as depots, warehouses, quality assurance department must be headed by licensed pharmacists.</p> <p>JUSTIFICATIONS</p> <p>The proposal ensures necessary healthy competition to KEMSA whilst also assuring competitively priced supplies when KEMSA is out of stock. In addition, not all HPTs that</p>
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STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 of 2021)

	<p>countries would want are available at KEMSA. Further counties have greatly contributed to a crippled KEMSA by perennially not paying their dues.</p>		
5.	<p>Kenya Healthcare Federation</p> <p>KHF approves the proposed amendments by the Bill.</p> <p>KHF additionally proposes that the words “Pharmacy and Poisons Board” be added before the word ‘Board’ in Section 4 (3)(a)</p> <p>JUSTIFICATIONS</p> <ul style="list-style-type: none"> • KHF avers that the provisions (Subsections 3 & 4) were passed in 2019 with lack of public participation. • KHF further submits that KEMSA should only focus on essential medicines, while allowing National and County hospitals to have the flexibility to procure specialized medical products and emergency medicines as was the case before the Health Laws (Amendment) Act No. 5 of 2019 was passed. Citing affordability and immediate availability. • As regards their proposed amendment 		Rejected

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

			<p>above, KHF seeks to remove all forms of ambiguity from the governing board which should approve the medicines as being the Pharmacy and Poisons Board</p>	
6.		<p>Mission for Essential Drugs and Supplies (MEDS)</p>	<ul style="list-style-type: none"> • MEDS is in agreement with suggested amendments to the KEMSA amendment Bill 2021 • Additionally, MEDS has the following submissions <p>i) Amend the law to allow Counties to:</p> <ul style="list-style-type: none"> - Procure health commodities from the Organizations that are able to provide quality and affordable health products to Counties and prices comparable to KEMSA - Enter into partnerships with health supply organizations such as UNICEF and MEDS to improve order fill rates. - procure health commodities only from health supply chain organizations that have demonstrated elaborate quality assurance and control systems that conform to WHO's Model Quality Assurance System (MQAS) for procurement agencies. 	<p align="center">Rejected</p>

STANDING COMMITTEE ON HEALTH

**STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE)
BILLS NO. 53 of 2021**

			<ul style="list-style-type: none"> - procure health commodities only from institutions, companies or organizations that have physical offices and warehouses in Kenya with adequate competent staff - procure from suppliers with adequate capacity to distribute health commodities to doorsteps of rural health facilities - direct procurement of health commodities from pre-qualified suppliers with the capacity to provide the required commodities within a short turnaround period (7-14 days) <p>ii) The bill should allow KEMSA to enter into partnerships with similar organizations representing or acting on behalf of non-state actors to pool quantities, identify manufacturers, negotiate and procure commodities for national interest at affordable prices</p>	
7.	Kenya Medical Supplies Authority (KEMSA)	KEMSA to be the first port of call for procurement. Warehousing and distribution of health products and technologies listed in the relevant lists (Kenya essential medicine lists, medical equipment and supplies list) as may be	Adopted only in respect to the Kenya Essential Medicines List, Medical Equipment and Supplies List	

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 of 2021)

			<p>revised from time to time, at the county referral level and it shall endeavor to establish branches within each county at such locations it may determine.</p>	
8.		<p>Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)</p>	<p>KELIN supports the amendment bill particularly the deletion of subsections 4(3 and 4(4) of the Kenya Medical Supplies Authority Act (KEMSA Act).</p> <p>JUSTIFICATION</p> <ol style="list-style-type: none"> 1. Article 43 of the COK stipulates that health is a right including the accessibility of medical supplies. 2. Sections 4(3) and 4(4) of the KEMSA Act 2013 limits the ability of counties to procure and manage health supplies from any other entity other than KEMSA, and makes it a criminal offense to do so. Hence when KEMSA is facing stockouts, county health facilities then experience stock outs of medical supplies. When this happens, and it has happened numerous times, it is the common mwananchi that suffers. People, especially vulnerable and marginalized communities, are denied 	<p>Rejected</p>

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE)
BILLS NO. 53 of 2021

			<p>their right to health – which leads to serious illness and deaths that could have been avoided.</p> <p>3. Early last year, when KEMSA faced allegations of corruption and mismanagement of COVID-19 funds, USAID decided not to use the state corporation for distribution of HIV commodities. This led to a stalemate that threatened the lives of over 1.3 million people living with HIV. For the entire year, Kenya faced chronic shortage of very important HIV-related commodities including but not limited to ARVs, viral load testing reagents, HIV test kits, including for early infant diagnostics (EID), shortage of condoms, laboratory and diagnostic supplies, among others. As the stalemate persisted, counties could not procure from elsewhere with the ripple effect experienced by over 1.3 million people living with HIV across the country.</p> <p>4. Therefore, the law should allow counties to procure medical supplies from other entities. This would enable them to take full responsibility for</p>	
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STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

		<p>Kenya Association of Pharmaceutical Industry(KAPI)</p>	<p>provision of health services at the county level – without the troubles of KEMSA creating a barrier to access. This will also prevent instances where county governments use KEMSA as a scapegoat anytime they experience stock out of commodities (even in instances where the blame would right fall back to the said county governments).</p> <p>5. The Ministry of Health through the Pharmacy and Poisons Board should ensure strict implementation of the existing regulations, standards and guidelines to ensure the quality of medical supplies procured from other sources meets the threshold and does not endanger the lives of people</p>	<p>Rejected</p>
<p>9.</p>			<p>KAPI supports the deletion of subsections 4(3) and 4(4) of the Kenya Medical Supplies Authority Act (KEMSA Act)</p> <p>JUSTIFICATION The proposed changes will provide public facilities with the freedom to source health products competitively and allow KEMSA to</p>	

STANDING COMMITTEE ON HEALTH

**STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE)
BILLS NO. 53 of 2021**

			<p>focus on essential supplies and emergency supplies. We believe that some of the advantages of the proposed amendments are as follows: 1. The amendments address the risks that come with a monopoly market such as: Non-competitive pricing, and Supply disruptions 2. Increased diversity 3. Promotion of Private Public Partnerships that will promote achievement of UHC.</p>	
10.	<p>Pharmacy and Poisons Board</p>		<ul style="list-style-type: none"> • The Board submits certain thresholds that must form part of the input when considering the Bill: • The procurement of only medical products registered or approved for use by the Board. This will ensure enforcement of the prescribed standards of quality, safety and efficacy of all medical products manufactured, imported into or exported out of the country in line with the Pharmacy and Poisons Act; <p>b. Procurement from only authorized</p>	

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

			<p>sellers of medical products licensed by the Board under the Pharmacy and Poisons Act. This will ensure that the personnel, premises and practices employed in the storage, marketing, distribution and sale of medical products comply with the defined codes of practice and other prescribed requirements.</p>	
11.	Sen. Olekina	<p>That the Bill be amended by—</p> <p>(a) Adding the following new subsections immediately after subsection (4)(e) –</p> <ol style="list-style-type: none"> 1. Prequalification of the local drug manufacturers and suppliers and distribution of the procured drugs using the NHIF Pharmacy Benefit Management platform 2. To ensure that essential Acute Products are manufactured and distributed only by local manufacturers (including products) for distributing through the supply 	<p>Redraft the provision to reflect the functional delineation of roles between the NHIF and KEMSA but ensure that the prequalified list is determined by a multisectoral arrangement between NHIF, PPB and KEMSA</p>	

STANDING COMMITTEE ON HEALTH

STAKEHOLDER VIEWS ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE)
BILLS NO. 53 OF 2021

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Stakeholders:

3. Ministry of Health
4. KENCO (Kenyan Network of Cancer Organisations)
5. FKPM (Federation of Kenya Pharmaceutical Manufacturers)
6. Pharmaceutical Society of Kenya
7. Kenya Healthcare Federation
8. Mission for Essential Drugs and Supplies (MEDS)
9. Kenya Medical Supplies Authority (KEMSA)
10. Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)
11. Kenya Association of Pharmaceutical Industry (KAPI)
12. Pharmacy and Poisons Board
13. Sen. Olekina

THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 MATRIX

ACT	CURRENT PROVISION OF THE ACT	PROVISION IN THE BILL	PROPOSED AMENDMENT BY HON. MEMBER	PROPOSED AMENDMENT BY KEMSA	JUSTIFICATION
<p>The Kenya Medical Supplies Authority Act, (No. 20 of 2013)</p>	<p><i>Section 4 of No. 20 of 2013 which it is proposed to amend-</i></p> <p>4. (1) The functions of the Authority shall be to—</p> <p>(a) procure, warehouse and distribute drugs and medical supplies for prescribed public health programmes, the national strategic stock reserve, prescribed essential health packages and national referral hospitals;</p> <p>(b) establish a network of storage, packaging and distribution facilities for the provision of drugs and medical supplies to health institutions;</p> <p>(c) enter into partnership with or establish frameworks with county Governments for purposes of providing services in procurement, warehousing, distribution of drugs and medical supplies;</p>	<p>Functions of the Authority</p>	<p>2. The Kenya Medical Supplies Authority Act, 2013, hereinafter referred to as the principal Act is amended in section 4 by –</p> <p>(a) Deleting subsection (3); and</p> <p>(b) Deleting subsection (4).</p>	<p>s. 4 Delete the following new section—</p> <p>4. (3) KEMSA shall be the point of first call for procurement, warehousing and distribution of HPTs listed in the relevant essential lists (Kenya Essential Medicines list, medical equipment and supplies list) as may revised to time to time, at the county referral level and it shall endeavor to establish branches within each county at such locations as it may determine.</p> <p>(4) A national and county public health facilities shall be required by law to</p>	<p>➤ These proposals intend for KEMSA to be rendered as the first point of call for the supply of drugs and medical supplies listed in the Kenya Essential Medicines List. In scenarios where a national referral hospital or a county public health facility orders for such and KEMSA confirms unavailability of such medicines in its inventory; upon request by the health facility, KEMSA shall advise the health facility on the sourcing of the declared commodities from other entities approved by the</p>

	<p>(d) collect information and provide regular reports to the national and county governments on the status and cost-effectiveness of procurement, the distribution and value of prescribed essential medical supplies delivered to health facilities, stock status and on any other aspects of supply system status and performance which may be required by stakeholders;</p> <p>(e) support county governments to establish and maintain appropriate supply chain systems for drugs and medical supplies.</p> <p>(2) The Cabinet Secretary shall, in consultation with the Authority and the appropriate county government organs, determine the requirement of drugs and medical supplies in public health facilities.</p> <p>(3) A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to—</p> <p>(a) the drug being duly registered by the Board; and</p>			<p>procure all such HPTs listed in the relevant essential lists being duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy as authorized by the Pharmacy and Poisons Board.</p>	<p>Pharmacy and Poisons Board.</p> <p>➤ That Counties be at liberty to procure drugs and medical supplies not listed in the Essential Health Products and Technologies Lists (KEML) from KEMSA upon an Express agreement with KEMSA on specified items.</p> <p>➤ The GOK has listed products that should be supplied directly in the Kenya Essential Medicines List, Medical Equipment and supplies list. These products have been duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy. KEMSA should be rendered the first point of call to ensure safety of the products in the health facilities.</p>
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	<p>(b) the drugs and medical supplies meet the standards of quality and are efficacious as authorized by the Board.</p> <p>(4) A person responsible for the procurement and distribution of drugs and medical supplies in a national or county public health facility and who contravenes provisions of this section, commits an offence and is liable on conviction to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both."</p>				<p>➤ Section 86 (f) of the Health Act mandates KEMSA to determine the market prices for the products listed in the Kenya Essential Medicines List, Medical Equipment and supplies list. All pharmaceutical and non-pharmaceutical products should correspond to Kenya Medical Supplies Authority market prices. Therefore, by counties contacting KEMSA as the first point of call, they shall be buying products at cost advantage in the purchasing economies of scale and benefitting in the optimum combination of cost, effectiveness and quality of value for money.</p>
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THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 MATRIX

ACT	CURRENT PROVISION OF THE ACT	PROVISION IN THE BILL	PROPOSED AMENDMENT BY HON. MEMBER	PROPOSED AMENDMENT BY KEMSA	JUSTIFICATION
The Kenya Medical Supplies Authority Act, (No. 20 of 2013)	<p>Section 4 of No. 20 of 2013 which it is proposed to amend-</p> <p>4. (1) The functions of the Authority shall be to—</p> <p>(a) procure, warehouse and distribute drugs and medical supplies for prescribed public health programmes, the national strategic stock reserve, prescribed essential health packages and national referral hospitals;</p> <p>(b) establish a network of storage, packaging and distribution facilities for the provision of drugs and medical supplies to health institutions;</p> <p>(c) enter into partnership with or establish frameworks with county Governments for purposes of providing services in procurement, warehousing, distribution of drugs and medical supplies;</p>	Functions of the Authority	<p>2. The Kenya Medical Supplies Authority Act, 2013, hereinafter referred to as the principal Act is amended in section 4 by –</p> <p>(a) Deleting subsection (3); and</p> <p>(b) Deleting subsection (4).</p>	<p>s. 4 Delete and substitute therefore the following new section—</p> <p>4. (3) KEMSA shall be the point of first call for procurement, warehousing and distribution of HPTs listed in the relevant essential lists (Kenya Essential Medicines list, medical equipment and supplies list) as may revised to time to time, at the county referral level and it shall endeavor to establish branches within each county at such locations as it may determine.</p> <p>(4) A national and county public health facilities shall be required by law to</p>	<p>➤ These proposals intend for KEMSA to be rendered as the first point of call for the supply of drugs and medical supplies listed in the Kenya Essential Medicines List. In scenarios where a national referral hospital or a county public health facility orders for such and KEMSA confirms unavailability of such medicines in its inventory; upon request by the health facility, KEMSA shall advise the health facility on the sourcing of the declared commodities from other entities approved by the</p>

	<p>(d) collect information and provide regular reports to the national and county governments on the status and cost-effectiveness of procurement, the distribution and value of prescribed essential medical supplies delivered to health facilities, stock status and on any other aspects of supply system status and performance which may be required by stakeholders;</p> <p>(e) support county governments to establish and maintain appropriate supply chain systems for drugs and medical supplies.</p> <p>(2) The Cabinet Secretary shall, in consultation with the Authority and the appropriate county government organs, determine the requirement of drugs and medical supplies in public health facilities.</p> <p>(3) A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to—</p> <p>(a) the drug being duly registered by the Board; and</p>			<p>procure all such HPTs listed in the relevant essential lists being duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy as authorized by the Pharmacy and Poisons Board.</p>	<p>Pharmacy and Poisons Board.</p> <p>➤ That Counties be at liberty to procure drugs and medical supplies not listed in the Essential Health Products and Technologies Lists (KEML) from KEMSA upon an Express agreement with KEMSA on specified items.</p> <p>➤ The GOK has listed products that should be supplied directly in the Kenya Essential Medicines List, Medical Equipment and supplies list. These products have been duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy. KEMSA should be rendered the first point of call to ensure safety of the products in the health facilities.</p>
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	<p>(b) the drugs and medical supplies meet the standards of quality and are efficacious as authorized by the Board.</p> <p>(4) A person responsible for the procurement and distribution of drugs and medical supplies in a national or county public health facility and who contravenes provisions of this section, commits an offence and is liable on conviction to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both."</p>				<p>➤ Section 86 (f) of the Health Act mandates KEMSA to determine the market prices for the products listed in the Kenya Essential Medicines List, Medical Equipment and supplies list. All pharmaceutical and non-pharmaceutical products should correspond to Kenya Medical Supplies Authority market prices. Therefore, by countries contacting KEMSA as the first point of call, they shall be buying products at cost advantage in the purchasing economies of scale and benefitting in the optimum combination of cost, effectiveness and quality of value for money.</p>
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27th January 2022

**The Clerk, Senate
Parliament Building
P.O. BOX 41842-00100
Nairobi, Kenya**

Attention: Mr. Jeremiah M. Nyegenye. CBS

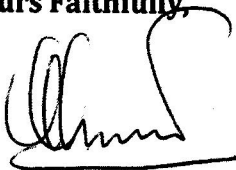
**RE: SUBMISSION OF MEMORANDUM ON THE KENYA MEDICAL SUPPLIES AUTHORITY
(AMENDMENT) BILL, 2021**

Greetings from Kenya Healthcare Federation (KHF).

On behalf of the members of the Kenya Healthcare Federation, we would like to submit our memorandum, enclosed herewith, in relation to the following Kenya Medical Supplies Authority (Amendment) Bill, 2021 of the National Assembly for due consideration by the relevant committee.

We look forward to your kind considerations of our proposal.

Yours Faithfully,



Dr. Anastasia Nyalita

Chief Executive Officer

Kenya Healthcare Federation

**KENYA HEALTHCARE FEDERATION
P. O. Box 3556 - 00100
NAIROBI, KENYA
Email: admin@khf.co.ke
Date: 27th January 2022**

**PROPOSED AMENDMENTS TO THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT)
BILL, 2021**

(Hereinafter THE BILL)

(KENYA GAZETTE SUPPLEMENT NO. 184, SENATE BILLS NO. 53)

**MEMORANDUM ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL,
2021 TO BE SUBMITTED TO THE SENATE**

CLAUSE	CURRENT CLAUSE	PROPOSED AMENDMENT	RATIONALE/JUSTIFICATION
Clause 2	The Kenya Medical Supplies Authority Act, 2013, hereinafter referred to as the principal Act is amended in section 4 by - (a) deleting subsection (3); and (b) deleting subsection (4).	We propose that this provision be Approved.	These provisions were passed in 2019 (THE HEALTH LAWS (AMENDMENT) ACT, 2019 No. 5 of 2019 Date of Assent: 13th May, 2019 Date of Commencement: 17th May, 2019) without public participation and hence should be subjected to public participation before this critical change can be enacted. KEMSA should focus on Essential Medicines and the National and County hospitals should be given the flexibility to procure specialized medical products and emergency medicines as was the case before the Health Laws (Amendment) Act, 2019 No. 5 of 2019 was passed. This ensures affordability and immediate availability

Chairman: Dr. Kanyenje Gakombe **Vice-Chair:** Dr. Elizabeth Wala **Treasurer:** Mr. Stephen Maina

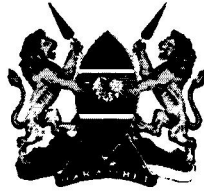
Directors: Dr. Francis Karanja Mr. Vinod Guptan Dr. Walter Obita Dr. Linus Ndegwa Dr. Daniella Munene Mr. Isaiah Okoth Mr. Antony Jaccodul

The Health Sector Board of KEPSA

			of specialized health products at the facility level whenever needed.
	<p>Section 4(3) (a) A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to -</p> <p>(a) the drug being duly registered by the Board.</p>	<p>We propose that the words “Pharmacy and Poisons” be added immediately before the word “Board” to read “Pharmacy and Poisons Board”.</p>	<p>For clarity of purpose and avoiding ambiguity as to which Board is referred to.</p> <p>The Pharmacy and Poisons Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.</p> <p>The Board’s objective is to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating drugs in force in Kenya.</p>

Chairman: Dr. Kanyenje Gakombe **Vice-Chair:** Dr. Elizabeth Wala **Treasurer:** Mr. Stephen Maina

Directors: Dr. Francis Karanja Mr. Vinod Guptan Dr. Walter Obita Dr. Linus Ndegwa Dr. Daniella Munene Mr. Isaiah Okoth Mr. Antony Jaccodul



MINISTRY OF HEALTH

SUBMISSION TO THE SENATE STANDING COMMITTEE ON HEALTH REGARDING KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

The Kenya Medical Supplies Agency (KEMSA) is mandated to procure, warehouse and distribute medicines to public health facilities as the national public procurement agency and is the point of first call for procurement of medicines at the county and national level.

The Ministry's position is that:-

- i. KEMSA should remain as the point of first call for procurement, warehousing and distribution of HPTs listed in the relevant essential lists (Kenya Essential Medicines List, Medical Equipment and Supplies List) as may be revised from time to time, at the county referral level and it shall endeavor to establish branches within each county at such locations as it may determine.
- ii. KEMSA proposes that the provisions of Section 4 (3) of the KEMSA Act be amended to the effect that National and County Public Health Facilities be required by law to procure all such HPTs listed in the relevant essential lists being duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy as authorized by the Board.

- iii. Currently, in facilitating access by the public to medical products that are of good quality, safety and efficacy, the Pharmacy and Poisons Board has facilitated KEMSA access to its Register of medical products and technologies. This ensures the procurement of only authorized medical products.
- iv. Access entails several dimensions i.e., *availability* at the time of need, at a facility within geographical reach of the patient; *affordability*, which entails the absence of financial barriers at the point of care; *safety, efficacy and quality* of the medicine; and *appropriateness* of the medicine for the patient and the condition being treated, and for the healthcare setting.
- v. KEMSA implements a bulk pooled procurement system therefore benefiting from the economies of scale due to competitive sourcing which should eventually lead to lower cost of medicines-thus affordability.

CONCLUSION

It is therefore our proposal to the Committee that in considering this Bill, it is reiterated that the applicable procurement is only of medical products registered by the Pharmacy and Poisons Board. This will ensure enforcement of the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country.

KEMSA should therefore be rendered the first point of call to ensure safety of the products in the health facilities.

In addition the Senate should consider to formulate a law providing for ring-fencing of county funds reserved for purchase of HPTs and for recovery of old county debts arising from HPTs supplied to

counties by KEMSA by way of a first charge against the consolidated fund.

The Ministry hereby requests the Senate to consider the amended proposal to ensure safety, affordability of medical products and technologies so as to guarantee achievement of Universal Health Coverage (UHC).

I hereby submit.

Susan N. Mochache, CBS
PRINCIPAL SECRETARY

3rd February, 2022



PHARMACEUTICAL SOCIETY OF KENYA
PCEA Foundation, Block C, Jabavu Rd.
P.O. Box 44290 - 00100 Nairobi - KENYA
T. +254 722 817 264
E. info@psk.or.ke
W. www.psk.or.ke

December 08, 2021

To the Clerk
The Senate
Parliament of Kenya
NAIROBI

Dear Sir

MEMORANDUM ON THE KEMSA (AMENDMENT) BILL, 2021

Please find below our memorandum on above-mentioned Bill

Proposed amendment	PSK position on amendment	Justification
<p><i>(3) A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to—</i></p> <p><i>(a) the drug being duly registered by the Board; and</i></p> <p><i>(b) the drugs and medical supplies meet the standards of quality and are efficacious as authorised by the Board.</i></p>	PSK is aligned with this amendment	We do not want to make KEMSA a monopoly.
<p><i>(4) A person responsible for the procurement and distribution of drugs and medical supplies in a national or county public health facility and who contravenes provisions of this section, commits an offence and is liable on conviction to a fine not exceeding two million shillings or to imprisonment for a term not exceeding five years, or to both.</i></p>	PSK is aligned with this amendment	This amendment will ensure counties get the HPTs they require and reduce stock outs, to better serve Kenyans

NATIONAL EXECUTIVES: DR. LOUIS S. MACHOGU (PRESIDENT) | DR. QABALE HUSSEIN (DEP. PRESIDENT) | DR. JULIET KONJE (HON. NAT. TREASURER)

BEST PRACTICE | PUBLIC INTEREST | PROFESSIONALISM



PHARMACEUTICAL SOCIETY OF KENYA

PCEA Foundation, Block C, Jabavu Rd.
P.O. Box 44290 - 00100 Nairobi - KENYA

T. +254 722 817 264

E. info@psk.or.ke

W. www.psk.or.ke

We submit further key considerations and recommendations towards the strengthening of KEMSA

Whereas

1. KEMSA has been an instrumental partner in provision of healthcare in the counties.
2. Health products and technologies are the biggest cost driver in healthcare
3. KEMSA if managed well can provide unmatched aggregation of HPTs leading to unparalleled cost reduction and increase in access to HPTs
4. Over the last 9 years, before this current decline in performance of KEMSA, there have been significant service delivery improvements at KEMSA occasioned by aggressive capacity building and installation of LMIS which led to fill rates of over 70% and on time last mile deliveries.
5. Counties have greatly contributed to a crippled KEMSA by perennially not paying their dues.
6. The public procurement Act hinders KEMSA from emergency procurement making it a long and laborious process.
7. While transiting to devolution, the Commission of the Implementation of the Constitution highlighted how procurement would be done post devolution where KEMSA and MEDS were mentioned quoting quality, cost, and logistical assessment.
8. Procuring from KEMSA shields counties from audit as it is government to government unlike with other suppliers, and this exposes counties to legal issues as documentation is poor at the counties. This must change.
9. Not all HPTs that counties would want are available at KEMSA.

We hereby make the following key recommendations:

1. Encourage counties to procure from commodity aggregators but not limited to KEMSA. This will provide necessary healthy competition to KEMSA whilst also assuring competitively priced supplies when KEMSA is out of stock
2. Expeditiously and efficiently pay what is owed by counties to KEMSA.
3. Restructure KEMSA to ensure the right professionals are driving KEMSA business. Technical departments must be staffed with the relevant professionals. Depots, warehouses, quality assurance department must be headed by licensed pharmacists.
4. Devolve KEMSA function to the counties or regional blocks
5. Subject KEMSA to periodic (at least once every 3 years) quality management system audits including good distribution practice (GDP) audits
6. Subject county procurement practices to audit even when they buy from KEMSA. They should demonstrate among other criteria that they procured the most responsive items at the most competitive price and from qualified suppliers.

NATIONAL EXECUTIVES: DR. LOUIS S. MACHOGU (PRESIDENT) | DR. QABALE HUSSEIN (DEP. PRESIDENT) | DR. JULIET KONJE (HON. NAT. TREASURER)

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PHARMACEUTICAL SOCIETY OF KENYA

PCEA Foundation, Block C, Jabavu Rd.

P.O. Box 44290 - 00100 Nairobi - KENYA

T. +254 722 817 264

E. info@psk.or.ke

W. www.psk.or.ke

Sincerely

DR DANIELLA MUNENE

CHIEF EXECUTIVE OFFICER

cc: Chair, Departmental Committee on Health, The Senate

NATIONAL EXECUTIVES: DR. LOUIS S. MACHOGU (PRESIDENT) | DR. QABALE HUSSEIN (DEP. PRESIDENT) | DR. JULIET KONJE (HON. NAT. TREASURER)

BEST PRACTICE | PUBLIC INTEREST | PROFESSIONALISM



**MEMORANDUM TO THE SENATE STANDING COMMITTEE ON
HEALTH ON DELEGATED LEGISLATION**

**IN RELATION TO THE KENYA MEDICAL SUPPLIES
AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)**

31st January, 2022

MEMORANDUM BY THE KENYA MEDICAL SUPPLIES AUTHORITY ON THE KENYA MEDICAL SUPPLIES AUTHORITY (AMENDMENT) BILL, 2021 (SENATE BILLS NO. 53 OF 2021)

To: The Clerk Senate
Parliament Buildings
P. O. Box 41842-00100
Nairobi.

Cc: Chairperson- Standing Committee on Health and Sanitation
Senate Parliament Buildings
P. O. Box 41842-00100
Nairobi.

MEMORANDUM

I. Background

1. KEMSA is an autonomous state corporation under the Ministry of Health previously established under the State Corporations Act vide the Kenya Medical Supplies Agency Order Number 17 of 2000.
2. With the promulgation of the new Constitution in 2010; and as a requirement for state corporations to align their legal mandate with the new constitution, KEMSA was transformed from an agency to an Authority through the enactment of the Kenya Medical Supplies Authority Act No. 20 of 2013.
3. Standing Order 140 (5) confers upon the Committee the power to consider whether any statutory instrument conforms to the Constitution and other laws (in terms of the elaborate criteria set thereunder) and to thereafter recommend whether the instrument is to be approved or annulled.

II. Amendment To The KEMSA Act No. 20 of 2013

4. In 2017, a circular issued from the Head of Public Service requiring state corporations to review/ amend their legislative and regulatory instruments.

5. Subsequently, the Principal Secretary Ministry of Health vide a letter dated 14th March 2017; asked the Session chair KEMSA to review and align the KEMSA Act to align to the Constitution and the Code of Governance for State Corporations- MWONGOZO. Ministry of Health through the Permanent Secretary directed KEMSA to submit amendment proposals in line with the circular.
6. KEMSA Board discussed and proposed the following amendments for consideration.
 - ✓ Appointment of the chairperson by the President without resorting to a competitive process;
 - ✓ Appointment of other Board of Directors by the Cabinet Secretary;
 - ✓ Incorporation of a representative of the County Governments into the Board;
 - ✓ Tenure of office of the Chief Executive Officer;
 - ✓ Incorporation of the office of the Corporation Secretary into the management of the Authority; and
 - ✓ The Affixing of the Common Seal to be authenticated by the CEO's and Corporation Secretary's signatures.

III. The Health Laws (Amendment) Act N0. 5 Of 2019

7. Following these proposals, The Health Laws (Amendment) Act of 2019 was enacted to make amendments to KEMSA ACT of 2013. The Act became operational on 17th May, 2019.
8. Among others; section 4 was amended to include new subsections 3 and 4. Section 4 (3) reads as follows: -
 - "(3)A national or county public health facility shall, in the procurement and distribution of drugs and medical supplies, obtain all such drugs and medical supplies from the Authority subject to-
 - a) Drug being duly registered by the Board; and
 - b) Drugs and medical supplies meet the standards of quality and are efficacious as authorized by the Board.
 - Section 4 (4) provides for penal sanctions for not adhering to the above subsection.

***This amendment rendered KEMSA a monopoly on supply of all medical commodities to government hospitals.**

IV. Implications of Amendment To Section 4 of The Act

9. Following this amendment, KEMSA was monopolized as the one stop for all counties' drugs and medical supplies needs and this caused an uproar by the Council of Governors and Senators on its constitutional legality.
10. The legality of the provision was challenged through litigation in court on 18th July, 2019, vide Petitions number 353 of 2019 and 284 of 2019 (consolidated); where the petitioners were the Council of County Governors and The Senate of the Republic of Kenya as against the respondents- the National Assembly & AG. The petitions sought to nullify the monopoly provision amongst other 23 Acts of Parliament as amended by the National Assembly without reference to the Senate, which under Article 96 has the mandate to represent counties and protect their interests.
11. The constitutional petitions were pegged on the fact that it is vital law under Article 2 (4) of the Constitution, that any law that is inconsistent with the Constitution is void to the extent to its consistency. This is underscored by the fact that the National Assembly breached Article 96 of the Constitution in passing the laws without reference to the Senate which mandates Senate to represent counties and protect their interests.
12. On the 29th October, 2020, the three-judge bench in their judgment as signed and delivered suspended their orders nullifying the impugned Acts for a period of 9 months from the judgment date. This period lapses on 29th July, 2021.
13. The amendment to section 4 of the KEMSA Act was declared contrary to Articles 6, 10, 43(1), 46(1), 73(1), 110(3) and 227(1) and therefore unconstitutional thus null and void.
14. Within the stipulated period, the respondents amongst them KEMSA ought to have regularized these amendments and the National Assembly to comply with Article 110 (3) of the constitution and in default the laws shall stand nullified.
15. In the judgment and orders delivered on the 19th November, 2021, the Court of Appeal concurred with the High Court finding that the enactment of sections 3 and 4 to the KEMSA Act was unconstitutional; as the provisions of the

amendment would fit within the description of health services assigned to the counties and thus would have required the participation of the Senate.

16. Following this judgment, it is imperative to note that the provision making KEMSA a monopoly on supply of all medical commodities to national and referral hospitals and county public health facilities is untenable as its technical soundness and constitutionality has proven flawed.

V. KEMSA's Proposed Amendments

17. The KEMSA Board of Directors at its 60th board meeting held on 3rd November, 2020; resolved that the following amendments to the provisions of the KEMSA ACT be made for consideration.

- i. KEMSA shall be the point of first call for procurement, warehousing and distribution of HPTs listed in the relevant essential lists (Kenya Essential Medicines list, medical equipment and supplies list) as may be revised to time to time, at the county referral level and it shall endeavor to establish branches within each county at such locations as it may determine.
- ii. KEMSA proposes that the provisions of section 4 (3) of the KEMSA Act be amended to the effect that national and county public health facilities be required by law to procure all such HPTs listed in the relevant essential lists being duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy as authorized by the said Board.

VI. Board of KEMSA Recommendations

The Board of Directors of KEMSA in the aforesaid meeting recommended that parliament may:

- i. Formulate a law providing for ring-fencing of county funds reserved for purchase of HPTs and for recovery of old county debts arising from HPTs supplied to counties by KEMSA by way of a first charge against the consolidated fund.

- ii. Formulate a bill for enactment into law by Parliament to establish a semi-autonomous inspectorate to monitor and enforce compliance by national and county public health facilities to procure essential HPTs listed in the relevant essential lists from KEMSA.

VII. Justifications

- i. These proposals intend for KEMSA to be rendered as the first point of call for the supply of drugs and medical supplies listed in the Kenya Essential Medicines List. In scenarios where a national referral hospital or a county public health facility orders for such and KEMSA confirms unavailability of such medicines in its inventory; upon request by the health facility, KEMSA shall advise the health facility on the sourcing of the declared commodities from other entities approved by the Pharmacy and Poisons Board.
- ii. That Counties be at liberty to procure drugs and medical supplies not listed in the Essential Health Products and Technologies Lists (KEML) from KEMSA upon an

Express agreement with KEMSA on specified items.
- iii. The GOK has listed products that should be supplied directly in the Kenya Essential Medicines List, Medical Equipment and supplies list. These products have been duly registered by the Pharmacy and Poisons Board and approved to have met the standards of quality and efficacy. KEMSA should be rendered the first point of call to ensure safety of the products in the health facilities.
- iv. Section 86 (f) of the Health Act mandates KEMSA to determine the market prices for the products listed in the Kenya Essential Medicines List, Medical Equipment and supplies list. All pharmaceutical and non-pharmaceutical products should correspond to Kenya Medical Supplies Authority market prices. Therefore, by counties contacting KEMSA as the first point of call, they shall be buying products at cost advantage in the purchasing economies of scale and benefitting in the optimum combination of cost, effectiveness and quality of value for money.

VI. CONCLUSION

18. For the reasons set out above, we urge the Honourable Committee to consider the above proposed amendments and recommend for their approval.