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COMMITTEE	Health
CLERK AT THE TABLE	M. Adjibodon



REPUBLIC OF KENYA



TWELFTH PARLIAMENT (FIFTH SESSION)

THE SENATE

STANDING COMMITTEE ON HEALTH

THIRD PROGRESS REPORT ON THE COVID-19 SITUATION IN KENYA

PRELIMINARY FINDINGS OF THE COMMITTEE ON THE NATIONWIDE

COVID-19 VACCINE ROLL-OUT

Clerk's Chambers,

First Floor,

Parliament Buildings,

NAIROBI.

COs

Recommended for approval
for tabling.

17/05/21

[Signature]

10th May, 2021

18/5/2021

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DC-EG

Recommended & Forwarded
for processing
17/05/21

ABBREVIATIONS

CoG	-	Council of County Governors
KHF	-	Kenya Healthcare Federation
MOH	-	Ministry of Health
PPB	-	Pharmacy and Poisons Board
KMA	-	Kenya Medical Association
KMPDU	-	Kenya Medical Practitioners and Dentists Union
KNUN	-	Kenya National Union of Nurses
NNAK	-	National Nurses Association of Kenya
KPNA	-	Kenya Progressive Nurses Association
KUCO	-	Kenya Union of Clinical Officers
KCOA	-	Kenya Clinical Officers Association
KPA	-	Kenya Pharmaceutical Association
KNUPT	-	Kenya National Union of Pharmaceutical Technologists
KNUMLO	-	Kenya National Union of Medical Laboratory Officers
KHPS	-	Kenya Health Professionals Society
APHO	-	Association of Public Health Officers

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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.
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, CBS, MP.
7. Sen. Fred Outa, MP.
8. Sen. Ledama Olekina, MP.
9. Sen. Millicent Omanga, MP.

Mr. Speaker,

The Third Progress Report of the Standing Committee on Health on the COVID-19 pandemic situation was developed within the context of Kenya’s third and deadliest wave of the COVID-19 pandemic yet, and the reintroduction (and subsequent easing) of stringent containment measures, including a lockdown by Presidential directive on 27th March, 2021 and 1st May, 2021 respectively.

Mr. Speaker,

According to the World Health Organisation (WHO), as of 17th March, 2021, more than 120 million cases of COVID-19 infections with more than 2 million deaths, had been reported worldwide. WHO identified vaccines as the best hope in the battle against COVID-19 through the prevention of further illness and death. Further to the above, in recognition of the vital role

that vaccines are expected to play in limiting the impact of the COVID-19 pandemic, the Ministry of Health (MoH) has identified vaccination as a key essential element of Kenya's COVID-19 pandemic preparedness and response.

Mr. Speaker,

Consequent to the above, at its sitting held on Tuesday, 9th March, 2021, the Standing Committee on Health considered matters relating to the nationwide COVID-19 vaccine roll-out and resolved to invite the Ministry of Health (MoH) and the Council of Governors to a meeting on Thursday, 18th March, 2021. Issues raised for clarification with the MoH included:

- a) Details of the COVID-19 vaccine that was being rolled-out in Kenya;
- b) Details of the safety profile, efficacy and known side effects of the vaccine;
- c) Any reports of adverse side effects and/or deaths that had been attributed to the vaccine so far;
- d) Detailed financial and budgetary implications of the COVID-19 vaccine roll-out (including cold chain, storage, logistics etc);
- e) Measures that the Ministry had put in place to facilitate the seamless roll-out of the vaccine to all Kenyans;
- f) Capacity of Kenya's cold chain system and vaccine storage facilities in relation to the COVID-19 vaccine roll-out; and
- g) Details of the measures that the Ministry had taken to ensure effective involvement and engagement of County Governments and other stakeholders in the vaccine roll-out.

In addition, the Committee requested the Council of Governors to apprise the Committee on the status of the COVID-19 vaccination drive across the counties.

Mr. Speaker,

As a precursor to the aforementioned meetings, the Committee invited various health worker representative groups to submit their views on the COVID-19 vaccine roll-out at a consultative meeting that was held on Wednesday, 17th March, 2021. Thirteen health professional associations and unions representing various cadres including doctors, pharmacists, nurses,

clinical officers, pharmaceutical technologists, medical laboratory officers, public health officers and allied health workers gave their submissions at the meeting as follows:

- Kenya Medical Association
- Kenya Medical Practitioners and Dentists Union
- Kenya National Union of Nurses
- National Nurses Association of Kenya
- Kenya Progressive Nurses Association
- Kenya Union of Clinical Officers
- Kenya Clinical Officers Association
- Kenya Pharmaceutical Association
- Kenya National Union of Pharmaceutical Technologists
- Kenya National Union of Medical Laboratory Officers
- Kenya Health Professionals Society
- Association of Public Health Officers

Subsequently, in relation to the COVID-19 vaccine roll-out, the Committee held meetings with the Pharmacy and Poisons Board (PPB) and various private sector players including the Kenya Healthcare Federation (KHF), Dinlas Pharma EPZ Ltd, Harleys Ltd and Unisel Pharma (K) Ltd. Based on issues that arose from its engagements with the various stakeholders, on diverse dates, the Committee held follow-up meetings with the MoH and the PPB in a bid to seek clarifications on the issues, and find a way forward.

This report thus details how the policy position of the Government on the COVID-19 vaccination has evolved, as well as the views and perspectives of critical stakeholders, including health workers and the private sector. It also details the Committee's preliminary observations and recommendations in this regard.

Mr. Speaker Sir,

It is important to note that the COVID pandemic situation is a highly evolving one: As such, the observations and recommendations contained in this report reflect the situational context, and information that was available to the Committee at the time of the writing of this report. Accordingly, as the COVID-19 outbreak situation evolves, and the Government's policy position and response evolves with it, some of the Committee's preliminary observations and recommendations on the thematic area of health may by necessity change or be reviewed.

Mr. Speaker,

As I conclude, I wish to inform the House that as of Monday, 19th April, 2021, the Standing Committee on Health commenced hearings with the 47 County Governments with a view towards getting clarifications on queries raised in the Special Audit Report by the Auditor-General on the utilization of COVID-19 Funds by the County Governments, and, establishing the level of pandemic preparedness and response across the counties. I am pleased to report that as of Monday, 10th May, 2021, the Committee had held hearings with seventeen County Governors on the subject. The Committee's findings, observations and recommendations in this regard will form the basis of subsequent progress reports.

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.....10th May, 2021.....

SEN. MBITO MICHAEL MALING'A, MP

CHAIRPERSON, STANDING COMMITTEE ON HEALTH

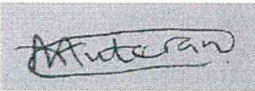
ADOPTION OF THE REPORT OF THE STANDING COMMITTEE ON HEALTH OF THE SENATE

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

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2. Sen. Mary Seneta, MP

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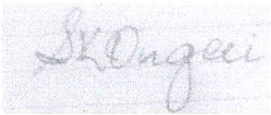
3. Sen. Beth Mugo, EGH, MP



4. Sen. Beatrice Kwamboka, MP

..... 

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

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

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7. Sen. Fred Outa, MP

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8. Sen. Millicent Omanga, MP

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9. Sen. Ledama Olekina, MP

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CHAPTER ONE

INTRODUCTION

A. Establishment, Mandate and Membership of the Committee

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.*”

The Membership of the Committee is composed of the following:

1. Sen. (Dr.) Michael Mbiti, MP.
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4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeru, EGH, MP.
6. Sen. (Dr.) Abdullahi Ali Ibrahim, CBS, MP.
7. Sen. Fred Outa, MP.
8. Sen. Ledama Olekina, MP.
9. Sen. Millicent Omanga, MP.

B. Background

1. About the Coronavirus Disease (COVID-19)

Coronaviruses are a large family of viruses that can cause illness in animals or humans. In humans, several known coronaviruses can cause respiratory infections ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS) and the Middle East Respiratory Syndrome (MERS).

COVID-19 is a disease caused by a novel strain of coronavirus that was first described in Wuhan, China in December, 2019. It literally stands for, ‘CO’ - corona; ‘VI’ - virus; ‘D’ - disease. It was formerly referred to as the ‘2019 novel coronavirus’ or ‘2019-nCoV’.

The symptoms of COVID-19 may be similar to the flu or common cold and include: fever, cough and shortness of breath. Other symptoms may include: aches and pains, sore throat, diarrhoea, conjunctivitis, headache, loss of taste and/or smell, skin rashes and discolouration of fingers and toes. In severe cases, the disease causes shortness of breath, difficulty in breathing, chest pain or pressure, loss of speech and/or movement, and even death.

The virus is spread through direct contact with respiratory droplets of an infected person (mostly through sneezing and coughing), and touching your face, eyes, mouth or nose after contact with contaminated surfaces. The virus may survive on surfaces for several hours, but is easily killed by simple disinfectants. Older people, and persons with chronic medical conditions such as heart disease, diabetes and hypertension are most at risk of contracting the disease, and developing severe symptoms.

Covid-19 transmission from one person to the next can be slowed or stopped. As with the flu, preventive actions such as handwashing, frequent cleaning surfaces and objects, covering the mouth when coughing and sneezing, social distancing etc, are critical to slowing the spread of the disease.

In recent weeks, there has been a global emergence of new highly transmissible SARS-CoV-2 variants, and a surge of confirmed cases and deaths in the region, and in Kenya in particular.

2. Declaration and Evolution of the COVID-19 Pandemic in Kenya

The World Health Organisation (WHO) declared the COVID-19 outbreak a Public Health Emergency of International Concern on 30th January, 2020. On 13th March, 2020, the Ministry of Health (MoH) announced the first confirmed case of COVID-19 within Kenyan borders.

Globally, as of 10th May, 2021, there had been 157,897,763 confirmed cases of COVID-19 with 3,287,082 deaths reported by the World Health Organisation (WHO). Of these, Africa reported 3,357,846 confirmed cases.

In Kenya, according to the WHO, as of 10th May, 2021, there had been 163,238 confirmed cases of COVID-19 with 2,883 deaths in Kenya. Comparatively, during the same period, WHO reported 42,308 confirmed cases of COVID 19 with 346 deaths in Uganda; 25,586 confirmed

cases with 338 deaths in Rwanda; and, 509 confirmed cases and 25 deaths in Tanzania.

3. Status of the Global COVID-19 Vaccine Roll-Out

To date, the WHO has approved five vaccines for deployment, namely: Pfizer BioNTech, Moderna, AstraZeneca, Johnson & Johnson and Sinopharm. Except for the Johnson and Johnson vaccine, these vaccines require two doses for optimal immunogenicity and efficacy as detailed below. According to the MoH, other vaccines are finalizing trials and are due to be reviewed by the WHO for registration soon.

Name of Vaccine	Dosage	Vaccine Type	Efficacy	Storage	Countries Using	Std Cost	Cost under CoVax Facility
Pfizer/ BioNTech	2 doses within 3 weeks	mRNA	95%	Sub-Zero	US, UK, Belgium, Canada, Greece, Germany, Sweden, Switzerland.	\$20/ dose	\$7/dose
Moderna	2 doses within 4 weeks	mRNA	95%	Sub-Zero	US, Germany, Canada, Netherlands , Spain	\$32-37 / dose	\$7/dose
Astrazeneca	2 doses within 4	Adenov irus	70%	Std. refrigerati	UK	\$3-4/ dose**	\$7/dose

	weeks	vector		on		*	
Johnson and Johnson	Single dose	Adenovirus vector	66%	Std. refrigeration	US, UK, Philippines, SA, Brazil, Columbia	\$10/dose** *	TBD
Sinopharm	2 doses within 3-4 weeks	Inactivated virus	79%	Std. refrigeration	China, UAE, Pakistan and Hungary	N/A	TBD

According to the WHO, as of 5th May, 2021, a total of 1,171,658,745 vaccine doses had been administered globally.

4. Status of the Nationwide COVID-19 Vaccine Roll-Out

According to the MoH, Kenya elected to roll-out the AstraZeneca vaccine. According to the MoH, the Astrazeneca vaccine is an adenovirus vector vaccine whose efficacy in clinical trials had been reported to range between 62-70% for disease prevention, and 100% for reduction in hospitalisation and death prevention.

According to the MoH, Kenya received her first vaccines (1,020,000 doses of the Astrazeneca vaccine from COVAX as an in-kind contribution, and 100,000 doses of the same from the Government of India as a donation) on 3rd March, 2021. The vaccines were subsequently distributed to all the 47 counties with vaccination commencing on 5th March, 2021. The total number of doses issued as of 9th May, 2021 were 1,099,000 leaving a balance of just 21,000 doses at the National Central Vaccine stores in Kitengela.

As a signed-up member of the WHO-endorsed CoVax facility, Kenya initially targeted to vaccinate 30% (or 15.8 Million) of her population within the initial phase of the roll out of the

vaccine. According to the National COVID-19 Vaccines Deployment and Vaccination Plan by the MoH (2021), targeted population groups in order of priority included: healthcare professionals, older persons above the age of 65 and people living with comorbidities, as follows:

- a. FY 2020-2021(Phase 1): 1.25 Million frontline health workers and critical/essential workers;
- b. FY 2021-2022 (Phase 2): 9.76 Million older persons (>50 years), and persons above 18 years with co-morbidities (9.76 Million); and
- c. FY 2022-2023 (Phase 3): 9.8 Million persons above 18 years in congregate settings, and in the hospitality and tourism industry (9.8 Million).

However, following a Presidential directive issued on 24th March, 2021, Kenya's targets for the COVID-19 vaccination roll-out were reviewed with 4 million Kenyan adults expected to be vaccinated by the end of June, 2021, and 26 million by end of June, 2022.

To note, according to the MoH, approximately 917,068 Kenyans had received the Government-approved AstraZeneca vaccine as of 9th March, 2021. Of these, 56% were male, while 44% were female.

According to the MoH '*Updates on the COVID-19 Vaccination Exercise*' published on 9th March, 2021, the best-performing counties in terms of total number of persons vaccinated included (*see Annex 2*):

- a) Nairobi: 277,321 (30.2%) persons vaccinated
- b) Nakuru: 63,191 (6.9%)
- c) Kiambu: 45,599 (5%)
- d) Uasin Gishu: 42,415 (4.6%)
- e) Nyeri: 34,759 (3.8%)

Conversely, counties with the least number of vaccinated persons were identified as follows:

- a) Wajir: 2,101 (0.2%)
- b) Isiolo: 1,630 (0.2%)
- c) Tana River: 842 (0.1%)

d) Lamu: 728 (0.1%)

e) Marsabit: 668 (0.1%)

With regards to progress made in meeting vaccination targets amongst target population groups, according to the MoH, as of 9th March, 2021, 29% of the total target population groups had been vaccinated broken down as follows: 77% of health workers; 43% of teachers and 11% of persons aged above 58 years of age 9 (*see Annex 2*).

To note, with the COVID-19 pandemic situation in the country escalating in recent weeks, the nationwide COVID-19 vaccine roll-out was expected to play a critical role in limiting the impact of the pandemic as a key essential element of Kenya's COVID-19 pandemic preparedness and response.

5. Financial and Budgetary Implications of the National COVID-19 Vaccination Roll-Out

According to the National COVID-19 Vaccines Deployment and Vaccination Plan by the MoH (2021) (*see Annex 3*), the total budget required to implement the COVID-19 vaccine exercise stood at Kshs.34.02 Billion at the commencement of the vaccine roll-out on 5th March, 2021. Of this, GAVI, through the COVID-19 Vaccine Global Access (COVAX) Facility was expected to provide in-kind support equivalent to Kshs.19.71 Billion through the procurement of vaccines and injection devices to vaccinate 20% of the population (approx. 11 million people). Conversely, GoK was expected to provide budgetary resources totaling Kshs.14.31 billion to vaccinate an additional 10% of the population (approx. 4.9 million people) and to cover all related operational costs.

To note, following the Presidential directive issued on 24th March, 2021, in which Kenya's performance targets for the COVID-19 vaccination roll-out were reviewed upwards to 4 million vaccinated Kenyan adults by the end of June, 2021, and 26 million by end of June, 2022, the financial and budgetary estimates for the COVID-19 vaccination roll-out as captured in the National COVID-19 Vaccines and Vaccination Plan (2021) are expected to change.

6. Methodology

Acknowledging the vital role that COVID-19 vaccines are expected to play in limiting the impact of the COVID-19 pandemic, and pursuant to the provisions of Article 118 of the Constitution and the Senate Standing Orders on public participation, between 17th March, 2021 and 30th April, 2021, the Committee invited various key stakeholders in the health sector to submit written and oral memoranda relevant to the national COVID-19 vaccine deployment and vaccination plan as follows:

a) Government Agencies and Departments

1. Ministry of Health
2. Council of Governors

b) Regulatory Bodies

3. Pharmacy and Poisons Board

c) Health Worker Representative Groups

4. Kenya Medical Association
5. Kenya Medical Practitioners and Dentists Union
6. Kenya National Union of Nurses
7. National Nurses Association of Kenya
8. Kenya Progressive Nurses Association
9. Kenya Union of Clinical Officers
10. Kenya Clinical Officers Association
11. Kenya Pharmaceutical Association
12. Kenya National Union of Pharmaceutical Technologists
13. Kenya National Union of Medical Laboratory Officers
14. Kenya Health Professionals Society
15. Association of Public Health Officers

d) Private Sector Representatives

16. Kenya Healthcare Federation (KHF)

17. Dinlas Pharma EPZ Ltd

18. Harleys Ltd

19. Unisel Pharma (K) Ltd

A summary of the Committees' findings, observations and recommendations arising from its stakeholder meetings on the nationwide COVID-19 vaccine roll-out have been captured in subsequent sections of this report.

CHAPTER TWO

COMMITTEE PROCEEDINGS

Between 17th March, 2021 and 30th April, 2021, the Committee met with, and received both written and oral memoranda from various key stakeholders in the health sector relevant to the national COVID-19 vaccine deployment and vaccination plan.

Below is a summary of the submissions presented before the Committee by the various stakeholders.

A. Health Worker Representative Groups

The Committee held a virtual consultative meeting with various health worker representative groups on Wednesday, 17th March, 2021. Key highlights of their submissions are summarised in the following section:

1. Submissions by Doctor Representative Groups

Led by Dr. Andrew Were, President, Kenya Medical Association (KMA) and Dr. Chibanzi Mwachonda, Ag. Secretary General, Kenya Medical Practitioners and Dentists Union, doctors identified the following issues and challenges in relation to the national COVID-19 vaccine deployment and vaccination plan:

- a) High levels of vaccine hesitancy and anxiety amongst health workers.
- b) Poor flow of information and communication from the MoH with regards to the vaccine roll-out.
- c) Lack of adequate engagement of health workers by the MoH prior to rolling out the vaccine leading to low uptake.
- d) Lack of clear information on accredited vaccine centres.
- e) Lack of a clear reporting structures for health workers who experienced adverse effects to the vaccine.
- f) Low levels of capacity-building and training.

Both KMA and KMPDU concluded their submissions by stating that a lot remained to be done to allay the fears of health workers in order to improve uptake of the vaccine.

2. Submissions by Nursing Representative Groups

Led by Mr. Alfred Obengo, President, National Nurses Association of Kenya (NNAK), Mr. Seth Panyako, Secretary-General, Kenya National Union of Nurses (KNUN) and Ms. Teresa Ireri, Kenya Progressive Nurses Association (KPNA), nurses identified the following key issues and challenges in relation to the national COVID-19 vaccine deployment and vaccination plan:

- a) Lack of involvement of health workers by the MoH.
- b) Lack of training and capacity-building of health workers.
- c) High levels of vaccine hesitancy amongst health workers, and low uptake of the vaccine.
- d) Low levels of acceptance and buy-in of the vaccine due to the lack of involvement and engagement of relevant stakeholders by the MoH.

Further to the above, KPNA submitted to the Committee that it had conducted a rapid assessment survey on the acceptability of the COVID-19 vaccine by nurses which had revealed that:

- 60.5% of nurses had received information on the COVID-19 vaccine;
- 19.5% were willing to get vaccinated, while 23% were unsure and 57.5% were unwilling;
- Of those who were not willing to get vaccinated, 59% had cited safety concerns; and
- Only 9.6% of nurses had indicated that they would advise their family or friends to get the COVID-19 vaccine.

Solutions offered towards addressing low vaccine uptake and hesitancy amongst nurses were identified as follows: scaling-up of training and capacity-building, involvement of nurses in national, county and sub-county planning processes, and payment of compensation for adverse effects.

3. Submissions by Clinical Officer Representative Groups

Led by Mr. Peter Wachira, Chairperson, Kenya Union of Clinical Officers (KUCO), clinical officers submitted that whilst they supported the vaccine roll-out, lack of information and poor communication from the MoH were key factors affecting the effective roll-out of the COVID-19

vaccine. They further raised concerns that vaccine hesitancy and anxiety amongst health workers was likely to extend to the community.

4. Submissions by Pharmacists

On behalf of the Pharmaceutical Society of Kenya (PSK), Dr. Louis Machogu iterated the need to better involve health workers in the vaccine roll-out. He further noted that vaccine hesitancy had been informed to a large extent by international reports of side effects to the Astrazeneca vaccine.

5. Submissions by Pharmaceutical Technologist Representative Groups

On behalf of the Kenya Pharmaceutical Association (KPA), Mr. Eric Gichane noted that while KPA supported the vaccine rollout exercise, there were safety concerns regarding the vaccine amongst majority of its members. He therefore called upon the MoH to deploy an innovative public awareness and communication strategy e.g. through the use of bulk SMS etc.

6. Submissions by Medical Laboratory Officer Representative Groups

On behalf of the Kenya National Union of Medical Laboratory Officers, Mr. Cliff Randa iterated the need for the MoH to effectively involve and engage health workers in the vaccination exercise.

7. Submissions by the Kenya Health Professionals Society

On behalf of the Kenya Health Professionals Society, Mr. Mohammed Duba stated that the MoH had not adequately involved or engaged health workers in the COVID-19 vaccine rollout exercise. This had in turn led to high levels of hesitancy amongst health workers, and low vaccine uptake.

B. Government Agencies and Departments

1. Ministry of Health

Led by Hon. Mutahi Kagwe, EGH, Cabinet Secretary, MoH, the Committee held a total four meetings in relation to the national COVID-19 vaccine roll-out exercise on diverse dates as follows: Thursday, 18th March, 2021, Thursday, 1st April, 2021, Thursday, 8th April, 2021 and Friday, 30th April, 2021. Key highlights of submissions by the MoH are summarised below:

1) Details of the COVID-19 vaccine that was being rolled-out in Kenya

At the meeting held on Thursday, 18th March, 2021, the MoH submitted that the Government of Kenya had elected to roll-out the AstraZeneca vaccine. According to the MoH, the AstraZeneca vaccine was an adenovirus vector vaccine whose efficacy in clinical trials had been reported to range between 62-70% for disease prevention, and 100% for reduction in hospitalisation and death prevention. To minimise the risk of resale of the vaccine, the MoH submitted that it was the sole distributor of the vaccine countrywide.

2) Global Supply Constraints of the AstraZeneca COVID-19 Vaccine in Kenya

The MoH submitted that Kenya had received 1,020,000 doses of AstraZeneca vaccine from COVAX as an in-kind contribution on 3rd March, 2021. The vaccines were distributed to all 47 counties with vaccination commencing on 5th March, 2021. In addition, the Government received a donation of 100,000 doses of the same vaccine from the Government of India. The total doses dispatched to regional stores as at 26th April, 2021, was 1,080,000 with a balance of 40,000 doses at the Kitengela Central Vaccines Stores.

Regarding growing concerns that the country was running out of the AstraZeneca vaccine, the MoH submitted that out of the 1.12 million AstraZeneca doses that Kenya had received, as of 30th April, 2021, the total number of persons vaccinated stood at 853,081. Fifty-six per cent (56%) of these are males while forty-four (44%) were females.

Noting that Kenya was facing an imminent vaccine shortage with the 853,081 vaccinated persons due for their second dose within 8-12 weeks, the MoH cited global supply constraints occasioned by the decision by the Government of India to prioritize vaccination for its own population, and the inability of the Serum Institute of India, which is the largest vaccine manufacturer in the

world to meet the global demand.

Consequent to the aforementioned decision by the Government of India, COVAX had informed Kenya of an expected delay in the shipment of 2.5 million out of the 3.5 million doses of AstraZeneca vaccines that had been allocated to Kenya for the period between February to May 2021.

Further to the global vaccine supply constraints, the MoH identified the following challenges as having triggered the vaccine shortage in the country:

- a) Variance in the initial target groups, and the expanded target groups following the Presidential directive to include elderly and vulnerable persons in Phase One of the vaccination exercise.
- b) Non-priority persons showing up at the vaccination centres.
- 3) Reporting challenges through the *Chanjo* System owing to overwhelmed health facilities opting to use manual systems.

4) *Contingency Measures taken by the Government to mitigate against the Global Supply Constraints of the AstraZeneca COVID-19 Vaccine in Kenya*

Noting that the global vaccine shortages were beyond Kenya and indeed Covax, the MoH outlined the following measures it had taken with a view towards ensuring availability and accessibility to COVID-19 vaccines in the country, and vaccinating the entire adult population of 26 million by June, 2022:

- a) Extension of the duration between the administration of the first dose and the second dose from 8 to 12 weeks. Consequent to this decision, the first recipients of the second dose would be expected to receive their booster dose during the first week of June 2021, by which time the supplies from Covax were expected to have been received.
- b) Engagement with the African Union for purposes of procuring 7 million doses of Pfizer and 10 million vaccine doses of Johnson and Johnson. This was expected to yield the vaccination of an additional 13.5 million Kenyans.
- c) Receipt of a donation of a further 20 million doses of Astrazeneca vaccine from COVAX, with plans to procure 11 million additional doses from the same facility.

5) Recommended Dosage of the AstraZeneca COVID-19 Vaccine in Kenya

In view of the prevailing global vaccine supply constraints, and taking into consideration guidance from the WHO and existing evidence that indicated that taking a booster dose at 12 weeks provided a higher immune response and better protection, the MoH submitted that it had revised the duration between the administration of the first and second dose from 8 to 12 weeks.

6) Target Populations in the National COVID-19 Vaccination Exercise

Noting that the greatest utility of COVID-19 vaccines was in preventing severe disease, reducing hospitalization and deaths, the MoH submitted that the Government was targeting to reach 4 million Kenyan adults by June, 2021 and 26 million by June, 2022.

The MoH further submitted that as of 27th April, 2021, 154,031 health workers, 70,467 security personnel, 129,527 teachers, 259,961 persons above 58 years of age and 226,089 'others' had received vaccinations. This represented 74% of targeted health workers, 39% of targeted teachers and 10% of persons above 58 years.

7) Reports of Adverse Side Effects and/or Deaths that had been attributed to the AstraZeneca vaccine

The MoH submitted that the common side effects associated with the AstraZeneca vaccine included pain at the injection site, headache, tiredness and muscle ache. The MoH further submitted that no major adverse effects and/or deaths had been reported against the vaccine.

While noting that some countries had suspended the use of the vaccine due to a linkage with blood clots, the MoH reported that no direct link or causality had been established. The MoH further noted that despite the reports of blood clots, several countries had resumed the use of the vaccine including Canada, Spain, Italy, France and Belgium. Nevertheless, the MoH and Pharmacy and Poisons Board were closely monitoring the situation.

8) Details of the Financial and Budgetary Implications of the COVID-19 vaccine roll-out (including cold chain, storage, logistics etc)

With regards to the financial and budgetary implications of the COVID-19 vaccine roll-out, at the meeting held on Thursday, 18th March, 2021, the MoH submitted that the Government of

Kenya was in the process of mobilising a total of KShs. 34,017,623,939.00 over a three-year period for the vaccination exercise as follows:

- a) Procurement of vaccines and injection devices for 30% of the population: KShs. 30,848,190,230.00 broken down as follows:
 - GoK: KShs. 11,137,133,621.00
 - GAVI: KShs. 19,711,056,609.00
- b) Operational costs (capacity-building, communication, mobilization, cold storage etc): KShs. 3,169,433,710.000

The MoH further submitted that the budget had been broken down across three financial years as follows:

- a) FY 2020-2021(Phase 1): KShs. 1.65B by the GoK, and KShs. 2.248B by GAVI;
- b) FY 2021-2022 (Phase 2): KShs. 3.755B by GoK, and KShs. 17.462B by GAVI; and
- c) FY 2022-2023 (Phase 3): KShs. 8.895B by GoK.

9) Proposed Mechanisms for the Public Procurement of COVID-19 Vaccines

With regards to how COVID-19 vaccines were going to be procured, the MoH submitted that the Government's intention was to procure any government-approved vaccines through three mechanisms:

- a) The COVAX Facility, through which Kenya was currently getting the AstraZeneca vaccine;
- b) The AFRICA CDC Platform; and/or
- c) Directly from manufacturers through bilateral agreements.

To note, the MoH submitted that no private companies and/or entities would be involved in the importation, distribution and/or administration of the Johnson and Johnson COVID-19 vaccine, or any other Government-approved COVID-19 vaccine for public distribution.

10) Measures taken by the MoH to facilitate the seamless roll-out of the vaccine to all Kenyans

With regards to which measures the MoH had taken to facilitate the seamless roll-out of the vaccine to all Kenyans, the MoH submitted as follows:

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- a) The MoH had developed and was implementing the National Vaccine Deployment Plan (NVDP);
 - b) The MoH had mapped out vaccine storage capacity for both positive and negative temperature vaccines at the central and regional vaccine stores;
 - c) Six-hundred and twenty-two (622) public, private and faith-based health facilities had been identified and mapped to administer the vaccine;
 - d) The MoH had deployed a robust county engagement exercise through a micro planning process aimed at mapping and validating target groups;
 - e) Training and capacity-building of 35 National Master Trainers, 235 county TOTs and 110 health workers; and
 - f) Development of a communication plan aimed at ensuring the buy-in of key stakeholders, creating vaccine demand and addressing hesitancy issues.

11) Capacity of Kenya's Cold Chain System and Vaccine Storage facilities in relation to the COVID-19 vaccine roll-out

On the capacity of Kenya's cold chain system and vaccine storage facilities in relation to the COVID-19 vaccine roll-out, the MoH submitted that it had adequate storage for the introduction and roll-out of the vaccines, including:

- a) The National Vaccine Depot in Kitengela;
- b) Nine regional depots in Kakamega, Kisumu, Nakuru, Eldoret, Meru, Mombasa, Garissa, Nyeri and Nairobi;
- c) Three County depots in Mandera, Wajir and Turkana;
- d) 290 sub-county vaccine stores; and
- e) 7,877 immunizing health facilities countrywide.

The MoH further submitted that while there existed significant inequities in cold chain capacity distribution across the counties, it intended to bridge any existing gaps through:

- a) Procurement and installation of additional cold chain equipment;
- b) Implementation of an ongoing Cold Chain Equipment Optimization Platform Project with the support of GAVI;
- c) Redistribution of cold chain equipment across the counties; and
- d) Collaboration with the private sector for cold chain storage.

12) Measures taken by the MoH to ensure the effective involvement and engagement of County Governments and other stakeholders in the Vaccine Roll-Out

With regards to what measures the MoH had taken to ensure the effective involvement and engagement of County Governments and other stakeholders in the vaccine roll-out, the MoH submitted that it had established multi-stakeholder coordination structures at national, county and sub-county levels.

Noting that the private, civic and religious sectors were represented at the national coordination level, the MoH submitted that the National Level Steering and Planning Committee provided overall policy direction, oversight and technical leadership , while county and sub-county coordination committees were responsible for executing the policies and service delivery.

13) Importation and Distribution of the Russian-Manufactured Sputnik-V Vaccine

a) Status of Approval of the Russian-Manufactured Sputnik-V Vaccine by the World Health Organisation

The MoH submitted that the Russian-manufactured Sputnik COVID-19 vaccine had not been approved for use by the World Health Organisation.

b) Status of Emergency Use Authorisation for the Importation and Distribution of the Russian-manufactured Sputnik-V vaccine in Kenya

With regards to the importation and distribution of the Russian-manufactured Sputnik-V vaccine in Kenya, at the meeting held on Thursday, 1st April, 2021, the MoH submitted that the vaccine had been granted Emergency Use Authorization (EUA) by the Pharmacy and Poisons Board for use in Kenya.

c) Processes and Procedures followed in providing the Emergency Use Authorisation for the Importation and Distribution of the Sputnik-V COVID-10 Vaccine in Kenya

In terms of the procedure that was followed in granting the EUA, the MoH submitted that the initial application was submitted on 5th February 2021. Subsequently, the first assessment on the quality, efficacy and safety of the vaccine was initiated on 8th February 2021 and completed on 24th February 2021. Communication was then sent out to the applicant(s) raising relevant queries on the product.

Subsequently, a second round of assessment of the vaccine was undertaken on 5th March 2021 whereby the responses made to the queries by the applicant were considered and found to be satisfactory. Consequently, based on available data on the safety, quality and efficacy, the vaccine was found to have met all the requirements for Emergency Use Authorization in line with the PPB Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA).

d) Authorised Companies for the Importation and Distribution of the Sputnik-V Vaccine

With regards to which companies had received authorization for the importation and distribution of the said vaccine, the MoH submitted that the authorized importer of the vaccine was Dinlas Pharma EPZ Ltd, as the local technical representative of the Emergency Use Authorization holder. Further, that as the authorized importer, Dinlas Pharma Ltd had appointed two (2) recognized wholesale distributors namely: Harleys Ltd and Unisel Pharma (K) Ltd to facilitate the distribution of the said vaccine in the country.

e) Safety Profile, Efficacy and known Side Effects of the Sputnik-V COVID-19 Vaccine

On the safety profile, efficacy and known side effects of the Sputnik COVID-19 vaccine, at the meeting held on Thursday, 1st April, 2021, the MoH reported that the safety and efficacy of the vaccine had been established through a multicenter clinical trial that was conducted in 25 clinical trial sites in Moscow. Clinical data derived from the study indicated evidence of high efficacy (96%) of the study vaccine. Side effects of the vaccine reported from the vaccine study were reported as follows:

- General disorders and reactions at the injection site included: pyrexia, pain, edema, itching at the vaccination site, asthenia, pain, malaise, pyrexia, increased skin temperature at the vaccination site, decreased appetite.
- Nervous system: headache.
- Gastrointestinal system: diarrhoea.
- Respiratory system, chest and mediastinal organs: pain in the oropharynx, nasal congestion, sore throat, rhinorrhoea.
- Laboratory and instrumental data: multidirectional deviations of indicators of immunological status.

f) Reports of Adverse Effects and/or Deaths attributable to the Sputnik-V Vaccine at the Global, Regional and Local Level

Further, with regards to which adverse side effects and/or deaths had been attributed to the Sputnik-V vaccine at the global, regional and local level, at the meeting held on Thursday, 1st April, 2021, the MoH reported that according to the World Health Organisation Global Database for individual case safety reports (ICSRs), as of 28th March 2021, all identified Adverse Events (AES) attributable to the Sputnik V vaccine had been considered mild, and less often of moderate severity with a flu-like syndrome which was stopped by painkillers and antihistamines. The MoH further submitted that the majority of the Adverse Events Following Immunisation (AEFIS) reported against the Sputnik V vaccine were not classified as serious. Typical adverse effects following immunisation were reported as follows: headache, myalgia (muscle soreness and achiness), hyperhidrosis (excessive sweating), fatigue and urticaria (skin rash). The MoH further reported that no deaths had been reported so far due to the vaccine.

g) Cancellation of Licenses for the Importation, Distribution and Administration of the Russian-Manufactured Sputnik V Vaccine

At the meeting held on Thursday, 8th April, 2021, the MoH submitted to the Committee that licenses for the importation, distribution and administration of Sputnik-V vaccine had been cancelled following a resolution of the National Emergency Response Committee (NERC). Justifications for the cancellation of the licenses were provided as outlined below:

- a) Need for greater transparency and accountability in the private importation, distribution and administration of COVID-19 vaccines in public interest.
- b) Illegal marketing of the vaccine by appointed distributors in contravention of PPB guidelines, which prohibit marketing when a product is still under Emergency Use Authorization (EUA).
- c) Irregular deployment of the Sputnik V vaccine by the appointed distributors thereby leading to concerns of the likely introduction of counterfeit vaccines into the Kenyan market thus putting the country at further risk of COVID-19 spread and increased morbidity and mortality.
- d) Lack of approval by the WHO under the Emergency Use Listing. As such, the Government would not be able to guarantee the safety of the vaccine being deployed.

Further, the MoH submitted that it was empowered under Section 158(1) of the Public Health Act, to prohibit the importation, manufacture or use of any such substance, which is considered to be unsafe or liable to be harmful or deleterious, thus: *"the Minister may provide for the inspection, sampling and examination, by officers of the Medical Department, of vaccines, vaccine lymph, sera and similar substances imported or manufactured in Kenya and intended or used for the prevention or treatment of human diseases, and may prohibit the importation, manufacture or use of any such substance which is considered to be unsafe or to be liable to be harmful or deleterious."*

However, the MoH stated that all persons who had received their first dose of Sputnik-V vaccine, and were due for a second dose in 3 weeks were assured of receiving their dose to complete the vaccination. The MoH however submitted that this criterion would only apply to the 527 vaccination cases which had been reported in the *Chanjo*-KE System at the time of the ban.

14) Government Position and Policy on the role and involvement of the Private Sector in the COVID-19 Vaccination Roll-Out

Regarding the official Government policy and position on the role and involvement of the private sector in the COVID-19 vaccination roll-out exercise, at the meeting held on 1st April, 2021, the MoH submitted that the Pharmacy and Poisons Board (PPB) had developed a Guidance Document on *'The Role of Private Sector In The Deployment of Covid-19 Vaccines'* to provide guidance to the private sector for the importation, distribution and deployment of COVID-19 vaccines in Kenya.

With regards to whether the private sector would be allowed to participate in the importation and distribution of COVID-19 vaccines, at the meeting held on 8th April, 2021, the MoH submitted that it had constituted a team with representatives from the Kenya Medical Practitioners and Dentists Council (KMPDC) and the PPB for purposes of engaging the private sector in developing a framework to guide private sector involvement in the importation, distribution and administration of approved COVID-19 vaccines. This was aimed at ensuring that the Government came up with a transparent and accountable system that would ensure public health safety at all times. With regards to the proposed timelines, the MoH stated that the plan was to

have the framework in place by the end of June, 2021, and for the private sector to join the vaccine roll-out plan by July, 2021.

However, at the meeting held on 30th April, 2021, the MoH communicated a shift in policy by the Government in which a decision had been reached to restrict the role of the private sector in the importation, distribution and administration of Covid-19 vaccines.

15) COVID-19 Vaccines awaiting registration/authorisation for use in Kenya

According to the MoH, Kenya was in receipt of applications for authorization of COVID-19 vaccines from various companies, including: COVAXIN manufactured by Bharat Biotech International Limited (India) whose local technical representative was Simba Pharmaceuticals Ltd, Pfizer, Johnson and Johnson, and various companies from China.

16) Measures taken by the Government to guarantee the health and safety of Kenyans in relation to the introduction of COVID-19 vaccines

With regards to what steps the MoH had undertaken to guarantee the health and safety of Kenyans in relation to the introduction of COVID-19 vaccines by private sector players, the MoH submitted that Kenya had put in place an independent National Vaccine Safety Advisory Committee (NVSAC) composed of experts from different professional backgrounds that continuously provided advice to the Ministry on matters regarding vaccine safety. The Committee consisted of pediatricians, vaccinology experts, epidemiologists, pharmacologists, physicians, pharmacists, pharmacovigilance experts, infectious disease specialists, pathologists and others.

The MoH further submitted that it had deployed a robust monitoring system to identify, report, and investigate all adverse events following immunization (AEFIs) by leveraging heavily on the current immunization AEFI reporting structures and the electronic PPB reporting system.

In addition, the MoH reported that it had undertaken training and capacity building of health workers on vaccine management and safety reporting (including vaccine pharmacovigilance) prior to the COVID Vaccine roll out for purposes of eliminating any programmatic errors and ensuring that AEFIs were picked up, reported in a timely manner and investigated.

Further, the MoH reported that it had invested in specialized vaccine storage and monitoring

equipment to ensure the COVID-19 Vaccines and others were maintained in the highest quality possible, to minimize any potential side effects.

16) *Monitoring and Evaluation of the COVID-19 Vaccines*

In order to monitor and evaluate the impact of the COVID-19 vaccine, the MoH submitted that it was monitoring the number of hospitalizations to establish whether infection rates were coming down or not. Further, it was checking amongst those hospitalized, who was vaccinated and who was not vaccinated so as to evaluate the impact of the vaccination.

As to the impact of the vaccination exercise on the overall transmission of the COVID-19 disease, the MoH submitted that it was going to monitor this by the number of confirmed cases. In addition, it was collaborating with KEMRI and other academic institutions to document the impact of its vaccination programme.

17) *Presence of COVID-19 Variants in Kenya*

With regards to the presence of COVID variants in the country, the MoH submitted that between 28th February and 5th March, 2021, they had sequenced approximately 33 samples that had been picked from Nairobi and the coastal region. Out of these, 19 variants of the coronavirus were picked, 15 of which were the South African variant, and one UK variant. Majority of the people in whom the variants were detected had a history of travel. Of note however, the MoH reported that it had also picked variants from people with no history of travel thus implying that Kenya had the seeds for variants that could potentially lead to community transmission.

Copies of the written submissions by MoH have been attached hereto as Annex 4.

2. Council of Governors

The Committee held a virtual consultative meeting with the Council of Governors led by Gov. (Prof.) Anyang Nyong'o, EGH, on Thursday, 18th March, 2021. Key highlights of submissions by COG are summarised below:

In its statement, COG submitted that the Government of Kenya had commenced the roll out of the COVID 19 Vaccination Program across the 47 counties with a view towards reducing COVID 19 transmission and reducing the burden of disease and deaths from COVID 19.

COG further stated that the nationwide COVID-19 vaccine roll out plan was targeting approximately 15 million persons (30% of the total population) to be undertaken in three phases between March 2021 to June 2023 at a total cost of KES 34 billion.

Noting that the COVID-19 vaccine roll-out process was being coordinated by the National COVID-19 Vaccine Deployment Task Force with oversight from the National COVID-19 Vaccine Deployment and Vaccination Steering Committee (NSC) at the national level, COG submitted that it was represented in the Steering Committee by the Chair of COG and the technical lead for the COG Health Committee in the Task Force.

At the county level, COG submitted that the process was overseen by County COVID-19 Vaccine Deployment and Vaccination Steering Committees (CSC) chaired by the Governor, with technical guidance from the County COVID-19 Vaccine Deployment and Vaccination Taskforce chaired by the County Director for Health at the county, and the sub-county director for health at the sub-county level. The COG further confirmed that all 47 County Governments had put in place the necessary governance and management structures to enable the effective roll out of the vaccine.

COG further submitted that all 47 County Governments had established covid-19 vaccine deployment and vaccination task forces, at both the County and sub-County levels which were responsible for coordinating Covid -19 vaccine roll out activities in the Counties. Further, the county task forces were responsible for closely monitoring the progress of the roll out activities and facilitating resolution of bottlenecks.

In addition, COG submitted that all 47 counties had undertaken readiness assessments of targeted COVID 19 – Vaccination sites, documented existing capacity gaps and mapped target population by catchment for the Phase 1 vaccination roll out.

Counties were also in the process of developing detailed plans (micro-plans) to cover the three phases of vaccination and comprehensively address aspects such as capacity building of staff, robust social mobilization and communication, supply planning for sites, safe storage, transportation, distribution and redistribution of vaccine doses, and monitoring and reporting on adverse effects.

Noting that counties had so far received COVID -19 vaccine doses totaling to 318,045, the COG submitted that each county government was expected to make the logistical arrangements necessary for picking up vaccines from the nearest regional vaccines depots and subsequently distributing them to their immunization sites.

Further, the COG reported that all counties were providing regular reports on the progress of COVID-19 Vaccine roll out through the *Chanjo* electronic logistics management information system (eLMIS).

With regards to training and capacity-building, the COG observed that the MoH had developed a training program that blended both physical and virtual components for building skills of county health staff on the COVID-19 disease; knowledge and skills in COVID-19 vaccine demand creation, health facility preparation, safe vaccine administration, infection control practices, patient data management, adverse event reporting and management, documentation and monitoring of vaccine utilization and logistics. Roll out of the training was ongoing with 329 Trainers of Trainers (TOT) having been trained from all the 47 counties. At the time of the meeting, COG reported that a total of 2,937 health care workers of various cadres had been trained on the Covid 19-vaccine for the Phase 1 roll-out. Further, COG submitted that plans for scaling up of the training to cover all staff involved in the immunization process had been formulated, and that counties were mobilizing resources for the same.

The COG further submitted that in terms of vaccination of target populations, a total of 15,305 frontline health care workers from the 47 counties had received the COVID 19 vaccine (1st dose) as of 16th March 2021.

Further, COG submitted that County Governments were undertaking close monitoring of the immunization processes including identification, reporting and investigation of adverse events in close collaboration with the National Vaccines Program (NVP) and the Pharmacy and Poisons Board (PPB). Further, that County governments had established systems to complement the national government in identifying and addressing safety concerns (both real and perceived) on a timely basis.

COG further submitted that all counties had instituted focal point persons for surveillance at county and sub-county levels who were responsible for collating incident reports from health workers and other sources. Based on the reports collated so far, the COG reported that common side effects to the Astrazeneca vaccine included: pain/swelling at the injection site, myalgia (muscle pain), headache, low grade fever, facial swelling, generalized body malaise, nausea and loose stool, abdominal discomfort, vomiting, dizziness and itchiness, fatigue, night sweats.

Despite the notable achievements demonstrated by the county governments, the COG noted the following challenges with the national roll-out of the Astrazeneca vaccine:

- a) Slow uptake of the vaccine by health care workers owing to social media misinformation on the side effects of the AstraZeneca vaccine (particularly blood clots) as well as global misinformation of the vaccine;
- b) Inadequate funding to support training and the vaccine roll out at the counties;
- c) Overstretched logistical and human resource capacity;
- d) Inadequate reporting tools including AEFI forms and tablets for online registration into the *Chanjo* system; and,
- e) High levels of internet downtime.

Further, the COG noted that since Phase 1 of the vaccination exercise was being carried out at level 4 and 5 facilities, staff had been compelled to travel long distances to designated sites thus increasing the opportunity cost on lost time for service delivery.

In conclusion, COG submitted that County Governments were making concerted efforts to address the above mentioned challenges through various means including stakeholder engagement, resource mobilisation and implementation of public awareness and sensitization activities.

Copies of the written submissions by COG have been attached hereto as Annex 5.

C. Health Regulatory Bodies

1. Pharmacy and Poisons Board

The Committee held a virtual consultative meeting with the Pharmacy and Poisons Board (PPB) led by Dr. Fred Siyoi on Monday, 29th March, 2021. Key highlights of submissions by PPB are summarised below:

In his statement, Dr. Siyoi stated that PPB had granted the Russian-manufactured Sputnik COVID-19 vaccine Emergency Use Authorization (EUA) in Kenya in line with the Pharmacy and Poisons Board Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA).

He further stated that with regard to the standard procedures and processes for the registration and/or authorization of health products in Kenya, particularly vaccines, the Board was guided by the Pharmacy and Poisons (Registration of Drugs) Rules, the details of which were contained in several technical guidelines available on the organization website namely:

- a. Guidelines for Registration of Human medicine
- b. Guidelines for Registration of Human Vaccine
- c. Medical devices and Invitro diagnostic Guideline
- d. Biotherapeutic Guideline
- e. Blood and Blood product Guideline
- f. Guidelines on herbal and Complementary/alternative medicines
- g. Guidelines on the Safety and Vigilance of Medical Products and Health Technologies

He further submitted that the PPB was mandated to implement several types of registrations/authorizations for medical products and health technologies including full Market Authorizations (MAs), Conditional marketing authorization, Listing and Emergency use Authorizations (EUAs).

In addition, Dr. Siyoi stated that in the wake of the COVID-19 pandemic, the Board had streamlined its processes to facilitate expedited access and availability of medical products and technologies. This had culminated in the development of the Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA) under Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244.

With regards to the requirements for EUA, he stated that while it required less comprehensive data (particularly, clinical data), it was subject to certain obligations. He further submitted that all EUA applicants were required to submit the current clinical trials data, arising pharmacovigilance issues, regulatory processes followed etc.

He further stated that the Board had issued a permit for the importation of the Sputnik V Vaccine to a private company known as DINLAS Pharma EPZ Ltd as it had met the Emergency use authorization requirements set out by the Board.

He further noted that as the authorized importer, Dinlas Pharma Ltd had appointed two (2) recognized wholesale distributors namely: Harleys Ltd and Unisel Pharma (K) Ltd to facilitate the distribution of the said vaccine in the country.

Regarding the processes and/or procedures that PPB had followed in authorising the importation of the Sputnik COVID-19 vaccines by private entities, the Board submitted that it had developed a Guidance Document on the '*Role of Private Sector In The Deployment of Covid-19 Vaccines*' to provide guidance to the pharmaceutical industry on the documentation requirements and procedure for rollout of COVID-19 vaccines by the private sector.

He further submitted a summary of the requirements followed in granting the import authorization for the vaccine as follows:

- a. The applicant must be duly licensed by the Board as a wholesale dealer in medical products and health technologies;
- b. The applicant must have an emergency use authorization (EUA) for the product duly issued by the Board;
- c. Proforma invoice/commercial invoice indicating what type of vaccine being imported and quantities;
- d. Certificate of analysis (COA)/Batch release certificates indicating the Batch numbers of the vaccines being imported;
- e. The applicant must provide a valid Indemnity insurance policy as a commitment to bear liability in case persons suffer loss or injury from the use of the vaccine;

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- f. In case of appointed distributors, provide a technical agreement between the emergency use authorization holder and the distributor clearly stipulating the roles and responsibilities of each party.

Regarding applications for the importation and distribution of COVID-19 vaccines by private entities that were awaiting registration/authorisation by the Poisons and Pharmacy Board, Dr. Siyoi submitted that as at 28th March 2021, the Pharmacy and Poisons Board had received only one (1) application for authorization of a COVID-19 vaccine namely: Product Name: COVAXIN manufactured by Bharat Biotech International Limited, India whose local technical representative was Simba Pharmaceuticals Ltd.

Dr. Siyoi further submitted that the emergency authorisation for the Sputnik vaccine had been done with the full knowledge and authority of the MoH. He further confirmed that the companies in question had fulfilled all the regulatory requirements to start distribution in Kenya.

With regards to its role in monitoring side effects and adverse events arising from the vaccine, the Board submitted that it was using the *Chanjo* Information management system as well as a robust pharmacovigilance system at health facility and individual level.

Copies of the written submissions by PPB have been attached hereto as Annex 6.

D. Private Sector Players

1. Dinlas Pharma EPZ Ltd

The Committee held a virtual consultative meeting with Dinlas Pharma EPZ Ltd on Monday, 29th March, 2021. Led by Mr. Rufus Maina, Director, Strategic Initiatives and Legal, Dinlas Pharma EPZ Ltd submitted its statement to the Committee as follows:

Dinlas submitted that the Sputnik vaccine was one of the top three globally recognised vaccines having been approved for use by government regulators in over 56 countries.

Dinlas further submitted that the Sputnik vaccine had been approved for emergency use by the PPB as the mandated regulatory body, and in accordance with the Pharmacy and Poisons (Registration of Drugs) Rules.

Dinlas further submitted that it had received emergency authorization from the PPB to import the Sputnik vaccine for use and distribution in Kenya as evidenced by the issuance of its Emergency Use Authorization (EUA) certificate (No. H2021/ctd/8457/19767EUA). The company further confirmed that it had received the emergency authorization on 9th March, 2021 having applied for it on 2nd February, 2021.

The company further stated that it had obtained all the relevant regulatory permits and approvals for the importation of the vaccine including the Emergency Use Authorization certificate, Import permit approvals and a Wholesale Dealers license.

With regards to COVID-19 vaccine-related consignments that the company had received for distribution in Kenya, Dinlas submitted that on 22nd March, 2021 it had received a total of 75,000 doses of the vaccine with 50,000 being Component I, and 25,000 being Component II. At the time of the meeting, the consignment was being held at a cold storage facility run by Freight-in-Time at the Jomo Kenyatta International Airport in Nairobi.

With regards to projected costs, Dinlas submitted that it was yet to determine the final cost of the vaccine as it was still incurring storage charges at the cold storage facility in JKIA. Further, it was yet to determine any additional logistics and transportation charges necessary to get the vaccine to the end-user.

The company further submitted that it had duly entered into technical and distribution agreements with Harley's Limited and Unisel Pharm (K) Ltd for the distribution of the vaccine in Kenya.

Copies of the written submissions by Dinlas Pharma EPZ Ltd have been attached hereto as Annex 7.

2. Harleys Ltd and Unisel Pharma Ltd

The Committee held a virtual consultative meeting with Harleys Ltd and Unisel Pharma Ltd on Monday, 29th March, 2021. Led by Mr. Sudhir Padhke (Unisel), Harleys Ltd and Unisel Pharma (K) Ltd issued a joint statement in which they submitted that the Sputnik vaccine was one of the top three globally recognised vaccines having been approved for use by government regulators in over 56 countries. The companies further submitted that the vaccine had been approved for emergency use by the Pharmacy and Poisons Board of Kenya as the mandated regulatory body, and in accordance with the Pharmacy and Poisons (Registration of Drugs) Rules.

Regarding whether the two companies had received authorization from the PPB to distribute the Sputnik vaccine, the companies responded in the affirmative and presented the relevant certification from PPB (Authorization UCR No. UCR202102594997).

The companies further submitted that they had received all the relevant regulatory permits and approvals for the distribution of the Sputnik COVID-19 vaccine in Kenya. They had however, not received any consignments for distribution from the importer, and had not commenced distribution to any hospitals at the time of the meeting.

The companies further submitted that they were yet to determine the cost of the vaccine as they were yet to determine the final pricing details from the importer.

Copies of the written submissions by Harleys Ltd and Unisel Pharma Ltd have been attached hereto as Annex 8.

3. Kenya Healthcare Federation

The Committee held a virtual consultative meeting with the Kenya Healthcare Federation (KHF) led by Dr. Amit Thakker, President on Monday, 19th April, 2021. Key highlights of submissions by KHF are summarised below:

In their submissions, KHF stated that within the context of the global pandemic, rising levels of confirmed cases and deaths attributable to COVID-19 amidst a third wave and a concomitant strain on the health system, multi-stakeholder engagement on the COVID-19 vaccine deployment in Kenya was key.

KHF further identified the following challenges affecting COVID-19 vaccine deployment in Kenya: sluggish/slow rate of deployment, over-reliance on COVAX, weak communication strategy by the MoH, high levels of vaccine hesitancy, confusion and angst.

The KHF further outlined the potential role of the private sector as follows: importation and sourcing, logistics and distribution, administration of vaccinations, technology and administrative support.

KHF further identified the following areas on which the private sector could be used to complement Government efforts in the deployment of the COVID-19 vaccine: administration of vaccinations at a dispensing fee at accredited private sector facilities; ICT and administrative support through the enhancement of the *Chanjo* information management system, communications and PR support etc; and, provision of logistics and distribution expertise to improve reach and enhance efficiency. The KHF further submitted that it was in the process of reviewing a policy framework in collaboration with PPB and the Kenya Medical Practitioners and Dentists Council (KMPDC) for the importation and distribution of COVID-19 vaccines.

In its submissions, KHF further submitted that it had appealed the Government's decision to cancel the licenses and permits for the importation, distribution and administration of the Russian-manufactured COVID-19 Sputnik-V vaccine. The federation nonetheless stated that the distributors of the vaccine had engaged in unscrupulous business practices by advertising the vaccine, and administering it in non-authorized premises.

Copies of the written submissions by KHF have been attached hereto as Annex 9.

CHAPTER THREE

COMMITTEE OBSERVATIONS

The Committee made the following observations:

a) Status of the National COVID-19 Vaccination Roll-Out

1. The Committee noted that according to the World Health Organisation (WHO) and the Ministry of Health (MoH), the greatest utility of COVID-19 vaccines is in the prevention of severe disease and in the reduction of hospitalizations and deaths.
2. The Committee noted that as a signed-up member of the WHO-endorsed COVAX facility, Kenya had initially targeted to vaccinate 30% (or 15.8 Million) of her population within the initial phase of the roll out of the vaccine. According to the National COVID-19 Vaccines Deployment and Vaccination Plan by the MoH (2021), targeted population groups in order of priority included: healthcare professionals, older persons above the age of 65 and people living with comorbidities, as follows:
 - FY 2020-2021(Phase 1): 1.25 Million frontline health workers and critical/essential workers;
 - FY 2021-2022 (Phase 2): 9.76 Million older persons (>50 years), and persons above 18 years with co-morbidities (9.76 Million); and
 - FY 2022-2023 (Phase 3): 9.8 Million persons above 18 years in congregate settings, and in the hospitality and tourism industry (9.8 Million).
3. The Committee further observed that, according to the Ministry of Health, following a Presidential directive issued on 24th March, 2021, the Government subsequently reviewed its vaccination targets upwards to 4 million Kenyan adults by June, 2021 and 26 million by June, 2022.
4. The Committee noted that the number of doses of the Astrazeneca vaccine that Kenya had received as at the time of writing this report was 1,020,000 doses from COVAX as an in-kind contribution on 3rd March, 2021, and 100,000 doses from the Government of India. The vaccines were subsequently distributed to all the 47 counties with vaccination commencing on 5th March, 2021. The total number of vaccine doses that had been issued as of 9th May, 2021 were 1,099,000 leaving a balance of just 21,000 doses at the

National Central Vaccine stores in Kitengela.

5. The Committee further noted that according to the MoH, out of the 1.12 million Astrazeneca doses that Kenya had received, as of 9th May, 2021, the total number of persons vaccinated stood at 917,068 of which 56% of these are males while 44% were females.

b) Financial and Budgetary Implications of the National COVID-19 Vaccination Roll-Out

6. The Committee noted that according to the National COVID-19 Vaccines Deployment and Vaccination Plan by the MoH (2021) the total budget required to implement the COVID-19 vaccine exercise stood at Kshs.34.02 Billion at the commencement of the vaccine roll-out on 5th March, 2021. Of this, GAVI, through the COVID-19 Vaccine Global Access (COVAX) Facility was expected to provide in-kind support equivalent to Kshs.19.71 Billion through the procurement of vaccines and injection devices to vaccinate 20% of the population (approx. 11 million people). Conversely, GoK was expected to provide budgetary resources totaling Kshs.14.31 billion to vaccinate an additional 10% of the population (approx. 4.9 million people) and to cover all related operational costs
7. The Committee observed that following the Presidential directive issued on 24th March, 2021, in which Kenya's performance targets for the COVID-19 vaccination roll-out were reviewed upwards to 4 million vaccinated Kenyan adults by the end of June, 2021, and 26 million by end of June, 2022, the financial and budgetary estimates for the COVID-19 vaccination roll-out as captured in the National COVID-19 Vaccines and Vaccination Plan (2021) were likely to change.

c) County Performance in the COVID-19 Vaccination Exercise

8. The Committee observed that according to the MoH '*Updates on the COVID-19 Vaccination Exercise*' published on 5th March, 2021, the best-performing counties in terms of total number of persons vaccinated included: Nairobi: 277,321 (30.2%) persons vaccinated; Nakuru: 63,191 (6.9%); Kiambu: 45,599 (5%); Uasin Gishu: 42,415 (4.6%); and, Nyeri: 34,759 (3.8%).

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9. Conversely, the Committee observed that the MoH had identified the counties with the least number of vaccinated persons as follows: Wajir: 2,101 (0.2%); Isiolo: 1,630 (0.2%); Tana River: 842 (0.1%); Lamu: 728 (0.1%) and Marsabit: 668 (0.1%)

d) Country Performance in Key Target Populations

10. In relation to Kenya's performance in key target populations, the Committee noted that, according to the MoH, as of 9th March, 2021, 29% of the total target population groups had received COVID-19 vaccinations broken down as follows: 77% of health workers (160,947 vaccinated against a target population of 208,481); 43% of teachers (143,684 vaccinated against a target of 330,671); and, 11% of persons aged above 58 years of age (280,876 against a target population of 2,594,585).
11. Noting that schools were set to open by 10th May, 2021, the Committee observed that at just 43%, the proportion of vaccinated teachers remained worryingly low and posed a significant risk for increased community transmission of COVID-19.

e) COVID-19 Vaccine Shortages in Kenya

12. Based on Kenya's target to vaccinate 4 million adults by June, 2021, against an availability of only approx. 21,000 AstraZeneca doses in Kenya's central vaccine stores in Kitengela as of 9th May, 2021, and in view of the fact that the 853,081 vaccinated persons will be due for their second dose by June, 2021, the Committee observed that Kenya faces an imminent acute shortage in the COVID-19 vaccine.
13. The Committee noted that the MoH had cited global supply constraints occasioned by the decision by the Government of India to prioritize the vaccination for its own population and the inability of the Serum Institute of India, the worlds' largest vaccine manufacturer to meet the global demand as key factors driving the vaccine shortage in Kenya.
14. Further to the global vaccine supply constraints, the Committee observed that the MoH had identified certain key challenges as having contributed to the vaccine shortage in the country, including: variations in the initial target groups and the expanded target groups following a Presidential directive to include elderly and vulnerable persons in Phase One of the vaccination exercise; non-priority persons accessing the vaccines; and, reporting challenges through the *Chanjo* System owing to overwhelmed health facilities opting to

use manual systems.

f) Contingency Measures to Address Prevailing COVID-19 Vaccine Shortages

15. The Committee further observed that in order to address the prevailing COVID-19 vaccine shortage in the country, the MoH had opted to extend the duration between the administration of the first dose and the second dose from 8 to 12 weeks. Consequently, the first recipients of the second dose will be expected to receive their booster dose during the first week of June 2021. According to the MoH, it is expected that the country will have received additional supplies from COVAX by this time.
16. The Committee also noted that in addition to extending the duration between the administration of the first and second doses of the vaccine, the Government had taken concrete steps to engage with the African Union for purposes of procuring 7 million doses of Pfizer and 10 million vaccine doses of Johnson and Johnson. This was expected to yield the vaccination of an additional 13.5 million Kenyans.

g) Safety Profile, Efficacy and Adverse Effects of the COVID-19 Vaccine

17. The Committee noted that according to the MoH, the Astrazeneca vaccine was an adenovirus vector vaccine whose efficacy in clinical trials had been reported to range between 62-70% for disease prevention, and 100% for reduction in hospitalisation and death prevention.
18. Further, the Committee observed that the MoH had not reported any major side effects or adverse events attributable to the vaccine with the most common side effects being reported as pain at the injection site, headache, tiredness and muscle ache.

h) Procurement of COVID-19 Vaccines

19. With regards to the mechanisms for procurement of government-approved COVID-19 vaccines, the Committee noted that according to the MoH, the Government intended to procure COVID-19 vaccines for public use through any of only three mechanisms, that is: through the COVAX facility; through the AFRICA CDC Platform; and/or, directly from manufacturers through bilateral agreements.

20. In this regard, the Committee observed that the MoH had effectively precluded the role of private companies and/or entities in the importation, distribution and/or administration of any Government-approved COVID-19 vaccines for public distribution.

i) Adequacy of Cold-Chain System and Vaccine Storage Facilities

21. On the capacity of Kenya's cold chain system and vaccine storage facilities in relation to the COVID-19 vaccine roll-out, the Committee observed that for purposes of COVID-19 vaccines that only required standard refrigeration, Kenya had adequate cold-chain capacity and storage, including: the National Vaccine Depot in Kitengela; nine regional depots in Kakamega, Kisumu, Nakuru, Eldoret, Meru, Mombasa, Garissa, Nyeri and Nairobi; three County depots in Mandera, Wajir and Turkana; 290 sub-county vaccine stores; and ,7,877 immunizing health facilities countrywide.
22. However, the Committee observed that Kenya has limited capacity to meet the cold chain storage requirements for the Pfizer vaccine which needs to be stored at sub-zero temperatures, and which the Government intends to procure. As such, while the Committee lauded efforts by the Government to bridge the country's shortage of COVID-19 vaccines brought about by global supply constraints of the AstraZeneca vaccine, the Committee noted that it was likely to result in the need to acquire additional costly cold chain equipment and transport and logistical supplies.

j) Involvement and Engagement of County Governments in the Vaccine Roll-Out

23. The Committee observed that according to the COG, County Governments had been adequately involved by the National Government and the MoH in the COVID-19 vaccination roll-out exercise.
24. The Committee further noted that according to submissions by the COG, all 47 County Governments had established covid-19 vaccine deployment and vaccination task forces at both the County and Sub-County levels for purposes of coordinating Covid -19 vaccine roll out activities in the Counties.
25. However, despite the notable achievements demonstrated by the county governments, the the Committee noted that the COG had identified key challenges with the national

roll-out of the Astrazeneca vaccine as follows: slow uptake of the vaccine by health care workers owing to social media misinformation on the side effects of the AstraZeneca vaccine (particularly blood clots) as well as global misinformation of the vaccine; inadequate funding to support training and the vaccine roll out at the counties; overstretched logistical and human resource capacity; inadequate reporting tools including AEFI forms and tablets for online registration into the *Chanjo* system; and, high levels of internet downtime.

k) Emergency Authorisation and Subsequent Cancellation of Licences for the Importation, Distribution and Administration of the Russian-Manufactured Sputnik-V Vaccine

26. With regards to the emergency authorisation and subsequent cancellation of licenses for the importation, distribution and administration of the Russian-manufactured Sputnik-V vaccine, the Committee made the following observations:

- a) Dinlas Pharma EPZ Ltd was duly issued with a permit for the importation of the COVID-19 Sputnik V vaccine having met the Emergency Use Authorisation requirements set out by the PPB and as evidenced by the issuance of its Emergency Use Authorisation (EUA) certificate (No. H2021/ctd/8457/1976EUA) (*see Annex 7*);
- b) Subsequent to the above, Dinlas Pharma Ltd had duly executed technical and distribution agreements with two recognised wholesale distributors i.e. Harleys Ltd and Unisel Pharma (K) Ltd to facilitate the distribution of the said vaccine into the country;
- c) Harleys Ltd and Unisel Pharma (K) Ltd were duly authorised by the PPB to distribute the Sputnik-V vaccine as evidenced by relevant certification from the PPB (Authorisation UCR No. UCR202102594997) (*see Annex 8*);
- d) However, following evidence of unscrupulous business practices by the distributors (that is, illegal marketing of the said vaccine contrary to the PPB terms and conditions for Emergency Use Authorisation and evidence of irregular deployment of the vaccine at non-authorised premises such as offices and homes contrary to the rules and regulations of the Kenya Medical Practitioners and

Dentists Council (KMPDC) amongst others), by a resolution of the National Emergency Response Committee dated 2nd April, 2021 (*see Annex 10*), the MoH proceeded to cancel the licenses that were issued for the importation, distribution and administration of the Sputnik V vaccine; and,

- e) The actions by the MoH were further buttressed by section 158(1) of the Public Health Act which prohibits the importation, manufacture or use of any such substance, which is considered to be unsafe or liable to be harmful or deleterious and states that: *"the Minister may provide for the inspection, sampling and examination, by officers of the Medical Department, of vaccines, vaccine lymph, sera and similar substances imported or manufactured in Kenya and intended or used for the prevention or treatment of human diseases, and may prohibit the importation, manufacture or use of any such substance which is considered to be unsafe or to be liable to be harmful or deleterious."*

27. Further to the above, the Committee observed that the MoH and PPB initially submitted conflicting and contradictory statements with regards to the emergency authorisation of the vaccine. Noting that the PPB is a regulatory body under the MoH, and that the MoH is responsible for providing policy direction, the Committee observed that PPB ought to have adequately consulted the MoH prior to providing emergency authorisation for the importation and distribution of COVID-19 vaccines by private entities in a pandemic situation.
28. The Committee further noted that according to the statement by Dinlas Pharma EPZ Ltd, as of 22nd March, 2021 it had received a total of 75,000 doses of the Sputnik vaccine. According to the MoH, the total number of Sputnik V vaccine doses that had been administered prior to the cancellation of the companies' licences and permits was 527 as captured in the *Chanjo* information management system. In relation to the above, the Committee noted that as per the statement by the MoH dated 6th April, 2021, persons who had received the first dose of the Sputnik V vaccine would be eligible to receive their second and final dose.
29. While acknowledging that *vide* a letter dated 6th April, 2021, Dinlas Pharma EPZ Ltd had requested the MoH for permission to re-export the remaining consignment of the Sputnik V vaccine to either Pakistan or Lebanon (*see Annex 11*), the

Committee noted that in view of the prevailing shortage of COVID-19 vaccines in the country, there was still an avenue for further engagement between the importer of the vaccine and the MoH for the authorisation of its use in Kenya.

l) Role and Engagement of the Private Sector in the COVID-19 Vaccination Roll-Out

30. With regard to private sector involvement in the COVID-19 vaccination roll-out, the Committee noted that according to the statement issued by the Pharmacy and Poisons Board (PPB) on Monday, 29th March, 2021, PPB had developed a Guidance Document on the '*Role of Private Sector in the Deployment of COVID-19 Vaccines*' to provide guidance to the pharmaceutical industry on the documentation requirements and procedures for the roll-out of COVID-19 vaccines in Kenya (*see Annex 6*). This position was validated by the MoH in its statement dated 30th April, 2021 (*see Annex 4*), and in its oral submissions at the meeting held on 1st April, 2021 (*see Annex 1 for minutes*).
31. Further, the Committee observed that during its meeting with the MOH held on 8th April, 2021, the MoH committed to develop a framework for private sector engagement by the end of June, 2021. Under this proposed framework, the private sector was expected to be integrated in the COVID-19 vaccine roll-out plan by July, 2021.
32. However, at a subsequent meeting held with the MoH on 30th April, 2021, the Committee noted that the MoH had since vacated this position and adopted a policy to preclude the role of the private sector in the importation, distribution and administration of Covid-19 vaccines altogether.
33. Noting that the private sector had an important role to play in the COVID-19 vaccination roll-out, the Committee observed that there was need for the MoH to expedite the development of a transparent and accountable framework for private sector engagement in the COVID-19 vaccination drive, and the creation of an enabling environment by the Government was necessary to facilitate this.

m) Adequacy of Measures taken by the Government of Kenya for the Health and Safety of Kenyans

34. The Committee observed that according to submissions made by the MoH, the Government, through the MoH, had put in place adequate measures to guarantee the health and safety of Kenyans, including: instituting an independent National Vaccine Safety Advisory Committee (NVSAC); deploying a robust monitoring system to identify, report, and investigate all adverse events following immunization (AEFIs); undertaking training and capacity building of health workers on vaccine management and safety reporting (including vaccine pharmacovigilance) etc.

n) Monitoring and Evaluation of the Impact of the COVID-19 Vaccination Drive

35. The Committee observed that there was a need for the Government to employ robust monitoring and evaluation processes to evaluate the impact of the COVID-19 vaccination exercise for purposes of informing government policy on the implementation or easing of any further containment measures.

36. The Committee further observed that it was necessary for the MoH to engage the Kenya Medical Research Institution (KEMRI) and other research and academic institutions in assessing the impact of the COVID-19 vaccination drive with a view towards informing official government policy.

o) Presence of COVID-19 Variants in Kenya

37. With regards to the presence of COVID variants in the country, the Committee noted that according to the MoH, between 28th February and 5th March, 2021, 19 variants of the coronavirus had been identified in Kenya, 15 of which were the South African variant, and one UK variant. Majority of the people in whom the variants were detected had a history of travel.

38. In addition, the Committee noted that according to a public statement issued by Dr. Patrick Amoth, Ag. Director General, MoH, Kenya had recorded five cases of the Indian COVID-19 variant on 5th March, 2021.

39. Noting that the COVID-19 variants had been proven to be highly transmissible, and more devastating to the life and health of victims, the Committee observed that there was need for the MoH to scale-up surveillance activities against all COVID-19 variants, particularly the Indian variant, with a view towards saving lives, and avoiding any further strains on the country's fragile and overwhelmed health system.

p) Lack of involvement and engagement of health workers in the COVID-19 Vaccination Roll-Out

40. The Committee observed that according to submissions made by various health worker representative groups that appeared before it, the MoH had failed to adequately involve and engage health workers in the COVID-19 vaccination roll-out. This had in turn, initially led to low vaccine uptake and high vaccine hesitancy by frontline health workers.

41. Key issues and challenges identified by health workers in relation to the COVID-19 vaccination were identified as follows: lack of involvement/engagement of health workers by the MoH in the initiation and roll-out vaccination exercise; poor communication and lack of information from the MoH; reported cases of adverse effects of the vaccine in other jurisdictions; lack of clear mechanisms for the handling of adverse reactions to the vaccine amongst health workers; lack of capacity-building and training of health workers prior to, and during the vaccine roll-out; lack of access to the vaccine by willing health workers due to lack of clarity on which health facilities had been accredited had been accredited as vaccination centers; reports of health workers being turned away from vaccination centers; and, lack of involvement of research institutions and the private sector.

To note, the Committee acknowledges that the COVID pandemic situation is a highly evolving one: As such, the observations and recommendations contained in this report reflect the situational context, and information that was available to the Committee at the time of the writing of this report. Accordingly, as the COVID-19 outbreak situation evolves, and the Government's policy position and response evolves with it, some of the Committee's preliminary observations and recommendations on the thematic area of health may by necessity change or be reviewed.

CHAPTER FOUR

COMMITTEE RECOMMENDATIONS

Based on the foregoing, the Committee made the following recommendations:

1. That the MoH act expeditiously to implement all contingency measures aimed at ensuring that Kenya is able to vaccinate 4 million Kenyan adults, and 26 million by June, 2021 as per the Presidential directive issued on 24th March, 2021;
2. That the MoH and the COG convene a consultative forum with County Governments aimed at improving county performance in the rate of COVID-19 vaccinations and addressing prevailing challenges that may be limiting their capacity to perform;
3. That the MoH, the Ministry of Education (MoE) and the Teachers Service Commission (TSC) act collaboratively and expeditiously to address the low uptake of the COVID-19 vaccine amongst teachers;
4. That the MoH act expeditiously to ensure that Kenya has the necessary capacity to meet the cold chain system and vaccine storage facilities requirements demanded by the incoming COVID-19 vaccines, particularly, Pfizer;
5. That the MoH and the PPB act urgently to develop the necessary framework and enabling environment to allow for private sector engagement and involvement in the COVID-19 vaccination roll-out in a transparent and accountable manner;
6. That the MoH, KEMRI and other academic and research institutions act urgently to collaborate for purposes of assessing the impact of COVID-19 vaccination drive with a view towards informing official government policy and actions;
7. That the MoH act urgently to prioritise, scale up and strengthen scale-up surveillance activities against all COVID-19 variants, particularly the Indian variant, with a view towards saving lives, and avoiding any further strains on the country's fragile and overwhelmed health system; and,
8. That the MoH act to set up mechanisms and structures to allow for adequate stakeholder engagement and involvement of health workers in the COVID-19 vaccination roll-out.

The Committee therefore determined that:

1. This report be dispatched to the Ministry of Health for purposes of: taking the necessary steps and measures to ensure the timely and effective implementation of contingency measures aimed at addressing the prevailing COVID-19 vaccine shortages; providing technical assistance and capacity-building to counties with a view towards scaling up the performance of counties in COVID-19 vaccination in collaboration; addressing low vaccine uptake amongst teachers in collaboration with the MoE and the TSC; strengthening Kenya's cold chain system for purposes of enabling the country meet the requisite demands for the Pfizer vaccine; developing the necessary framework and enabling environment for private sector engagement and involvement in the COVID-19 vaccination roll-out in collaboration with PPB and KMPDC; providing a comprehensive assessment of the impact of the COVID-19 vaccination roll-out in collaboration with KEMRI and other research and academic institutions; and, setting up mechanisms and structures to provide for adequate stakeholder engagement and involvement of health workers in the COVID-19 vaccination roll-out. The MoH is to report back to the Committee within **three (3) months** receipt of this report.



**NATIONAL EMERGENCY RESPONSE COMMITTEE ON
CORONAVIRUS**

RESOLUTIONS OF VIRTUAL MEETING HELD

ON APRIL 2ND 2021

Good afternoon members of the press and welcome to our daily briefing on the status of Coronavirus in the country.

Fellow Kenyans,

Today we held a meeting of the National Emergency Response Committee during which a number of issues were discussed and agreed upon. I now wish to read out the resolutions of the meeting.

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1. Following recommendations of the Inter Governmental Committee on Health, the National Emergency Response Committee calls on all agencies charged with the responsibility of enforcing the ongoing containment measures to be more vigilant in their efforts and humanely ensure no laxity in the observance of Covid-19 mitigation measures.
 2. All people resident in Kenya are urged to continue observing all the laid down protocols, including the recent curfew and restriction of movement in the disease infected zone counties. The committee has noted that the measures are already bearing fruit and it's expected that the situation could improve sooner rather than later.
 3. To ensure we get a better account of Covid-19 situation in the country, there is a need to increase our testing capacity. In this regard, the Committee noted the deployment of additional 17 PCR machines to the

counties and looks forward to more samples taken and tested.

4. The Government is making all efforts to acquire more vaccines through either the COVAX Facility, Africa CDC Platform, or bilateral arrangements.
5. The committee noted that participation of the private sector in the vaccination exercise threatens the gains made in the fight against Covid-19 and puts the country at international risk should counterfeit commodities find their way into the Kenyan market.

To ensure transparency and accountability in the vaccination exercise, and to protect the integrity of the country, the Government is effective today closing the window of private sector importation, distribution and administration of vaccines until such a time when it is confident that there is greater transparency and accountability in the entire process in the interest of public health safety.

Consequently, there will be no licensing of private players in the importation of vaccines and any such license given will be and is hereby cancelled. Any person advertising or vaccinating people for a fee will therefore be in contravention of the Public Health Act and will be liable for prosecution. The only agent for vaccination in Kenya will remain the Government of the Republic of Kenya until further notice.

The Government assures those who have already taken their first dose of vaccines outside the Government deployment plan by this date will receive their second dose when due.

6. All County Governments are required to prepare adequately for vaccine deployment and especially on the use of the IT platform, Chanjo.ke, for data management, increased transparency and accountability. Additionally, all counties are encouraged

to step up their vaccination efforts to ensure more of the targeted groups are vaccinated.

7. Vaccine deployment is scheduled to run in a phased approach with every phase targeting specific groups of our society. This is an appeal to Kenyans and others resident in the country, please ensure you get the vaccine during the phase in which the group you belong to is targeted. If you are not in the targeted category in the ongoing phase, do not turn up but instead await your turn.

It's important to note that the decisions for group targeting were informed by an assessment of vulnerabilities and potential for infection, hospitalization and even death. The idea is to make sure those at the greatest risk are prioritized as vaccines become available.

Further, counties are encouraged not to withhold vaccines from targeted groups with the excuse of holding for the second dose. The second Astrazeneca dose is to be

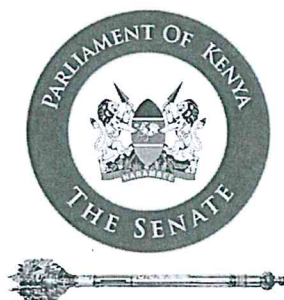
administered between 8 and 12 weeks from the first dose and its our expectation that the second consignment will be in time for the second dose and roll out of phase two according to our deployment plan.

8. The Committee has taken notice of information that some countries wish to put our country on the red list. NERC recommends that the Ministry of foreign affairs takes up the matters and where necessary, a reciprocal arrangement be adopted.
9. There will be a need for up scaling of communication both on Covid-19 and deployment of vaccines to ensure the public is better informed.

I thank You

A handwritten signature in black ink, consisting of a large, stylized 'M' followed by a series of loops and a long horizontal stroke extending to the right.

Sen. Mutahi Kagwe, EGH
Cabinet Secretary.



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON WEDNESDAY, 17TH MARCH, 2021, AT 9.00 A.M. ON THE
ZOOM ONLINE MEETING PLATFORM.**

PRESENT

- 1) Sen. Ledama Olekina, MP - Chairing
- 2) Sen. Beth Mugo, EGH, MP
- 3) Sen. Beatrice Kwamboka, MP
- 4) Sen. Mary Seneta, MP
- 5) Sen. Millicent Omanga, MP
- 6) Sen. Fred Outa, MP

APOLOGIES

- 1) Sen. (Dr.) Michael Mbito, MP - Chairperson
- 2) Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
- 3) Sen. (Prof) Samson Ongeru, EGH, MP

IN ATTENDANCE

A. Kenya Medical Association

1. Dr. Andrew Were - President
2. Dr. Simon Kigundu - Treasurer

B. Kenya Medical Practitioners and Dentists Union

1. Dr. Mwachonda Chibanzi - Ag. Secretary General

C. Kenya Union of Clinical Officers

-
1. Mr. Peterson Wachira - Chairman
 2. Mr. Gibore - Secretary General
- D. Kenya Clinical Officers Association**
1. Mr. Albert Taiti - Chairman
- E. National Nurses Association of Kenya**
1. Mr. Alfred Abengo - President
- F. Kenya Progressive Nurses Association**
1. Mr. Michael Nyongesa - Chairman
 2. Ms. Teresa Njeri
- G. Kenya National Union of Nurses**
1. Mr. Seth Panyako - Secretary General
- H. Pharmaceutical Society of Kenya**
1. Dr. Louis Machogu
 2. Dr. Daniella Munene
- I. Kenya Pharmaceutical Association**
1. Mr. Eric Gichane - Secretary General
- J. Kenya National Union of Pharmaceutical Technologists**
- K. Kenya National Union of Medical Laboratory Officers**
1. Mr. Cliff Randa
- L. Kenya Health Professionals Society**
1. Mr. Mohammed Duba- Chairman

SECRETARIAT

- 1) Ms. Christine Sagini - Research Officer/Clerk Asst
- 2) Ms. Farhiya Ali - Sergeant-at-Arms
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Frank Mutula - Media Relations Officer
- 5) Mr. Robert Rop - Audio Officer

The Chairperson called the meeting to order at 9:05 A.M and the meeting commenced by a word of prayer.

The Committee adopted the agenda of the Sitting, as set out below, having been proposed by Sen. Millicent Omanga, MP, and seconded by Sen. Olekina Ledama, MP: -

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Meeting with health worker representative groups to receive their views and submissions on the nationwide COVID-19 vaccination roll-out exercise:*
 - a) *Doctors*
 - *Kenya Medical Association*
 - *Kenya Medical Practitioners and Dentists Union*
 - b) *Nurses*
 - *Kenya National Union of Nurses*
 - *National Nurses Association of Kenya*
 - *Kenya Progressive Nurses Association*
 - c) *Clinical Officers*
 - *Kenya Union of Clinical Officers*
 - *Kenya Clinical Officers Association*
 - d) *Pharmacists*
 - *Pharmaceutical Society of Kenya*
 - e) *Pharmaceutical Technologists*
 - *Kenya Pharmaceutical Association*
 - *Kenya National Union of Pharmaceutical Technologists*
 - f) *Medical Laboratory Officers*
 - *Kenya National Union of Medical Laboratory Officers*
 - g) *Kenya Health Professionals Society*
3. Any other business.

4. Date of the Next Meeting.

5. Adjournment.

MIN. NO. SCH2/109/2020 SUBMISSIONS BY DOCTOR REPRESENTATIVE GROUPS

Dr. Andrew Were, President, Kenya Medical Association (KMA) submitted to the Committee that whilst KMA supported the roll-out of the COVID-19 vaccine, it had noted a high level of vaccine hesitancy and anxiety amongst health workers. He further noted that the flow of information and communication from the Ministry of Health with regards to the vaccine had been poor. He concluded that a lot remained to be done to allay the fears of health workers in order to improve uptake of the vaccine.

On behalf of the Kenya Medical Practitioners and Dentists Union (KMPDU), Dr. Mwachonda, Ag. Secretary General, stated that the Ministry of Health had not engaged health workers prior to rolling out the vaccine leading to low uptake. He further noted that there was lack of clear information on the accredited vaccine centres. He further identified other challenges with the roll-out including: lack of a clear reporting pathway for health workers who experienced adverse effects; low capacity-building and training; and, poor communication from the MoH.

MIN. NO. SCH2/109/2020 SUBMISSIONS BY NURSING REPRESENTATIVE GROUPS

Speaking on behalf of the Kenya National Union of Nurses, Mr. Seth Panyako identified the following challenges in relation to the COVID-19 vaccine roll-out: lack of involvement of health workers by the MoH and lack of training and capacity-building leading to high levels of vaccine hesitancy amongst health workers, and low uptake of the vaccine.

Mr. Alfred Obengo, President, National Nurses Association of Kenya (NNAK) noted that there had been low acceptance and buy-in of the vaccine due to the lack of involvement and engagement of relevant stakeholders by the MoH.

Speaking on behalf of the Kenya Progressive Nurses Association (KPNA), Ms. Teresa Ireri stated that KPNA had conducted a rapid assessment survey on the acceptability of the COVID-19 vaccine by nurses which had revealed that:

-
- 60.5% had received information on the COVID-19 vaccine;
 - 19.5% were willing to get vaccinated, while 23% were unsure and 57.5% were unwilling;
 - Of those who were not willing to get vaccinated, 59% had cited safety concerns; and
 - Only 9.6% would advise their family or friends to get the vaccine

She further stated KPNA recommended capacity-building, involvement of nurses in planning processes and payment of compensation for adverse effects as key factors that would improve the uptake of the vaccine.

**MIN. NO. SCH2/109/2020 SUBMISSIONS BY CLINICAL OFFICER
REPRESENTATIVE GROUPS**

On behalf of the Kenya Union of Clinical Officers (KUCO), Mr. Peter Wachira stated that whilst KUCO supported the vaccine roll-out, lack of information and poor communication from the MoH were key factors affecting the effective roll-out of the COVID-19 vaccine. He further raised concerns that vaccine hesitancy and anxiety amongst health workers was likely to extend to the community.

MIN. NO. SCH2/109/2020 SUBMISSIONS BY PHARMACISTS

Dr. Louis Machogu, Pharmaceutical Society of Kenya (PSK) iterated the need to better involve health workers in the vaccine roll-out. He further noted that vaccine hesitancy had been informed to a large degree by international reports of serious side effects.

**MIN. NO. SCH2/109/2020 SUBMISSIONS BY PHARMACEUTICAL TECHNOLOGIST
REPRESENTATIVE GROUPS**

On behalf of the Kenya Pharmaceutical Association (KPA), Mr. Eric Gichane noted that while KPA supported the vaccine rollout exercise, there were safety concerns regarding the vaccine amongst majority of its members. He therefore called upon the MoH to deploy innovative methods of reaching the public including bulk SMS etc.

**MIN. NO. SCH2/109/2020 SUBMISSIONS BY MEDICAL LABORATORY OFFICER
REPRESENTATIVE GROUPS**

On behalf of the Kenya National Union of Medical Laboratory Officers, Mr. Cliff Randa iterated the need for the Moh to effectively involve and engage health workers in the vaccination exercise.

MIN. NO. SCH2/109/2020 SUBMISSIONS BY THE KENYA HEALTH PROFESSIONALS SOCIETY

Mr. Mohammed Duba, Chair, Kenya Health Professionals Society stated that the Moh had not adequately involved or engaged health workers in the COVID-19 vaccine rollout exercise, leading to high vaccine hesitancy amongst health workers, and low uptake.

The meeting concluded with the Chair assuring the various health worker representative groups present at the meeting that the Committee would raise their concerns with the MoH at a subsequent meeting.

MIN. NO. SCH2/111/2020 ADJOURNMENT

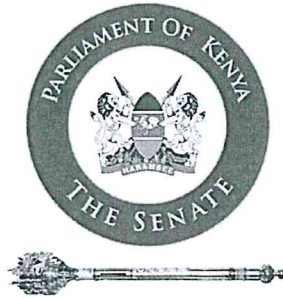
There being no other business, the committee adjourned at 10.03 a.m.



SIGNED:.....
(CHAIRPERSON)

25/3/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON THURSDAY, 18TH MARCH, 2021, AT 9.00 A.M. ON THE ZOOM
ONLINE MEETING PLATFORM.**

PRESENT

- 1) Sen. Fred Outa, MP - Chairing
- 2) Sen. Ledama Olekina, MP
- 3) Sen. Beth Mugo, EGH, MP
- 4) Sen. Beatrice Kwamboka, MP
- 5) Sen. Mary Seneta, MP
- 6) Sen. Millicent Omanga, MP

APOLOGIES

- 1) Sen. (Dr.) Michael Mbiti, MP - Chairperson
- 2) Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
- 3) Sen. (Prof) Samson Ongeru, EGH, MP

IN ATTENDANCE

A. Ministry of Health

1. Hon. Mutahi Kagwe, EGH - Cabinet Secretary
2. Dr. Mercy Mwangangi - Chief Administrative Secretary
3. Dr. Willis Angwale - Chair, COVID-19 Task Force
4. Ms. Rose Mudibo - Director, Parliamentary Liaison

SECRETARIAT

- | | | |
|-------------------------|---|-----------------------------|
| 1) Ms. Christine Sagini | - | Research Officer/Clerk Asst |
| 2) Ms. Farhiya Ali | - | Sergeant-at-Arms |
| 3) Ms. Sombe Toona | - | Legal Counsel |
| 4) Mr. Frank Mutula | - | Media Relations Officer |
| 5) Mr. Robert Rop | - | Audio Officer |

MIN. NO. SCH2/107/2020

PRELIMINARIES

The Chairperson called the meeting to order at 9:15 A.M and the meeting commenced by a word of prayer.

MIN. NO. SCH2/108/2020

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. Olekina Ledama, MP: -

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Statement by the Ministry of Health on the nationwide COVID-19 vaccination roll-out exercise:*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/109/2020 STATEMENT BY THE MINISTRY OF HEALTH ON THE NATIONWIDE COVID-19 VACCINATION ROLL-OUT

Led by Hon. (Sen.) Mutahi Kagwe, EGH, Cabinet Secretary, the Ministry of Health submitted its Statement to the Committee as summarised below:

Regarding the details of the COVID-19 vaccine that was being rolled-out in Kenya, the MoH submitted that Kenya had rolled out the Astrazeneca vaccine, which had demonstrated an efficacy of 62-70% for disease prevention and 100% for reduction in hospitalisation and death prevention.

The MoH submitted that the common side effects associated with the vaccine included pain at the injection site, headache, tiredness and muscle ache. The MoH further submitted that no major adverse effects had been reported against the vaccine.

While noting that some countries had suspended the use of the vaccine due to a linkage with blood clots, no direct link or causality had been established. The MoH further noted that despite the reports of blood clots, several countries had resumed the use of the vaccine including Canada, Spain, Italy, France and Belgium. Nevertheless, the MoH and Pharmacy and Poisons Board were closely monitoring the situation.

Noting that at least 20,000 people had been vaccinated by the time of the meeting, the MoH submitted that the most common reported side effects included: pain/swelling at the injection site, muscle pain, headache and low grade fever.

With regards to the financial and budgetary implications of the COVID-19 vaccine roll-out, the MoH submitted that the Government of Kenya was in the process of mobilising a total of KShs. 34,017,623,939.00 for the vaccination exercise as follows:

- a) Procurement of vaccines and injection devices for 30% of the population: KShs. 30,848,190,230.00 broken down as follows:
 - GoK: KShs. 11,137,133,621.00
 - GAVI: KShs. 19,711,056,609.00
- b) Operational costs (capacity-building, communication, mobilization, cold storage etc): KShs. 3,169,433,710.000

The MoH further submitted that the budget had been broken down across three financial years as follows:

- 1) FY 2020-2021(Phase 1): KShs. 1.65B by the GoK, and KShs. 2.248B by GAVI;
- 2) FY 2021-2022 (Phase 2): KShs. 3.755B by GoK, and KShs. 17.462B by GAVI; and
- 3) FY 2022-2023 (Phase 3): KShs. 8.895B by GoK.

In order to facilitate the seamless roll-out of the vaccine to all Kenyans, the MoH submitted that it had taken the following measures:

- 1) The MoH had developed and was implementing the National Vaccine Deployment Plan (NVDP);
- 2) The MoH had mapped out vaccine storage capacity for both positive and negative temperature vaccines at the central and regional vaccine stores;
- 3) Six-hundred and twenty-two (622) public, private and faith-based health facilities had been identified and mapped to administer the vaccine;
- 4) The MoH had deployed a robust county engagement exercise through a micro planning process aimed at mapping and validating target groups;
- 5) Training and capacity-building of 35 National Master Trainers, 235 county TOTs and 110 health workers; and
- 6) Development of a communication plan aimed at ensuring the buy-in of key stakeholders, creating vaccine demand and addressing hesitancy issues.

On the capacity of Kenya's cold chain system and vaccine storage facilities in relation to the COVID-19 vaccine roll-out, the MoH submitted that it had adequate storage for the introduction of the vaccines, including:

- a) The National Vaccine Depot in Kitengela;
- b) Nine regional depots in Kakamega, Kisumu, Nakuru, Eldoret, Meru, Mombasa, Garissa, Nyeri and Nairobi;
- c) Three County depots in Mandera, Wajir and Turkana;
- d) 290 sub-county vaccine stores; and
- e) 7,877 immunizing health facilities countrywide.

The MoH further submitted that while there existed significant inequities in cold chain capacity distribution across the counties, it intended to bridge any existing gaps through:

- a) Procurement and installation of additional cold chain equipment;
- b) Implementation of an ongoing Cold Chain Equipment Optimization Platform Project with the support of GAVI;
- c) Redistribution of cold chain equipment across the counties; and

d) Collaboration with the private sector for cold chain storage.

With regards to what measures the MoH had taken to ensure effective involvement and engagement of County Governments and other stakeholders in the vaccine roll-out, the MoH submitted that it had established multi-stakeholder coordination structures at national, county and sub-county levels.

Noting that the private, civic and religious sectors were represented at the national coordination level, the MoH submitted that the National Level Steering and Planning Committee provided overall policy direction, oversight and technical leadership , while county and sub-county coordination committees were responsible for executing the policies and service delivery.

During plenary, Members raised key issues in relation to the vaccine roll-out exercise as follows:

- a) Lack of involvement/engagement of health workers by the MoH in the initiation and roll-out vaccination exercise;
- b) Low uptake of the COVID-19 vaccine by health workers and other essential personnel with only 20,000 persons having been vaccinated against a total target of 1.2 M people by July, 2021; and
- c) The need for the prudent use of resources during the vaccination exercise.

Members further called for the MoH to take the necessary steps and measures to ensure that unscrupulous private entities did not hijack the process for their own benefit.

In addition, whilst acknowledging that not every stakeholder could be engaged or involved at the National Steering Committee level, Members emphasised to the MoH the need to adequately engage with, and involve health workers in the vaccine roll-out exercise.

In conclusion, the Committee recognised the MoH for a job well done and iterated its support towards ensuring the successful implementation of the vaccination roll-out and implementation exercise.

MIN. NO. SCH2/111/2020 ADJOURNMENT

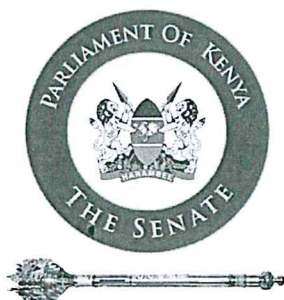
There being no other business, the committee adjourned at 10.37 a.m.

SIGNED:..... 

(CHAIRPERSON)

25/3/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON THURSDAY, 18TH MARCH, 2021, AT 11.00 A.M. ON THE ZOOM
ONLINE MEETING PLATFORM.**

PRESENT

- 1) Sen. Fred Outa, MP - Chairing
- 2) Sen. Beth Mugo, EGH, MP
- 3) Sen. Beatrice Kwamboka, MP
- 4) Sen. Mary Seneta, MP
- 5) Sen. Millicent Omanga, MP

APOLOGIES

- 1) Sen. (Dr.) Michael Mbito, MP - Chairperson
- 2) Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP
- 3) Sen. (Prof) Samson Ongeru, EGH, MP
- 4) Sen. Ledama Olekina, MP

IN ATTENDANCE

A. Council of Governors

- 1) Gov. (Prof.) Anyang Nyongo, EGH - Chair, Health Committee
- 2) Ms. Khatra - Health Committee Secretariat

SECRETARIAT

- 1) Ms. Christine Sagini - Research Officer/Clerk Asst
- 2) Ms. Farhiya Ali - Sergeant-at-Arms
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Frank Mutula - Media Relations Officer
- 5) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/107/2020

PRELIMINARIES

The Chairperson called the meeting to order at 11:05 A.M and the meeting commenced by a word of prayer.

MIN. NO. SCH2/108/2020

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. Olekina Ledama, MP: -

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. ***Statement by the Council of Governors on the nationwide COVID-19 vaccination roll-out exercise:***
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/109/2020

STATEMENT BY THE COUNCIL OF GOVERNORS ON

THE NATIONWIDE COVID-19 VACCINATION ROLL-OUT

Led by Gov. (Prof.) Anyang Nyongo, EGH, the Council of Governors (COG) submitted its Statement to the Committee as summarised below:

The COG submitted that the Government of Kenya had commenced roll out of the COVID 19 Vaccination Program across the 47 counties with a view towards reducing COVID 19 transmission, reducing the burden of disease and deaths from COVID 19.

Further, that the COVID-19 vaccine roll out plan was targeting approximately 15 million persons (30% of the total population) to be undertaken in three phases between March 2021 to June 2023 at a total cost of KES 34 billion.

Noting that the COVID-19 vaccine roll-out process was coordinated by the National COVID-19 Vaccine Deployment Task Force with oversight from the National COVID-19 Vaccine Deployment and Vaccination Steering Committee (NSC) at the national level, COG submitted that it was representative in the Steering committee by the Chair of COG and the technical lead for the COG Health Committee in the Task Force.

At the county level, COG submitted that the process was overseen by a County COVID-19 Vaccine Deployment and Vaccination Steering Committee (CSC) chaired by the Governor with

technical guidance from the County COVID-19 Vaccine Deployment and Vaccination Taskforce chaired by the County Director for Health at the county, and the sub-county director for health at the sub-county level. The COG further confirmed that all 47 County Governments have put in place the necessary governance and management structures for the roll out.

COG further submitted that all 47 County Governments had established covid-19 vaccine deployment and vaccination task forces, at both the County and sub-County levels which were responsible for coordinating Covid -19 vaccine roll out activities in the Counties. Further, the county task forces were responsible for closely monitoring the progress of the roll out activities and facilitating resolution of bottlenecks.

COG further submitted that all 47 counties had undertaken readiness assessment of targeted COVID 19 – Vaccination sites, documented existing capacity gaps and mapped target population by catchment for Phase 1 roll out. Counties were also in the process of developing detailed plans (micro-plans) to cover the three phases of vaccination and comprehensively address aspects such as capacity building of staff, robust social mobilization and communication, supply planning for sites, safe storage, transportation, distribution and redistribution of vaccine doses, and monitoring and reporting on adverse effects.

Noting that counties had so far received COVID -19 vaccine doses totaling to 318,045, the COG submitted that each county governments was expected to make the logistical arrangements necessary for picking up vaccines from the nearest regional vaccines depots and subsequently distributing them to their immunization sites.

Further, the COG reported that all counties were providing regular reports on the progress of COVID-19 Vaccine roll out through the ‘Chanjo’ electronic logistics management information system (eLMIS).

With regards to training and capacity-building, the COG observed that the MoH had developed a training program that blended both physical and virtual components for building skills of county health staff on the COVID-19 disease; knowledge and skills in COVID-19 vaccine demand creation, health facility preparation, safe vaccine administration, infection control practices, patient data management, adverse event reporting and management, documentation and monitoring of vaccine utilization and logistics. Roll out of the training was ongoing with 329 Trainers of Trainers (TOT) having been trained from all the 47 counties. At the time of the meeting, a total of 2,937 health care workers of various cadres have been trained on Covid 19-vaccine roll out for phase 1. Further, plans for scaling up of the training to cover all staff

involved in the immunization process had been formulated, and counties are mobilizing resources for the same.

The COG further submitted that in terms of vaccination of the target population, a total of 15,305 frontline health care workers from the 47 counties had received the COVID 19 vaccine (1st dose) as of 16th March 2021.

Further, that all County Governments were undertaking close monitoring of the immunization processes including identification, reporting and investigation of adverse events in close collaboration with the National Vaccines Program (NVP) and the Pharmacy and Poisons Board (PPB). Further, that County governments have established systems to complement the national government in identifying and addressing safety concerns (both real and perceived) on a timely basis.

All counties instituted focal point persons for surveillance at county and sub-county levels who were responsible for collating incident reports from health workers and other sources. Based on the reports collated so far, the COG reported that common side effects to the vaccine included: pain/swelling at the injection site, myalgia (muscle pain), headache, low grade fever, facial swelling, generalized body malaise, nausea and loose stool, abdominal discomfort, vomiting, dizziness and itchiness, fatigue, night sweats.

Despite the notable achievements demonstrated by the county governments, the COG noted that there had been several significant challenges, including: slow uptake of the vaccine by health care workers owing to social media misinformation on the side effects of the AstraZeneca vaccine (blood clots) as well as global misinformation of the vaccine; inadequate funding to support training and the vaccine roll out at the counties; overstretched logistical and human resource capacity; inadequate reporting tools including AEFI forms and tablets for online registration into the chanjo system; and, internet downtime. Further, the COG noted that since Phase 1 was being carried out at level 4 and 5 facilities, staff had been compelled to travel long distances to designated sites thus increasing the opportunity cost on lost time for service delivery.

The COG further submitted that County Governments were making concerted efforts to address the above challenges through various means including stakeholder engagement, resource mobilisation and implementation of public awareness and sensitization activities.

MIN. NO. SCH2/111/2020 ADJOURNMENT

There being no other business, the committee adjourned at 12.11 p.m.

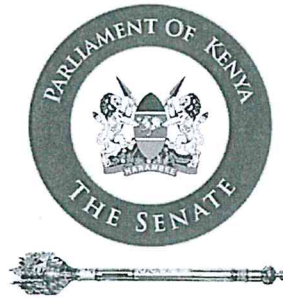
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SIGNED:.....

(CHAIRPERSON)

25/03/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON THURSDAY, 25TH MARCH, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

APOLOGIES

1. Sen. (Dr.) Michael Mbiti, MP - Chairperson

SECRETARIAT

- 1) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 2) Ms. Farhiya Ali - Sergeant-at-Arms
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:19 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

ADOPTION OF THE AGENDA

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

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. **Confirmation of Minutes of the Sittings held on:**
 - **10th March, 2021;**
 - **17th March, 2021;**
 - **18th March, 2021 (9.00 am);**
 - **18th March, 2021 (11.00 am); and**
 - **23rd March, 2021.**
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

CONFIRMATION OF MINUTES

The Minutes of the Sitting held on Wednesday, 10th March, 2021 were confirmed as a true record having been proposed by Sen. Mary Seneta, MP and confirmed by Sen. (Dr.) Adullahi Ali, CBS, MP.

The Minutes of the Sitting held on Wednesday, 17th March, 2021 were confirmed as a true record having been proposed by Sen. Beatrice Kwamboka, MP and confirmed by Sen. Beth Mugo, EGH, MP.

The Minutes of the Sitting held on Thursday, 18th March, 2021 (9.00 am) were confirmed as a true record having been proposed by Sen. Beth Mugo, EGH, MP and confirmed by Sen. Beatrice Kwamboka, MP.

The Minutes of the Sitting held on Thursday, 18th March, 2021 (11.00 am) were confirmed as a true record having been proposed by Sen. Beatrice Kwamboka, MP and confirmed by Sen. Ledama Olekina, MP.

The Minutes of the Sitting held on Tuesday, 23rd March, 2021 (11.00 am) were confirmed as a true record having been proposed by Sen. Millicent Omanga, MP and seconded by Sen. Beatrice Kwamboka, MP.

MIN. NO. SCH2/051/2020

MATTERS ARISING

Sen. Ledama Olekina raised a matter under MIN.NO.SCH2/109/2020 on the ‘Statement by the Ministry of Health on the Nationwide COVID-19 Vaccination Roll-Out’ and noted that in his statement, the Cabinet Secretary of Health, Sen. Mutahi Kagwe, EGH, had indicated that the MoH was yet to develop protocols and guidelines for private sector involvement in the COVID-19 vaccination roll-out. However, Sen. Ledama stated that it had come to his attention that private entities had been granted authorisation to import and distribute the Russian-manufactured vaccine, Sputnik V, into the country as follows:

- 1) Dinlas Pharma EPZ Ltd: Had received emergency authorisation to import the Sputnik V vaccine into the country.
- 2) Harley’s Limited and Unisel Pharma (K) Ltd: Had been granted sole distributorship of the vaccine.

Following deliberations, the Committee resolved to call the following stakeholders to an emergency meeting on Monday, 29th March, 2021 to respond to concerns arising from the entry of the vaccine into the Kenyan market:

- 1) Ministry of Health
- 2) Pharmacy and Poisons Board
- 3) Dinlas Pharma EPZ Ltd
- 4) Harley’s Limited
- 5) Unisel Pharma (K) Ltd

Issues to be raised in the correspondence to the aforementioned stakeholders were provided as outlined below:

- 1) Whether or not the vaccine had been approved for use by the World Health Organisation (WHO).
- 2) Whether or not the vaccine had been authorised for use in Kenya. And if so, who had granted the authorisation.
- 3) Details of the consignment that had arrived in Kenya.
- 4) Costing of the vaccine etc.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

Sen. Beatrice Kwamboka, MP, requested the secretariat to organise a site visit to a National Vaccine Storage facility for purposes of verifying the availability of the Astrazeneca COVID-19 vaccine.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

There being no other business, the committee adjourned at 11:30 a.m.

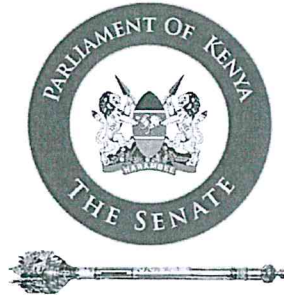


SIGNED:.....

(CHAIRPERSON)

31/03/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON MONDAY, 29TH MARCH, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

APOLOGIES

1. Sen. (Dr.) Michael Mbiti, MP - Chairperson

IN ATTENDANCE

- A. Pharmacy and Poisons Board
- B. Dinlas Pharma EPZ Ltd
- C. Harleys Ltd
- D. Unisel Pharma (K) Ltd

SECRETARIAT

- 1) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 2) Ms. Farhiya Ali - Sergeant-at-Arms
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:05 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

ADOPTION OF THE AGENDA

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

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Submission of Statements regarding the importation and distribution of the Russian-manufactured Sputnik Vaccine by :*
 - *Cabinet Secretary, Ministry of Health;*
 - *Registrar, Pharmacy and Poisons Board;*
 - *Dinlas Pharma Ltd;*
 - *Harleys Ltd); and*
 - *Unisel Pharma (K) Ltd.*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

SUBMISSION OF STATEMENTS REGARDING THE IMPORTATION AND DISTRIBUTION OF THE RUSSIAN-MANUFACTURED SPUTNIK V VACCINE

The Sitting commenced with an update from the secretariat whereby Members were informed that *vide* a letter, ref: MOH/ADM/VOL.2/36, dated 29th March, 2021, the Cabinet Secretary of Health, Sen. Mutahi Kagwe, EGH, citing the Presidential Directive of Friday, 26th March, 2021, Public Order No. 2 of 2021 on the Coronavirus Pandemic to suspend all ordinary sessions of the August Houses including those of their Committees, had indicated his inability to attend the meeting. He had, however, submitted a comprehensive response to the issues raised to the Ministry.

Following deliberations, the Committee resolved that pending the Speakers' advice on the matter, the Committee should re-invite the CS, Health for a meeting in consideration of the importance of the matter, and in acknowledgement of the independence of Parliament. Sen. Ledama Olékina, the Acting Chair, committed to take up the matter.

Further to the above, following deliberations, the Committee resolved to hold a closed-door meeting in acknowledgment of the sensitivity of the day's agenda, and heightened public anxiety concerning vaccination owing to widespread misinformation.

MIN. NO. SCH2/051/2020

STATEMENT BY DINLAS PHARMA EPZ LTD

Led by Mr. Rufus Maina, Dinlas Pharma EPZ Ltd submitted its statement to the Committee as follows:

Dinlas submitted that the Sputnik vaccine was one of the top three vaccines globally recognised vaccines by government regulators with over 56 countries having approved it for use. Dinlas further submitted that the vaccine had been approved for emergency use by the Pharmacy and Poisons Board of Kenya as the mandated regulatory body, and in accordance with the Pharmacy and Poisons (Registration of Drugs) Rules.

Dinlas further submitted that it had received emergency authorization from the PPB to import the Sputnik vaccine for use and distribution in Kenya as evidenced by the issuance of its Emergency Use Authorization (EUA) certificate (No. H2021/ctd/8457/19767EUA). The company further confirmed that it had received the emergency authorization on 9th March, 2021 having applied for it on 2nd February, 2021.

The company further stated that it had obtained all the relevant regulatory permits and approvals for the importation of the vaccine including the Emergency Use Authorization certificate, Import Permit approval and Wholesale Dealers license.

With regards to any COVID-19 vaccine-related consignments that the company had received for distribution in Kenya, Dinlas submitted that on 22nd March, 2021 it had received a total of 75,000 doses of the vaccine with 50,000 being Component I, and 25,000 being Component II. At the time of the meeting, the consignment was being held at a cold storage facility run by Freight-in-Time.

With regards to the cost, Dinlas submitted that it was yet to determine the final cost as it was still incurring storage charges at the cold storage facility in JKIA, and was yet to determine any additional logistics and transportation charges necessary to get the vaccine to the end-user.

The company further submitted that it had duly entered into technical and distribution agreements with Harley's Limited and Unisel Pharm (K) Ltd for the distribution of the vaccine in Kenya.

MIN. NO. SCH2/051/2020

**STATEMENT BY HARLEYS LTD AND UNISEL
PHARMA (K) LTD**

Led by Mr. Sudhir Padhke (Unisel), Harleys Ltd and Unisel Pharma (K) Ltd issued a joint statement in which they submitted that the Sputnik vaccine was one of the top three vaccines globally recognised vaccines by government regulators with over 56 countries having approved it for use. The companies further submitted that the vaccine had been approved for emergency use by the Pharmacy and Poisons Board of Kenya as the mandated regulatory body, and in accordance with the Pharmacy and Poisons (Registration of Drugs) Rules.

Regarding whether the two companies had received authorization from the PPB to distribute the Sputnik vaccine, the companies responded in the affirmative and presented the relevant certification from PPB (Authorization UCR No. UCR202102594997).

The companies further submitted that they had received all the relevant regulatory permits and approvals for the COVID-19 vaccine in Kenya. They had however, not received any consignments for distribution from the importer, and had not commenced distribution to any hospitals.

The companies further submitted that they were yet to determine the cost of the vaccine as they were yet to determine the final pricing details from the importer.

In response to their Statement, the Committee directed the two companies to submit separate statements and documentation for purposes of record.

MIN. NO. SCH2/051/2020

**STATEMENT BY THE PHARMACY AND POISONS
BOARD**

Dr. Fred. Siyoi, CEO/Registrar, Pharmacy and Poisons Board, took the Committee through the Statement by PPB as outlined below:

The Russian-manufactured Sputnik COVID-19 vaccine had been granted Emergency Use Authorization (EUA) by the Board for use in Kenya in line with the Pharmacy and Poisons

Board Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA) and based on available data on safety, quality and efficacy the product.

With regard to the standard procedures and processes for the registration and/or authorization of health products in Kenya, particularly vaccines, the Board submitted that the procedures and processes for registration of medical products and technologies are outlined under the Pharmacy and Poisons (Registration of Drugs) Rules with the details contained in several technical guidelines available on the organization website namely:

- Guidelines for Registration of Human medicine
- Guidelines for Registration of Human Vaccine
- Medical devices and Invitro diagnostic Guideline
- Biotherapeutic Guideline
- Blood and Blood product Guideline
- Guidelines on herbal and Complementary/alternative medicines
- Guidelines on the Safety and Vigilance of Medical Products and Health Technologies

The Board further submitted that it implements several types of registrations/authorizations for medical products and health technologies including full Market Authorizations (MAs), Conditional marketing authorization, Listing and Emergency use Authorizations (EUAs).

In addition, Dr. Siyoi stated that in the wake of the COVID-19 pandemic, the Board had streamlined its processes to facilitate expedited access and availability of medical products and technologies. This had culminated in the development of the Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA) under Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244. Accordingly, the COVID-19 vaccines were thus being evaluated in Kenya under the guidelines on ECUA as had been the case worldwide taking into consideration available data on quality, safety and efficacy.

With regards to the requirements for EUA, he stated that it requires less comprehensive data (particularly, clinical data) and is subject to certain obligations. He further submitted that applicants are expected to submit the current clinical trials data available, state vigilance issues observed, regulatory processes followed by SRAs to determine acceptability of submitted data.

He further stated that the Board had issued a permit for the importation of the Sputnik V Vaccine to a private company DINLAS Pharma EPZ Ltd, which had met the Emergency use authorization requirements set out by the Board. As such, the authorized importer of the Sputnik

vaccine was DINLAS Pharma EPZ Ltd, as the local technical representative of the Emergency Use Authorization holder.

Further, as the authorized importer, Dinlas Pharma Ltd had appointed two (2) recognized wholesale distributors namely: Harleys Ltd and Unisel Pharma (K) Ltd to facilitate the distribution of the said vaccine in the country.

Regarding the processes and/or procedures the Pharmacy and Poisons Board had followed in authorising the importation of the Sputnik COVID-19 vaccines by private entities, the Board submitted that it had developed a Guidance Document on The Role of Private Sector In The Deployment of Covid-19 Vaccines to provide guidance to the pharmaceutical industry on the documentation requirements and procedure for rollout of COVID-19 vaccines by the private sector. It further submitted a summary of the requirements followed in granting the import authorization for the vaccine as follows:

1. The applicant must be duly licensed by the Board as a wholesale dealer in medical products and health technologies;
2. The applicant must have an emergency use authorization (EUA) for the product duly issued by the Board;
3. Proforma invoice/commercial invoice indicating what type of vaccine being imported and quantities;
4. Certificate of analysis (COA)/Batch release certificates indicating the Batch numbers of the vaccines being imported;
5. The applicant must provide a valid Indemnity insurance policy as a commitment to bear liability in case persons suffer loss or injury from the use of the vaccine;
6. In case of appointed distributors, provide a technical agreement between the emergency use authorization holder and the distributor clearly stipulating the roles and responsibilities of each party;

Regarding applications for the importation and distribution of COVID-19 vaccines by private entities that were awaiting registration/authorisation by the Poisons and Pharmacy Board, Dr. Siyoi submitted that as at 28th March 2021, the Pharmacy and Poisons Board had received only one (1) application for authorization of a COVID-19 vaccine namely: Product Name: COVAXIN manufactured by Bharat Biotech International Limited, India whose local technical representative was Simba Pharmaceuticals Ltd.

Dr. Siyoi further submitted that the emergency authorisation for the Sputnik vaccine had been done with the full knowledge and authority of the Ministry of Health. He further confirmed that

the companies in question had fulfilled all the regulatory requirements to start distribution in Kenya.

With regards to its role in monitoring side effects and adverse events arising from the vaccine, the Board submitted that it was using the Chanjo Information management system as well as a robust pharmacovigilance system at health facility and individual level.

The Board further submitted that with regards to which party or person was responsible in the event of serious side effects and/or adverse events arising from the use of the vaccine, the importer, that is, Dinlas Pharma EPZ Ltd, had been required to take an indemnity cover with a recognised insurer as a precondition for the issuance of the emergency authorization.

Having concluded listening to all the statements, and following deliberations, the Committee observed that the companies in question had met all the regulatory requirements. The Committee further noted that further delays in allowing the vaccine's distribution in Kenya would further drive up costs owing to the escalating freight charges. The Committee therefore resolved to hold a follow-up meeting with the Ministry of Health aimed at resolving the matter.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

There being no other business, the committee adjourned at 12.27 p.m.

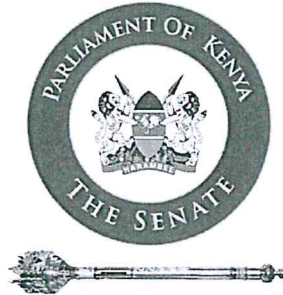


SIGNED:.....

(CHAIRPERSON)

31/03/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON WEDNESDAY, 31st MARCH, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

- 1) Sen. Ledama Olekina, MP - Chairing
- 2) Sen. Fred Outa, MP
- 3) Sen. Beth Mugo, EGH, MP
- 4) Sen. (Prof) Samson Ongeru, EGH, MP
- 5) Sen. Beatrice Kwamboka, MP
- 6) Sen. Mary Seneta, MP
- 7) Sen. Millicent Omanga, MP

APOLOGIES

1. Sen. (Dr.) Michael Mbiti, MP - Chairperson
2. Sen. (Dr) Abdullahi Ali Ibrahim, CBS, MP

SECRETARIAT

- 1) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 2) Ms. Farhiya Ali - Sergeant-at-Arms
- 3) Ms. Sombe Toona - Legal Counsel
- 4) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:10 a.m with a word of prayer from the Ag. Chairperson.

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

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Confirmation of Minutes of the Sittings held on:*
 - *25th March, 2021;*
 - *29th March, 2021 (9.00 am); and*
 - *29th March, 2021 (12.30 pm).*
3. *Proposed Schedule of Committee Hearings with the 47 County Governments in relation to the Special Audit Report by the Auditor-General on the Utilisation of COVID-19 Funds by County Governments*
4. Any other business.
5. Date of the Next Meeting.
6. Adjournment.

The Minutes of the Sitting held on Thursday, 25th March, 2021 at 9.00 am were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Fred Outa, MP and seconded by Sen. Mary Seneta, MP.

The Minutes of the Sitting held on Tuesday, 29th March, 2021 at 9.00 am were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Millicent Omanga, MP and seconded by Sen. Fred Outa, MP.

The Minutes of the Sitting held on Tuesday, 29th March, 2021 at 2.00 pm were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Mary Seneta, MP and seconded by Sen. Fred Outa, MP.

**HEARINGS WITH THE 47 COUNTY
GOVERNMENTS IN RELATION TO THE SPECIAL
AUDIT REPORT BY THE AUDITOR-GENERAL ON
THE UTILISATION OF COVID-19 FUNDS**

Members considered the proposed schedule of Committee hearings with the 47 County Governments in relation to the Special Audit Report by the Auditor-General on the utilisation of COVID-19 funds and proposed the following amendments:

1. Adjust the schedule of hearings to two sittings per day (Monday - Thursday) at 9.00 am and 2.00 pm;
2. Prioritise the counties of Trans Nzoia, Narok, Kisii, Kajiado, Kisumu and Wajir.

Further, the Committee resolved to start holding hearings in relation to the Special Audit Report from the week 12th April, 2021, in order to allow for the Committee to obtain baseline information from relevant government agencies and departments, including: the Ministry of Health, Council of Governors, Kenya Medical Practitioners and Dentists Council, Office of the Auditor-General, the private sector and relevant professional associations.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

1. The Committee deliberated the ongoing nationwide COVID-19 vaccine roll-out by the Government and made the following observations:
 - a) There was slow uptake of the vaccine amongst health workers;
 - b) Following the Government's decision to open up access to the vaccine to members of the public, demand for the vaccine had risen leading to shortages at health facilities, long queues, and reported instances of Kenyans being turned away from vaccination centres.
 - c) There was an emerging disparity with growing public perception that the government-provided Astrazeneca vaccine was for the poor, while the Sputnik V vaccine was for the rich. This was likely to affect future uptake of the Astrazeneca vaccine.
2. In relation to the above, and in anticipation of an upcoming meeting with Cabinet Secretary, Ministry of Health on the same that was scheduled for Thursday, 1st April, 2021 at 2.00 pm, the Committee instructed the secretariat to prepare a comprehensive brief with a focus on the following:
 - a) The status of vaccine deployment;

- b) Logistical and cold chain arrangements in relation to the vaccine roll-out.
 - c) Budgetary provisions in relation to the vaccine roll-out including current expenditure.
 - d) Status of availability of the vaccine across the counties.
 - e) Contingency plans by the MoH to respond to the upsurge in demand for the vaccine.
 - f) Current policy position of the MoH in relation to the prioritisation of the health workers and essential workers such as teachers, policemen etc.
 - g) Government efforts to reach vulnerable groups such as persons with disabilities.
3. In relation to the Committee's Progress Reports on the COVID-19 Pandemic Situation, the secretariat informed the Committee that based on the sittings that had been held the previous week, and that were scheduled to be held until 12th April, 2021, the following draft Progress Reports were being prepared for its consideration and adoption:
- a) Third Progress Report (Preliminary Report on the Nationwide COVID-19 Vaccine Roll-Out Exercise).
 - b) Fourth Progress Report (Level of Preparedness in Counties in relation to the COVID-19 Pandemic).
4. The Committee was further informed about two new Statements that had been referred to the Committee in relation to the COVID-19 Pandemic as follows:
- a) Statement by Sen. Petronilla Were, MP regarding the authorisation of the use of the Russian-manufactured Sputnik V COVID-19 vaccine.
 - b) Statement by Sen. Samson Cherarkey, MP regarding the nationwide roll-out of the Astrazeneca vaccine.
5. The Committee further resolved to postpone a planned site visit to the National Vaccine Storage Facility in Kitengela in consideration of the communication from the Speaker regarding physical sittings.

MIN. NO. SCH2/051/2020

ADJOURNMENT

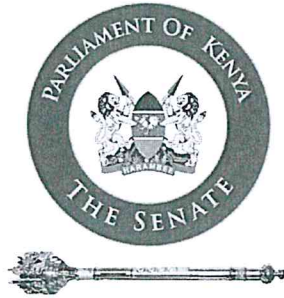
There being no other business, the meeting was adjourned at 11.05 am.



SIGNED:.....

(CHAIRPERSON)

DATE:.....7/4/2021.....



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON THURSDAY, 1ST APRIL, 2021 AT 2:00 P.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

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

APOLOGIES

1. Sen. (Dr.) Michael Mbitio, MP - Chairperson

IN ATTENDANCE

A. Ministry of Health

1. Sen. Mutahi Kagwe, EGH - Cabinet Secretary
2. Mrs. Susan Mochache - Principal Secretary
3. Dr. Patrick Amoth - Ag. Director General
4. Dr. Willis Akhwale - Chairperson, National COVID-19 Vaccine Taskforce
5. Dr. Rabera Kenyenyra
6. Mrs. Nurseline Onsongo
7. Dr. Ian Were

B. Pharmacy and Poisons Board

1. Dr. Fred Siyoi - CEO/Registrar
2. Dr. Ronald Inyangala - Product Evaluation and Registration

3.	Dr. Dominic Kariuki	-	Inspectorate and Enforcement
4.	Dr. Allan Kyalo	-	Trade Affairs
5.	Dr. Kariuki Gachoki	-	Product Safety
6.	Dr. Peter Mbwiiri	-	Chief Principal Regulatory Officer
7.	Dr. Jacinta Wasike	-	Corporate affairs
8.	Ms. Arunga Nancy	-	Legal

SECRETARIAT

1)	Ms. Emmy Chepkwony	-	Principal Clerk Assistant
2)	Dr. Christine Sagini	-	Research Officer/Clerk Assistant
3)	Ms. Farhiya Ali	-	Sergeant-at-Arms
4)	Ms. Sombe Toona	-	Legal Counsel
5)	Mr. Robert Rop	-	Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 2:05 p.m with a word of prayer from the Ag. Chairperson.

MIN. NO. SCH2/051/2020

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. Fred Outa, MP:-

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Submission of Statements regarding the importation and distribution of the Russian-manufactured Sputnik Vaccine by :*
 - *Cabinet Secretary, Ministry of Health; and*
 - *Registrar, Pharmacy and Poisons Board,*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

PRELIMINARIES

In relation to the emergency authorisation of the Russian-manufactured Sputnik V vaccine, Members noted that the Pharmacy and Poisons Board had previously given contradictory information to its parent Ministry, the Ministry of Health on the status of approval. Noting that the differences between the regulator and the Ministry were likely to play out in the public, and in acknowledgment of the sensitivity of the day's agenda, and heightened public anxiety concerning vaccination owing to widespread misinformation, following deliberations, the Committee resolved to hold a closed-door meeting

MIN. NO. SCH2/051/2020

STATEMENTS BY THE CABINET SECRETARY OF
HEALTH AND THE PHARMACY AND POISONS BOARD
REGARDING THE IMPORTATION AND DISTRIBUTION
OF THE RUSSIAN-MANUFACTURED SPUTNIK V
VACCINE

Sen. Mutahi Kagwe began his statement by apologising for his failure to attend the initial meeting that was held on 18th March, 2021. Stating that his failure to attend had been occasioned by confusion following the Presidential directive on Parliament Sittings, he nonetheless iterated his respect and regard for the Senate having previously served as a Senator.

He further indicated that the COVID-19 pandemic was a very fast-moving and very dynamic situation in which everything was fluid and changed very quickly.

With regard to the questions that the Committee had been sent to the Ministry, he stated that while the Russian-manufactured Sputnik COVID-19 vaccine had not been approved for use by the World Health Organisation, clinical data and quality data review is ongoing.

Regarding whether the Ministry of Health had developed the necessary protocols and guidelines for the engagement of the private sector for the importation, distribution and deployment of COVID-19 vaccines in Kenya, the CS stated that the Pharmacy and Poisons Board had developed a Guidance Document on 'The Role of Private Sector In The Deployment of Covid-19 Vaccines' to provide guidance to the pharmaceutical industry on the documentation requirements and procedure for rollout of COVID-19 vaccines by the private sector.

Regarding whether the Russian-manufactured Sputnik COVID-19 vaccine had been approved for use in Kenya, the CS stated that the vaccine had been granted Emergency Use Authorization (EUA) by the Pharmacy and Poisons Board for use in Kenya and that the vaccine was in use in over sixty (60) countries across the world. Further, that the Emergency Use Authorization Holder of the Vaccine was the Federal Government Budgetary Institution N. F. Gamaleya National Research Center of Epidemiology and Microbiology of the Ministry of Health of the Russian Federation (FSBI N.F. Gamaleya NRCEM of the Ministry of Health of Russia) and their Local Technical Representative (LTR) is Dinlas Pharma EPZ.

In terms of the procedure that was followed in granting the EUA, he stated that the initial application was submitted on 5th February 2021 and the first assessment on quality, efficacy and safety initiated on 8th February 2021 with rolling submission of data.

The first assessment was completed on 24th February 2021 and communication sent out on the same

day raising scientific queries/questions on the product. The second round of assessment of the product took place on 5th March 2021 whereby the responses made to the queries by the applicant were considered and found to be satisfactory. As such based on available data on safety, quality and efficacy the product was found to have met all the requirements for Emergency Use authorization in line with the Pharmacy and Poisons Board Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies (ECUA).

With regards to which companies had received authorization for the importation and distribution of the said vaccine, the CS indicated that the authorized importer of the vaccine was Dinlas Pharma EPZ Ltd, as the local technical representative of the Emergency Use Authorization holder. Further, as the authorized importer, Dinlas Pharma Ltd has appointed two (2) recognized wholesale distributors namely: Harleys Ltd and Unisel Pharma (K) Ltd to facilitate the distribution of the said vaccine in the country.

On the safety profile, efficacy and known side effects of the Sputnik COVID-19 vaccine, the CS iterated that the vaccine had been established through a multicenter clinical trial that was conducted in 25 clinical trial sites in Moscow. Clinical data derived from the study indicated evidence of high efficacy (96%) of the study vaccine. Side effects of the vaccine reported from the vaccine study were reported as follows:

- a) General disorders and reactions at the injection site included: pyrexia, pain, edema, itching at the vaccination site, asthenia, pain, malaise, pyrexia, increased skin temperature at the vaccination site, decreased appetite.
- b) Nervous system: headache
- c) Gastrointestinal system: diarrhoea.
- d) Respiratory system, chest and mediastinal organs: pain in the oropharynx, nasal congestion, sore throat, rhinorrhoea.
- e) Laboratory and instrumental data: multidirectional deviations of indicators of immunological status.

Further, with regards to which adverse side effects and/or deaths had been attributed to the vaccine at the global, regional and local level, the CS indicated that according to the World Health Organisation Global Database for individual case safety reports (ICSRs), as of 28th March 2021, all identified Adverse Events (AES) attributed to the Sputnik V vaccine were considered mild and less often of moderate severity with a flu-like syndrome which was stopped by the appointment of non-steroidal anti-inflammatory drugs (pain killers) and antihistamines were prescribed. Further, that majority of the Adverse Events Following Immunisation (AEFIS) reported were not classified as serious and only about 5% of the serious ones caused/prolonged hospitalisation. Typical adverse effects following immunisation were reported as follows: headache, myalgia (muscle soreness and aching), hyperhidrosis (excessive sweating), fatigue and urticaria (skin rash). He further reported that no deaths had been reported so far due to the vaccine.

He further informed the Committee that as of 28th March 2021, the Pharmacy and Poisons Board was in receipt of only one (1) application for authorization of a COVID-19 vaccine namely, COVAXIN manufactured by Bharat Biotech International Limited, India whose local technical representative was Simba Pharmaceuticals Ltd.

With regards to the steps that the Ministry of Health had undertaken to guarantee the health and safety of Kenyans in relation to COVID-19 Vaccines, he stated that Kenya had put in place an independent National Vaccine Safety Advisory Committee (NVSAC) composed of experts from different professional backgrounds that continuously provided advice to the MoH on matters regarding vaccine safety. The Committee consisted of pediatricians, vaccinology experts, epidemiologists, pharmacologists, physicians, pharmacists, pharmacovigilance experts, infectious disease specialists, pathologists and others. Further, that the Ministry had deployed a robust monitoring system to identify, report, and investigate all adverse events following immunization (AEFIs) leveraging heavily on the current immunization AEFI reporting structure and the electronic PPB reporting system. In addition, training and capacity building of health workers on vaccine management and safety reporting (including vaccine pharmacovigilance) prior to the COVID Vaccine roll out had been done to eliminate any programmatic errors and ensure that AEFIs were picked up, reported in a timely manner and investigated. He further stated that the MoH was investing in specialized vaccine storage and monitoring equipment to ensure the COVID-19 Vaccines and others were maintained in the highest quality possible, to minimize any potential side effects.

During the plenary session, the CS stated that the MoH had adopted a cautious approach with opening the window for private sector involvement in COVID-19 vaccines. Stating that the country was already in receipt of applications from Pfizer, Johnson & Johnson and companies from China, he emphasised that the approach by the MoH was necessary for purposes of minimising the risk of scandal.

He further stated that the GoK had minimised the risk of the sale of Astrazeneca vaccines by being the sole distributor in Kenya.

Regarding social media reports that there were people planning to take both the Astrazeneca and Sputnik vaccines, he iterated that it was inadvisable for persons to mix vaccines.

He further stated that the MoH was in receipt of inquiries from major hospitals with independent sourcing systems who were seeking approval to import various vaccines. In this regard, he informed the Committee that the COVAX and AU programmes were in discussions on the possibility of opening the private window within one or two weeks. Through this arrangement, with the approval of the Government, reputable private institutions and hospitals would be enabled to purchase vaccines privately through COVAX and the AU programmes. He further

cited the Philippines as a country that had incorporated the private sector into the COVAX facility.

Further, stating that the greatest utility of the COVID-19 vaccines was in preventing severe disease, reducing hospitalization and deaths, he stated that the Government was targeting to reach at least 26 million of the adult population as follows:

Noting that the MoH's initial target population was to reach 16 million by June, 2023 comprising of: 1.5 million frontline healthcare workers, 10 million elderly and persons with underlying conditions and 5 million people in refugee camps, informal settlements and prisons. However, following a directive from the Head of State, the new target was to reach 4 million people by June, 2021 and 26 million Kenyans by June, 2022.

With regards to achieving herd immunity, the MoH submitted that even if they were to vaccinate the entire adult population (excluding pregnant women and persons under 18 years), the maximum population coverage they were capable of achieving was 50%.

In order to monitor and evaluate the impact of the COVID-19 vaccine, the MoH submitted that it was monitoring the number of hospitalizations, and estimating whether infection rates are coming down or not. Further, that they were checking amongst those hospitalized, who was vaccinated and who was not vaccinated so as to evaluate the impact of the vaccination.

As to the impact of the vaccination exercise on the overall transmission of the COVID-19 disease, the MoH submitted that it was going to monitor this by the number of confirmed cases. Further, that it was collaborating with KEMRI and other academic institutions to document the impact of its vaccination programme.

Regarding the recommended duration between the first and the second dose of the AstraZeneca COVID-19 vaccine, the MoH submitted that the taskforce in Kenya chose eight weeks so as to allow for coverage of as many people from the first shipment, with people who had received the vaccine being due for their second dose in May, 2021. The MoH however noted that WHO recommends that the second dose can be given even after 12 weeks.

With regards to COVID variants in the country, the MoH submitted that from 28th February to 5th March, 2021 they sequenced about 33 samples that had been picked from Nairobi and the coastal region. Out of those, they picked 19 variants, 15 of which were the South African variant, and one UK variant. Majority of those people had history of travel. Of note, they had also picked variants from people with no history of travel thus implying that Kenya had the seeds for variants that could potentially lead to community transmission.

With regards to challenges in the *Chanjo* information system and the long queues that had been observed at vaccination centres, the MoH submitted that the system had since been upgraded to allow for self registration. This was expected to eliminate waiting times, and reduce the queues at the centers.

Regarding growing concerns that the country was running out of the Astrazeneca vaccine, the MoH submitted that it had received a total of 1,020,000 AstraZeneca doses from the COVAX arrangement. In addition to that, it had also received an additional 100,000 doses as a contribution from the Government of India adding up to 1.2 million doses in the country. Noting that they had already vaccinated 200,000 people by the time of the meeting, the MoH stated that in order to allow for people to get the second dose, they would vaccinate up to 900,000 people with the first dose, and leave only a small window for the second dose because they expected to receive another 2.6 million doses in the next three weeks.

The MoH further submitted that the potential shortage had been occasioned by the variance in the initial target groups, and the expanded target groups following the Presidential directive to include the elderly and vulnerable.

He further stated that there was a challenge in the global market arising from the suspension of exports of the Astrazeneca vaccine by India.

As a contingency measure, the MoH had signed up for the South Africa -manufactured Johnson and Johnson vaccine which was expected to roll out by June, 2021. To this effect, the CS stated that Kenya had already reserved 20 million doses.

With regards to the challenges that the MoH was facing, the CS highlighted the following:

- a) Persons not on the priority lists are showing up at the vaccination centres.
- b) Reporting challenges through the *Chanjo* System owing to overwhelmed health facilities opting to use manual systems

Regarding licensing of affordable rapid tests to allow for the lifting of the lockdown, the MoH submitted that no rapid tests had been licensed in the country owing to efficacy concerns. However, the country would soon deploy WHO-approved rapid tests at border points in order to mitigate the socioeconomic impact of the pandemic.

The MoH further stated that it was in the process of developing guidelines to ensure correct pricing of privately-sourced COVID-19 vaccines.

There being no other business, the meeting was adjourned at 5.45 pm.

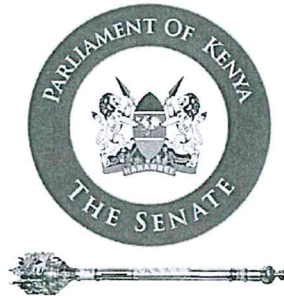


SIGNED:.....

(CHAIRPERSON)

7/4/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON TUESDAY, 6TH APRIL, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

APOLOGIES

- 1) Sen. Millicent Omanga, MP

SECRETARIAT

- 1) Ms. Emmy Chepkwony - Principal Clerk Assistant
- 2) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 3) Ms. Farhiya Ali - Sergeant-at-Arms
- 4) Ms. Sombe Toona - Legal Counsel
- 5) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:01 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

ADOPTION OF THE AGENDA

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

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. ***Cancellation of licenses to private sector entities in the importation, distribution and administration of COVID-19 vaccines;***
3. ***The looming ARV Crisis;***
4. Any other business.
5. Date of the Next Meeting.
6. Adjournment.

MIN. NO. SCH2/051/2020

**CANCELLATION OF LICENCES TO PRIVATE
SECTOR ENTITIES IN THE IMPORTATION,
DISTRIBUTION AND ADMINISTRATION OF
COVID-19 VACCINES INTO KENYA**

—

Members deliberated on a public statement issued by the Cabinet Secretary, Ministry of Health on 2nd April, 2021 in which he announced the cancellation of licenses to private sector entities in the importation, distribution and administration of COVID-19 vaccines. In relation to the above, Members noted several issues with regards to the cancellation as summarised below:

1. That the public statement issued by the CS, Health on 2nd April, 2021 contradicted previous statements that he had made to the Committee on diverse dates;
2. Further, that there were ethical issues to be considered in relation to the 527 citizens who had already received the first dose of the Russian Sputnik V and were due to receive the second dose.
3. In addition, there was need for the Government to consider compensating the private companies that were involved in the importation and distribution of the

Russian Sputnik V vaccine in light of the fact that the vaccine was already in use, and that the companies had been duly licensed and had received all the necessary approvals to import and distribute the said vaccine.

Further, the Committee raised queries regarding whether any private companies and/or entities would be involved in the importation, distribution and/or administration of the Johnson and Johnson COVID-19 vaccine, or any other government-approved COVID-19 vaccine for public distribution. Further, whether private sector entities would be allowed to participate in the importation and distribution of COVID-19 vaccines in the future.

In relation to the above captured issues, the Committee instructed the secretariat to invite the Cabinet Secretary of Health for an urgent meeting to respond to the queries raised on Thursday, 8th April, 2021 and 9.00 am.

MIN. NO. SCH2/051/2020

THE LOOMING ARV CRISIS

The Committee was taken through a summary of the looming countrywide ARV crisis as summarised below:

That according to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018, there were 1.3 million adult Kenyans (15-64 years) and 139,000 children (0-14 years) living with HIV in 2018.

Of these, approximately 79.4% of adults knew their status (approx. 1,032,000). Of those who knew their status, 95.7% were receiving ARV treatment (or 987,816 children and adults).

The Committee was further informed that the survey had found that HIV prevalence was highest in Kisii (6.1%), Turkana (6.8%), Busia (9.9%), Siaya (15.3%), Kisumu (17.5%), Homabay (19.6%) and Migori (13.0%).

The Committee was further informed that according to a public statement by the Pharmaceutical Society of Kenya, USAID had raised several governance and accountability issues with the supply chain of ARVs donated and distributed through

KEMSA. Accordingly, in August 2020, USAID/Global Fund pulled out of the KEMSA system and began to work with private supply chain suppliers (presumably MEDS) allegedly owing to corruption at KEMSA. As a consequence, the GoK had removed all tax incentives on HIV donations from USAID/Global Fund. As a result, billions worth of donations for HIV treatment were stuck at the port awaiting clearance for taxes and other levies.

Considering that Kenya was heavily reliant on USAID and other donors for ARVs and other essential drugs, the standoff between the GoK and USAID had put the lives and health of the approximately one million people on antiretroviral therapy at risk.

Following deliberations, the Committee resolved to organise a meeting with the Ministry of Health and the Ministry of Finance and National Treasury as the key stakeholders involved in the impasse.

Further, in consideration of the fact that the matter was effectively under the National Government, the Committee resolved to handle the matter jointly with the Departmental Committee on Health of the National Assembly. Key issues to be addressed at the meeting were provided as summarised below:

- a) What were the terms and conditions of the USAID/Global Fund grant for ARVs, and what had changed.
- b) What were the legislative issues or gaps that needed to be addressed with regards to the grant and similar grants for other essential medicines e.g. antimalarials, anti-TB treatment etc.
- c) What had triggered the impasses and what remedial actions could be taken?

MIN. NO. SCH2/051/2020

ADJOURNMENT

There being no other business, the meeting was adjourned at 10.45 am.



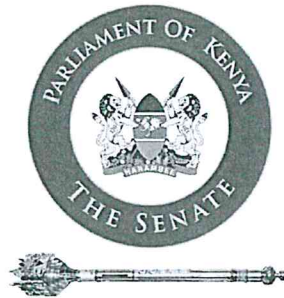
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(CHAIRPERSON)

14/4/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON THURSDAY, 8TH APRIL, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

IN ATTENDANCE

- | | | |
|---------------------------------------|---|----------------------|
| 1) Dr. Rashid Abdi Aman, BPharm., Phd | - | CAS |
| 2) Dr. Patrick Amoth | - | Ag. Director-General |
| 3) Dr. Kepha Ombacho | - | |
| 4) Dr. Collins Taabu | - | Head, KEPI |
| 5) Dr. Fred Siyoi | - | CEO, PPB |
| 6) Dr. Kariuki | - | PPB |
| 7) Ms. Rose Mudibo | - | MoH |
| 8) Dr. Ian Were | - | MoH |

SECRETARIAT

- | | | |
|-------------------------|---|----------------------------------|
| 1) Ms. Emmy Chepkwony | - | Principal Clerk Assistant |
| 2) Dr. Christine Sagini | - | Research Officer/Clerk Assistant |

- | | | |
|--------------------|---|------------------|
| 3) Ms. Farhiya Ali | - | Sergeant-at-Arms |
| 4) Ms. Sombe Toona | - | Legal Counsel |
| 5) Mr. Robert Rop | - | Audio Officer |

MIN. NO. SCH2/050/2020 **PRELIMINARIES**

The Meeting commenced at 9:07 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020 **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. Mary Seneta, MP:-

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Statement by the Cabinet Secretary, Ministry of Health on the cancellation of licenses to private sector entities for the importation, distribution and administration of COVID-19 vaccines;*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020 **HOUSEKEEPING**

Prior to inviting the guests to join the meeting, the Chairperson brought it to the Committees' attention that owing to an unforeseen engagement with the Head of State, the Cabinet Secretary of Health had begged leave to be represented at the meeting by Dr. Rashid Abdi Aman, Chief Administrative Secretary (CAS), Ministry of Health (MoH). After several discussions, the Committee resolved to allow the CAS to represent the CS, Health at the meeting. Further, the Committee resolved that if the responses received from the CAS, Health would prove to be inadequate, a further invitation would be sent to the CS, Health to appear in person.

MIN. NO. SCH2/051/2020 **STATEMENT BY THE MINISTRY OF HEALTH
ON THE CANCELLATION OF LICENSES TO
PRIVATE SECTOR ENTITIES FOR THE
IMPORTATION, DISTRIBUTION AND
ADMINISTRATION OF COVID-19 VACCINES**

According to Dr. Rashid Abdi Aman, CAS, MoH, who read a statement on behalf of the Cabinet Secretary of Health, the changing positions by the MoH on the role of the private sector in the importation, distribution and administration of COVID-19 vaccines as evidenced by its statements to the Committee dated 18th March, 2021 and 29th March, 2021, the oral submissions by the Cabinet Secretary of Health at the Committee meeting held on Thursday, 1st April, 2021, and a public statement issued by the Cabinet Secretary of Health on 2nd April, 2021, had been necessitated by a resolution of the National Emergency Response Committee (NERC) to put on hold the participation of the private sector until such a time as greater transparency and accountability in private importation, distribution and administration of COVID-19 vaccines could be assured and in public interest.

He further stated that it had come to the NERC's attention that the appointed distributors of the Sputnik V vaccine were engaged in marketing of the vaccine in contravention of the guidelines issued by Pharmacy and Poisons Board, which prohibit marketing when a product is still under Emergency Use Authorization (EUA).

Further, he stated that the NERC's decision had been informed by concerns that the irregular deployment of the Sputnik V vaccine was likely to reverse the gains that had been made in the fight against the pandemic by facilitating the introduction of counterfeit vaccines into the Kenyan market and putting the country at further risk of COVID-19 spread and increased morbidity and mortality.

Further, he stated that the NERC's decision was informed by the fact that the Sputnik V vaccine was yet to receive the WHO Emergency Use Listing. As such, the Government would not be able to guarantee the safety of the vaccine being deployed.

With regards to what ethical considerations had informed the decision to cancel the importation, distribution and administration of the Sputnik V vaccine considering the Government's assurance to members of public who had received the first vaccine that they will duly receive the second dose, he stated that since the mixing of vaccines was not recommended by either WHO or other experts due to their different modes of action, the Government of Kenya thought it ethical to ensure that those who had received the first dose of Sputnik V vaccine and were due for the 2nd dose in 3 weeks were assured of receiving their dose to complete the vaccination. He further noted that this criterion would only apply to the 527 vaccination cases which had been reported in the Chanjo-KE System at the time of the ban.

On whether the private entities involved in the importation and distribution of the Russian-manufactured Sputnik V vaccine would receive just compensation for their vaccines in light of the fact they were duly licensed, had received all the necessary approvals to import and distribute the said vaccine and the vaccine was already in use, he observed that the Ministry was not in a position to pronounce itself on the matter as the cancellation of the licenses had been done in the best interests for the Public Health of all Kenyans.

He further stated that no private companies and/or entities would be involved in the importation, distribution and/or administration of the Johnson and Johnson COVID-19 vaccine, or any other Government-approved COVID-19 vaccine for public distribution. He further stated that the Government's intention was to procure any government-approved vaccines through three mechanisms:

- a) The COVAX Facility, through which Kenya was currently getting the AstraZeneca vaccine;
- b) The AFRICA CDC Platform; and/or
- c) Directly from manufacturers through bilateral agreements.

In relation to the above, he noted that when Johnson and Johnson vaccine became available under any of the above mentioned mechanisms, the Government would proceed to procure, or in the case of COVAX, receive it as a donation.

With regards to whether the private sector would be allowed to participate in the importation and distribution of COVID-19 vaccines, he noted that the MoH had constituted a team with representation from the Kenya Medical Practitioners and Dentists Council and the Pharmacy and Poisons Board which would engage the private sector in developing a framework to guide private sector involvement in the importation, distribution and administration of approved COVID-19 vaccines. He further noted that the aim was to ensure that the Government came up with a transparent and accountable system that would ensure public health safety at all times. With regards to the proposed timelines, he stated that the plan was to have the framework in place by the end of June, 2021 and for the private sector to join the vaccine roll-out plan by July, 2021.

MIN. NO. SCH2/051/2020

ADJOURNMENT

There being no other business, the meeting was adjourned at 12.27 pm.

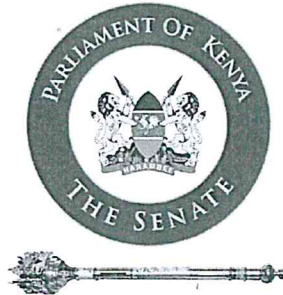
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SIGNED:.....

(CHAIRPERSON)

14/4/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON WEDNESDAY, 14TH APRIL, 2021 AT 9:00 A.M. ON THE
ZOOM ONLINE PLATFORM**

PRESENT

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

APOLOGIES

- 1) Sen. Beatrice Kwamboka, MP
- 2) Sen. (Prof) Samson Ongeru, EGH, MP
- 3) Sen. Mary Seneta MP

SECRETARIAT

- 1) Ms. Emmy Chepkwony - Principal Clerk Assistant
- 2) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 3) Ms. Farhiya Ali - Sergeant-at-Arms
- 4) Ms. Sombe Toona - Legal Counsel
- 5) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:00 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

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. Mary Seneta, MP:-

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Confirmation of Minutes of the Sittings held on:*
 - *6th April, 2021;*
 - *7th April, 2021; and*
 - *8th April, 2021*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

CONFIRMATION OF MINUTES

The Minutes of the Sitting held on Wednesday, 6th April, 2021 were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Ledama Olekina, MP and seconded by Sen. Beth Mugo, MP.

The Minutes of the Sitting held on Thursday, 7th April, 2021 were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Beth Mugo, MP and seconded by Sen. (Dr.) Abdullahi Ali, MP.

The Minutes of the Sitting held on Friday, 8th April, 2021 were confirmed as a true record of the Committee's deliberations having been proposed by Sen. Millicent Omanga, MP and seconded by Sen. Beth Mugo, MP.

The Committee deliberated on the meeting with the Ministry of Health that was held on 8th April, 2021, at which the Cabinet Secretary was represented by Dr. Rashid Aman, Chief Administrative Secretary. The Committee observed that the responses it received to its supplementary questions did not satisfactorily address the questions raised by the Committee.

The Committee therefore resolved to invite the Cabinet Secretary of Health to a meeting to provide further clarifications on the issues that arose. In particular, the Committee identified the issue regarding the role of the Ministry of Health and the National Emergency Response Committee *vis-à-vis* that of the Pharmacy and Poisons Board, in the approval and revocation of licenses to private entities for the importation, distribution and administration of health products, including vaccines.

The Committee proposed to hold the meeting on Wednesday, 28th April, 2021 at 9.00 am, and instructed the secretariat to inform the MoH that the Cabinet Secretary of Health would be required to attend the meeting in person.

MIN. NO. SCH2/051/2020

ADJOURNMENT

There being no other business, the meeting was adjourned at 10.15 am.



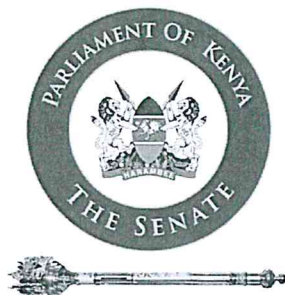
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(CHAIRPERSON)

10/3/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON TUESDAY, 20TH APRIL, 2021 AT 9:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

IN ATTENDANCE

- 1) Dr. Amit Thakker - Chairman, Kenya Healthcare Federation (KHF)
- 2) Dr. Elizabeth Wala - Vice-Chair

SECRETARIAT

- 1) Ms. Emmy Chepkwony - Principal Clerk Assistant
- 2) Dr. Christine Sagini - Research Officer/Clerk Assistant
- 3) Ms. Farhiya Ali - Sergeant-at-Arms
- 4) Ms. Sombe Toona - Legal Counsel
- 5) Mr. Robert Rop - Audio Officer

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 9:02 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

ADOPTION OF THE AGENDA

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

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. *Meeting with the Kenya Private Sector Alliance and the Kenya Healthcare Federation to discuss the role of the Private Sector in the COVID-19 Pandemic*
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

**ROLE OF THE PRIVATE SECTOR IN THE
COVID-19 PANDEMIC RESPONSE**

Led by the Chairperson, Dr. Amit Thakker, KHF made submissions to the Committee as summarised below:

Dr. Amit commenced his presentation by introducing his team, and providing background information on KHF.

With regards to the role of the private sector in the national COVID-19 vaccination roll-out exercise, Dr. Amit stated that within the context of the global pandemic, rising levels of confirmed cases and deaths attributable to COVID-19 amidst a third wave and a concomitant strain on the health system, multi-stakeholder engagement on the COVID-19 vaccine deployment in Kenya was key.

He further identified the following challenges affecting COVID-19 vaccine deployment in Kenya: sluggish/slow rate of deployment, over-reliance on COVAX, weak communication strategy by the MoH, high levels of vaccine hesitancy, confusion and angst.

He outlined the potential role of the private sector as follows: importation and sourcing, logistics and distribution, administration of vaccinations, technology and administrative support.

He also identified the following areas under which the private sector could be used to complement Government efforts in the deployment of the COVID-19 vaccine: administration of

vaccinations at a dispensing fee at accredited private sector facilities; ICT and administrative support through the enhancement of the *Chanjo* information management system, communications and PR support etc; and, provision of logistics and distribution expertise to improve reach and enhance efficiency.

He further submitted that KHF was in the process of reviewing a policy framework in collaboration with PPB and the Kenya Medical Practitioners and Dentists Council (KMPDC) for the importation and distribution of COVID-19 vaccines.

With regards to the cancellation of the license for the Russian-manufactured Sputnik vaccine, he stated that KHF had appealed the Government's decision to cancel the licenses and permits for the importation, distribution and administration of the Russian-manufactured COVID-19 Sputnik-V vaccine. The federation nonetheless stated that the distributors of the vaccine had engaged in unscrupulous business practices by advertising the vaccine, and administering it in non-authorised premises.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

There being no other business, the committee adjourned at 11.30 a.m.



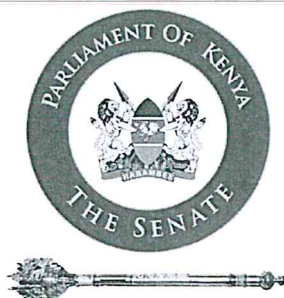
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10/3/2021

DATE:.....

TWELFTH PARLIAMENT | FIFTH SESSION



MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON 30TH APRIL, 2021 AT 2:30 P.M. ON THE ZOOM ONLINE PLATFORM

PRESENT

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

APOLOGIES

1. Sen. (Dr.) Michael Mbitu, MP - Chairperson

IN ATTENDANCE

A. Ministry of Health

1. Sen. Mutahi Kagwe, EGH - Cabinet Secretary
2. Mrs. Susan Mochache - Principal Secretary
3. Dr. Patrick Amoth - Ag. Director General
4. Dr. Willis Akhwale - Chairperson, National COVID-19 Vaccine Taskforce
5. Ms. Rose Mudibo - Director, Parliamentary Liaison
6. Dr. Rabera Kenyenyra
7. Mrs. Nurseline Onsongo
8. Dr. Ian Were

B. Pharmacy and Poisons Board

1. Dr. Fred Siyoi - CEO/Registrar

SECRETARIAT

- | | | |
|-------------------------|---|----------------------------------|
| 1) Ms. Emmy Chepkwony | - | Principal Clerk Assistant |
| 2) Dr. Christine Sagini | - | Research Officer/Clerk Assistant |
| 3) Ms. Farhiya Ali | - | Sergeant-at-Arms |
| 4) Ms. Sombe Toona | - | Legal Counsel |
| 5) Mr. Robert Rop | - | Audio Officer |

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 2:05 p.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

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. Fred Outa, MP:-

1. Preliminaries
 - a) *Prayer*
 - b) *Adoption of the Agenda*
2. ***Submission of Statement by the Cabinet Secretary, Ministry of Health, on the status of the national COVID-19 vaccination roll-out.***
3. Any other business.
4. Date of the Next Meeting.
5. Adjournment.

MIN. NO. SCH2/051/2020

STATEMENT BY THE CABINET SECRETARY OF HEALTH ON THE COVID-19 VACCINATION ROLL-OUT

Led by the Hon. Mutahi Kagwe, Cabinet Secretary, the Ministry of Health (MoH) updated the Committee on the status of the COVID-19 vaccination roll-out as summarised below:

With regards to the role of the MoH and the National Emergency Response Committee *vis-a-vis* that of the Pharmacy and Poisons Board in the approval and revocation of licenses to private entities for the importation, distribution and administration of health products, including vaccines, the Cabinet Secretary stated that the MoH is responsible for Health Policy under the Fourth Schedule of the Constitution, and is mandated to implement the principles in Articles 10 and 232, and Chapters 6 and 12 of the Constitution.

He further stated that the Pharmacy and Poisons Board (PPB) falls under the MoH , and is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act (Cap 244). It is responsible for the regulation of health products and technologies, and is mandated, *inter alia*, to: grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medical substances; ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy; and, ensure that the personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances comply with the defined codes of practice, and other prescribed requirements.

He further stated that according to the Pharmacy and Poisons Rules, appeals of decisions made by the PPB lie with the CS, Health.

In specific relation to the cancellation of licenses and permits for the importation, distribution and administration of vaccines, he submitted that it was empowered under Section 158(1) of the Public Health Act, to prohibit the importation, manufacture or use of any such substance, which is considered to be unsafe or liable to be harmful or deleterious, thus: *"the Minister may provide for the inspection, sampling and examination, by officers of the Medical Department, of vaccines, vaccine lymph, sera and similar substances imported or manufactured in Kenya and intended or used for the prevention or treatment of human diseases, and may prohibit the importation, manufacture or use of any such substance which is considered to be unsafe or to be liable to be harmful or deleterious."*

He further stated that the National Emergency Response Committee on the Coronavirus Disease was established by H.E. The President on 28th February, 2020 *vide* Executive Order No. 2 of 2020. Among others, its terms of reference include the coordination of Kenya's preparedness, prevention and response to the threat of the Coronavirus disease.

Noting that the MoH was responsible for issuing and providing policy direction to PPB , and noting that health products and technologies was a key policy orientation under the Kenya Health Policy (2014-2030), he noted that under the unprecedented emergency of the pandemic, regulatory emergency responses , including emergency use authorisation, import licenses for

products under emergency authorisation and Good Distribution Practices, preceded specific policy directions on the same.

Noting that the NERC's mandate enabled it to influence policy relating to the management of the pandemic, he stated that its resolutions had led to the policy decision to restrict import, distribution and administration of COVID-19 vaccines to the Government only. In this regard, the PPB as the implementing agency was expected to enforce the policy.

With regards to reported shortages of the Astrazeneca vaccine, and the measures that the Government had taken to ensure that all eligible persons receive their first and booster vaccine doses in a timely manner, the CS informed the Committee that as 26th April, 2021, out of 1,080,000 AstraZeneca vaccine doses that the Government had received, there was a balance of 40,000 vaccine doses at the Kitengela Central Vaccine stores.

He further informed the Committee that the total number of persons vaccinated stood at 853,081, 56% of whom were males, while 44% were females.

Of the targeted population groups, 74% of health workers had been vaccinated, 39% of teachers, and 10% of persons aged above 58 years.

With regards to the issuance of the 2nd dose of AstraZeneca, he stated that global supply constraints arising from the decision by the Government of India to prioritise the vaccination of its own population, and the inability of the Serum Institute of India to meet global demand, had led to delays in the delivery of 2.5 million vaccine doses that the Kenya was in line to receive under the COVAX facility. Noting that the issue was global, and beyond Kenya and/or COVAX, he nevertheless stated that there were concerted international efforts to address the challenges.

He further stated that in reliance of current evidence and WHO guidance, the MoH had made a policy decision to extend the duration between the first and second AstraZeneca vaccine doses from 8-12 weeks. Noting that the first recipients of the second dose were expected to receive their booster dose in the first week of June, 2021, he stated that supplies from COVAX were expected to have been received by then.

He further stated that the MoH had engaged the African Union with a view to procure 7 million doses of Pfizer, and 10 million doses of Johnson and Johnson. This was expected to provide for the vaccination of 13.5 million Kenyans.

Further, indicating that the country also expected to receive a further donation of 20 million doses from COVAX, plus 11 million of self-procured vaccines, he stated that Kenya expected to fully vaccinate its entire adult population by the end of June, 2022.

MIN. NO. SCH2/051/2020

ADJOURNMENT

There being no other business, the meeting was adjourned at 4.25 pm.

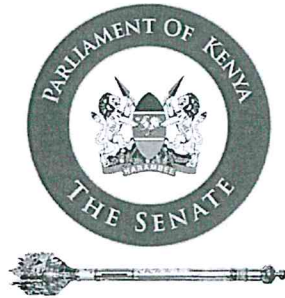


SIGNED:.....

(CHAIRPERSON)

10/3/2021

DATE:.....



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON
HEALTH, HELD ON MONDAY, 10TH MAY, 2021 AT 8:00 A.M. ON THE ZOOM
ONLINE PLATFORM**

PRESENT

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

SECRETARIAT

- | | | |
|-------------------------|---|----------------------------------|
| 1) Ms. Emmy Chepkwony | - | Principal Clerk Assistant |
| 2) Dr. Christine Sagini | - | Research Officer/Clerk Assistant |
| 3) Ms. Farhiya Ali | - | Sergeant-at-Arms |
| 4) Ms. Sombe Toona | - | Legal Counsel |
| 5) Mr. Robert Rop | - | Audio Officer |

MIN. NO. SCH2/050/2020

PRELIMINARIES

The Meeting commenced at 8:19 a.m with a word of prayer from the Chairperson.

MIN. NO. SCH2/051/2020

ADOPTION OF THE AGENDA

The Committee adopted the agenda of the sitting, as set out below, having been proposed by Sen. Beatrice Kwamboka, MP and seconded by Sen. (Prof.) Sam Ongeru, EGH, MP:-

1. Preliminaries

a) Prayer

b) Adoption of the Agenda

2. *Consideration and adoption of the Third Progress Report of the Committee on the COVID-19 Pandemic Situation.*

3. Any other business.

4. Date of the Next Meeting.

5. Adjournment.

MIN. NO. SCH2/051/2020

**CONSIDERATION AND ADOPTION OF THE
THIRD PROGRESS REPORT OF THE COMMITTEE
ON THE COVID-19 PANDEMIC SITUATION**

The Committee considered and adopted the Third Progress Report of the Standing Committee on Health on the COVID-19 Pandemic Situation (Preliminary Findings of the Committee on the National COVID-19 Vaccine Roll-Out) with amendments having been proposed by Sen. (Dr.) Abdullahi Ali, CBS, MP and confirmed by Sen. Mary Seneta, MP. Committee amendments to the report were proposed under Committee Observations relating to the emergency authorisation and cancellation of licenses and permits for the importation, distribution and administration of the Russian-manufactured Sputnik-V vaccine.

MIN. NO. SCH2/051/2020

ANY OTHER BUSINESS

There being no other business, the committee adjourned at 9.30 a.m.



SIGNED:.....

(CHAIRPERSON)

10/3/2021

DATE:.....