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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.

COY  
Recommended for approval  
for tabling

17/05/21

Approved  
mm

10<sup>th</sup> May, 2021

18/5/2021

① DC-EG  
Recommended & Forwarded  
for Processing  
17/25/21

## **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 Mbito, MP.
2. Sen. Mary Seneta, MP.
3. Sen. Beth Mugo, EGH, MP.
4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeri, 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 27<sup>th</sup> March, 2021 and 1<sup>st</sup> May, 2021 respectively.

**Mr. Speaker,**

According to the World Health Organisation (WHO), as of 17<sup>th</sup> 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,**

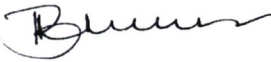
It is important to note that the COVID pandemic situation is a highly evolving one: As such, the observations and recommendations contained in this report reflect the situational context, and information that was available to the Committee at the time of the writing of this report. Accordingly, as the 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, 19<sup>th</sup> 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, 10<sup>th</sup> 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.....10<sup>th</sup> May, 2021.....

**SEN. MBITO MICHAEL MALING'A, MP**

**CHAIRPERSON, STANDING COMMITTEE ON HEALTH**

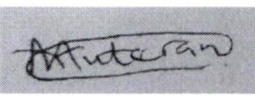
**ADOPTION OF THE REPORT OF THE STANDING COMMITTEE ON HEALTH OF THE SENATE**

**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 Mbitu, MP

..... 

2. Sen. Mary Seneta, MP

..... 

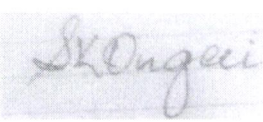
3. Sen. Beth Mugo, EGH, MP

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4. Sen. Beatrice Kwamboka, MP

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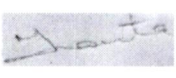
5. Sen. (Prof) Samson Ongeri, EGH, MP

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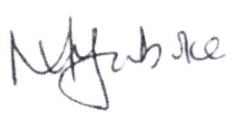
6. Sen. (Dr) Abdullahi Ali Ibrahim, MP

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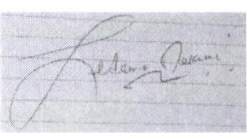
7. Sen. Fred Outa, MP

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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.*”

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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 of 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 10<sup>th</sup> 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 10<sup>th</sup> 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 5<sup>th</sup> 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 9<sup>th</sup> 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 17<sup>th</sup> March, 2021 and 30<sup>th</sup> 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 17<sup>th</sup> March, 2021 and 30<sup>th</sup> 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, 17<sup>th</sup> 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, 18<sup>th</sup> March, 2021, Thursday, 1<sup>st</sup> April, 2021, Thursday, 8<sup>th</sup> April, 2021 and Friday, 30<sup>th</sup> 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, 18<sup>th</sup> 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 3<sup>rd</sup> March, 2021. The vaccines were distributed to all 47 counties with vaccination commencing on 5<sup>th</sup> 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 26<sup>th</sup> 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 30<sup>th</sup> 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:

- 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 28<sup>th</sup> February and 5<sup>th</sup> 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, 18<sup>th</sup> 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 (1<sup>st</sup> dose) as of 16<sup>th</sup> 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, 29<sup>th</sup> 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;

- 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, 29<sup>th</sup> 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, 29<sup>th</sup> 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, 19<sup>th</sup> 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-authorised 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%).

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.

***1) 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 28<sup>th</sup> February and 5<sup>th</sup> 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

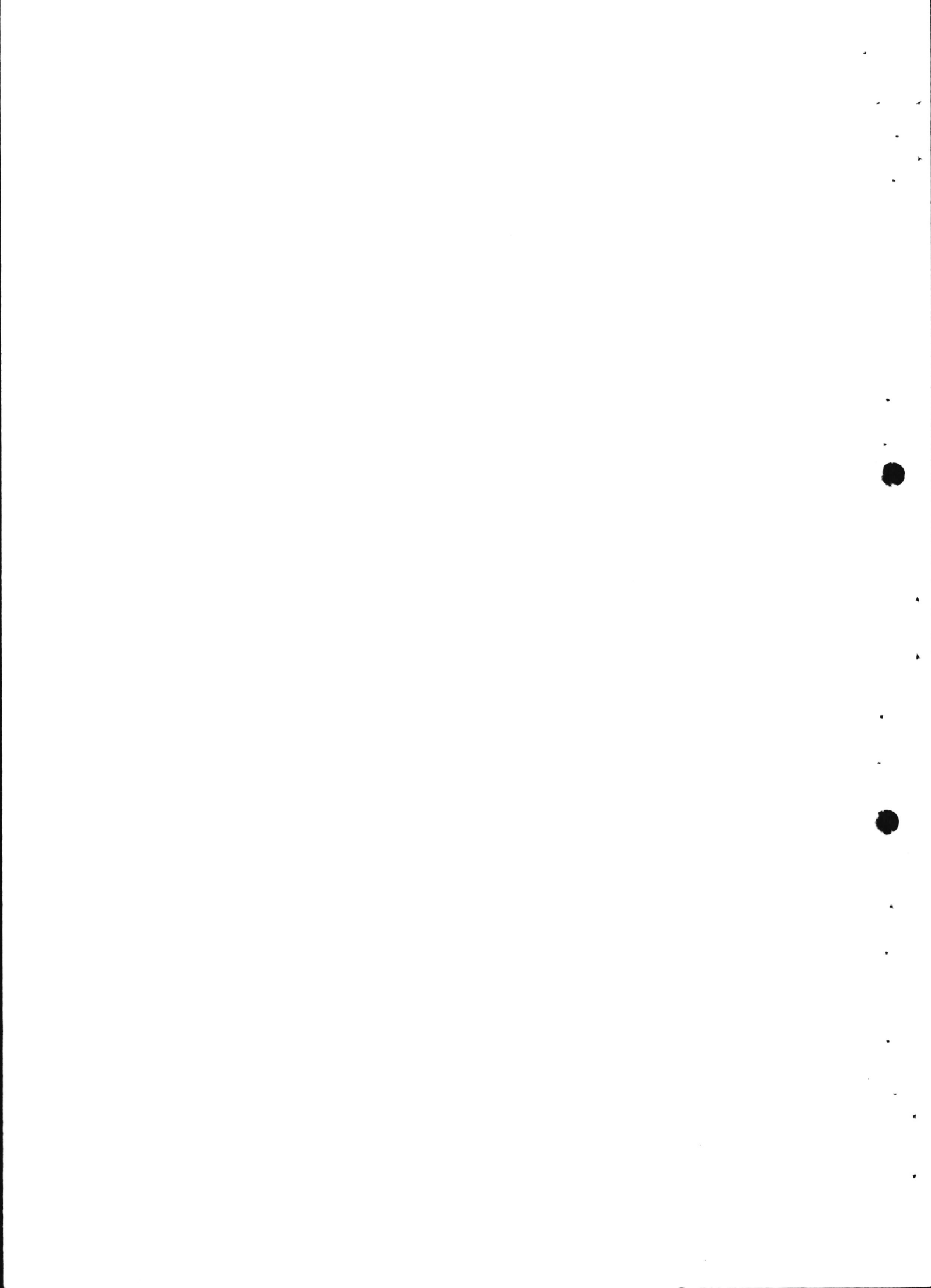
Based on the foregoing, the Committee made the following recommendations:

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 2<sup>ND</sup> 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.

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.

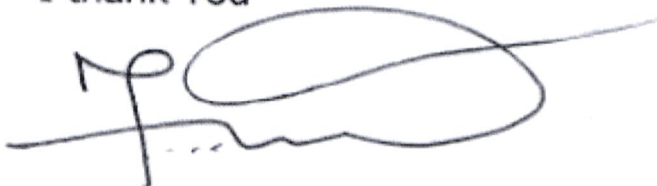
It's important to note that the decisions for group targeting were informed by an assessment of vulnerabilities and potential for infection, hospitalization and even death. The idea is to make sure those at the greatest risk are prioritized as vaccines become available.

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.

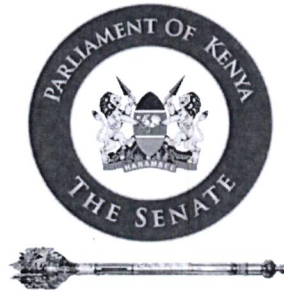
8. The Committee has taken notice of information that some countries wish to put our country on the red list. NERC recommends that the Ministry of foreign affairs takes up the matters and where necessary, a reciprocal arrangement be adopted.
9. There will be a need for up scaling of communication both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

TWELFTH PARLIAMENT |FOURTH SESSION



**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 Mbitio, 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

**MIN. NO. SCH2/107/2020**

**PRELIMINARIES**

The Chairperson called the meeting to order at 9:05 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. 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 Ileri 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:**.....

TWELFTH PARLIAMENT | FIFTH SESSION



**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 Ongeri, 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:.....

**TWELFTH PARLIAMENT | FIFTH SESSION**



**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 Nyong'o, 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 (1<sup>st</sup> dose) as of 16<sup>th</sup> 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.

A handwritten signature in cursive script, appearing to read 'B. ...', is written in black ink.

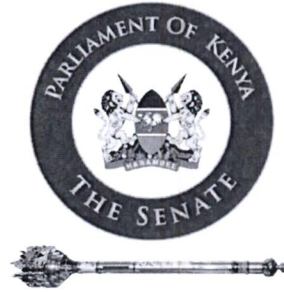
**SIGNED:**.....

**(CHAIRPERSON)**

**25/03/2021**

**DATE:**.....

TWELFTH PARLIAMENT | FIFTH SESSION



**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 Mbitu, 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:**.....

TWELFTH PARLIAMENT | FIFTH SESSION



**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 Ongeri, 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. 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 Olekina, 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.



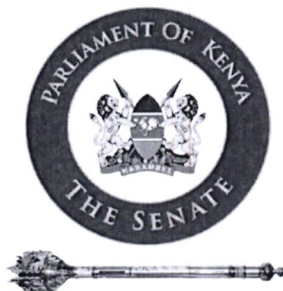
**SIGNED:**.....

**(CHAIRPERSON)**

**31/03/2021**

**DATE:**.....

**TWELFTH PARLIAMENT | FIFTH SESSION**



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON  
HEALTH, HELD ON WEDNESDAY, 31<sup>st</sup> 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.

**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. 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.

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

**CONFIRMATION OF MINUTES**

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.

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

**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**

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.

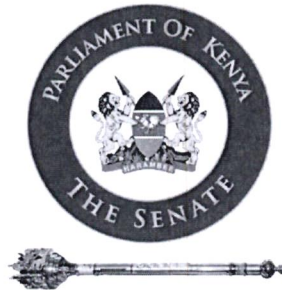


SIGNED:.....

**(CHAIRPERSON)**

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

TWELFTH PARLIAMENT | FIFTH SESSION



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON THURSDAY, 1<sup>ST</sup> 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 Mbiti, 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 Mbwiri    | - | 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 Sitings, 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 28<sup>th</sup> February to 5<sup>th</sup> 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.

MIN. NO. SCH2/051/2020

ADJOURNMENT

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

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SIGNED:.....

(CHAIRPERSON)

7/4/2021

DATE:.....

**TWELFTH PARLIAMENT | FIFTH SESSION**



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON  
HEALTH, HELD ON TUESDAY, 6<sup>TH</sup> 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**

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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.



**SIGNED:**.....

...

**(CHAIRPERSON)**

**14/4/2021**

**DATE:.....**



- |                    |   |                  |
|--------------------|---|------------------|
| 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.

*Bruce*

SIGNED:.....

(CHAIRPERSON)

14/4/2021

DATE:.....

**TWELFTH PARLIAMENT | FIFTH SESSION**



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

**PRESENT**

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

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

**MATTERS ARISING**

The Committee deliberated on the meeting with the Ministry of Health that was held on 8<sup>th</sup> 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, 28<sup>th</sup> 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.



**SIGNED:**.....

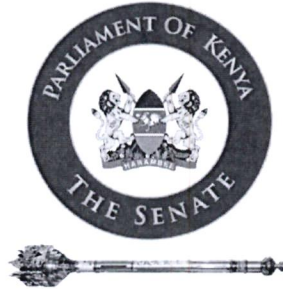
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**(CHAIRPERSON)**

**10/3/2021**

**DATE:**.....

TWELFTH PARLIAMENT | FIFTH SESSION



**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.



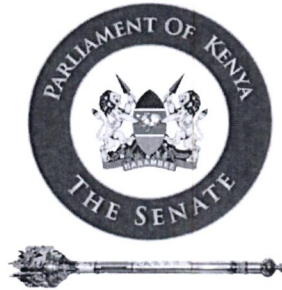
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**(CHAIRPERSON)**

**10/3/2021**

**DATE:**.....

TWELFTH PARLIAMENT | FIFTH SESSION



**MINUTES OF THE SITTING OF THE SENATE STANDING COMMITTEE ON HEALTH, HELD ON 30<sup>TH</sup> 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 Mbiti, 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 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:.....

TWELFTH PARLIAMENT | FIFTH SESSION



**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:.....

**REPUBLIC OF KENYA**



**MINISTRY OF HEALTH**

**National COVID-19 Vaccines  
Deployment and Vaccination Plan,  
2021**

**National Vaccine & Immunization Program**

**January 2021**

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## Abbreviations and definitions

DSRU	Disease surveillance and response unit
COVID-19	Corona Virus Disease-2019
WHO	World Health Organization
CEPI	Coalition for Epidemic Preparedness Innovations
ACT	Access to COVID-19 Tools (ACT)
PHEIC	Public Health Emergency of International Concern
UNICEF	United Nations International Children's Emergency Fund
UNICEF SD	United Nations International Children's Emergency Fund-Supply Division
MCHIP	Maternal and Child Health Integrated Program
CHAI	Clinton Health Access Initiative
CIHEB-Kenya	Center for International Health Education and Biosecurity
KANCO	Kenya Aids NGOs Consortium
GAVI	The Vaccine Alliance
EPI	Expanded Programme on Immunization
EVMA	Effective Vaccines Management Assessment
MERS	Middle East respiratory syndrome
SARS	Severe acute respiratory syndrome
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
PHC	Primary health care
AEFI	Adverse event following immunization
AESI	Adverse event of special interest
UHC	Universal health coverage
PPB	Pharmacy and Poisons Board
NDRA	National Drug Regulatory Authority
KENITAG	Kenya National Immunisation Technical Advisory Group
NVIP	National Vaccine Immunisation Program
IA2030	Immunization Agenda 2030
SDGs	Sustainable Development Goals
KEHP	Kenya Essential Health Package
cMYP	comprehensive multi-year strategic plans
IPC	Infection prevention and control
PPE	Personal protective equipment
ICAT	Infection Control and Assessment Toolkit
MoH	Ministry of Health
IM	Intramuscular
JICA	Japan International Cooperation Agency
IPV	Inactivated polio vaccine
DVS	District Vaccine Stores
HF	Health Facilities
KFW	German state-owned development bank
HSS	Health Systems Strengthening

ToTs	Trainer of Trainees
CHMTs	County Health Management Teams
VVM	Vial Vaccine Monitor
SOPs	Standard Operating Procedure
HIV	Human Immunodeficiency Virus
NGOs	Non-Governmental Organizations
CSOs	Civil Society Organizations
VE	Vaccine Effectiveness

## Executive Summary

Kenya has a well-established immunization program and a robust disease surveillance and response unit (DSRU) which serves as an early warning system, to identify public health emergencies, guide public health policy and strategies, document impact of an intervention or progress towards specified public health targets/goals and understand/monitor the epidemiology of a condition to set priorities and guide public health policy and strategies.

Vaccination plays a critical role in limiting the impact of COVID-19 pandemic and is an essential element of pandemic COVID-19 preparedness and response. The overarching goal for COVID-19 vaccines is to save lives and mitigate the effects of the COVID-19 pandemic. As a country, we are cognizant of the fact that speed is of the essence to deliver a pandemic vaccine. The main goal is deployment within seven days of vaccine availability with subsequent rapid in-country vaccination.

As a signed-up member of the WHO endorsed COVAX facility, Kenya has targeted to vaccinate 30% of her population within the initial phase of the roll out of the vaccine. The number of doses will depend on the dose regimen of the vaccine and number of doses per vial. The targeted populations in order of priority will be healthcare professionals, older persons above the age of 65 and people living with comorbidities. Additional target groups will be based on those deemed most at risk. The country targets to have the vaccine within the country by end of **February 2021** and initiate vaccination by **March of 2021**

## 1. Introduction

COVID-19 was unknown prior to the outbreak in Wuhan, China, in December 2019. The disease spread rapidly across the globe. On 30 January 2020, WHO declared the COVID-19 outbreak a Public Health Emergency of International Concern (PHEIC) and on 11 March characterized it as a pandemic. Globally, as of 2 December 2020, there have been 102,399,513 confirmed cases of COVID-19, including 2,217,005 deaths, reported to WHO. In the African region, there have been 2,570,574 confirmed cases.

Kenya's index case was reported on 12th March 2020. As at 31st January 2021, 100,773 cases and 1,763 deaths have been reported. This ranks Kenya as 7th on the case fatality rate in Africa.

The COVID-19 vaccine program is part of the effort to reduce the spread and transmission of covid-19, and therefore limit the morbidity and mortality associated with infection and the broader socio-economic effects of the pandemic.

The objectives of Kenya's National Vaccine Deployment plan (NVDP) is to outline a strategy for:

1. Deployment, implementation and monitoring of the COVID-19 vaccine(s) in Kenya.
2. Ensure the plan and related financing is well aligned to the overall national COVID-19 recovery and response plans.

This document consists of 10 chapters covering the major areas and key activities necessary to successfully deploy, implement and monitor COVID-19 vaccination. The understanding of COVID-19 epidemiology continues to evolve and is rapidly changing. A description of the COVID-19 disease, what is currently understood of its transmission patterns and the situation in Kenya can be found in Annex 8. Properties of current available vaccines are described in annex 7

*Trends of COVID-19 Outbreak cases Kenya*

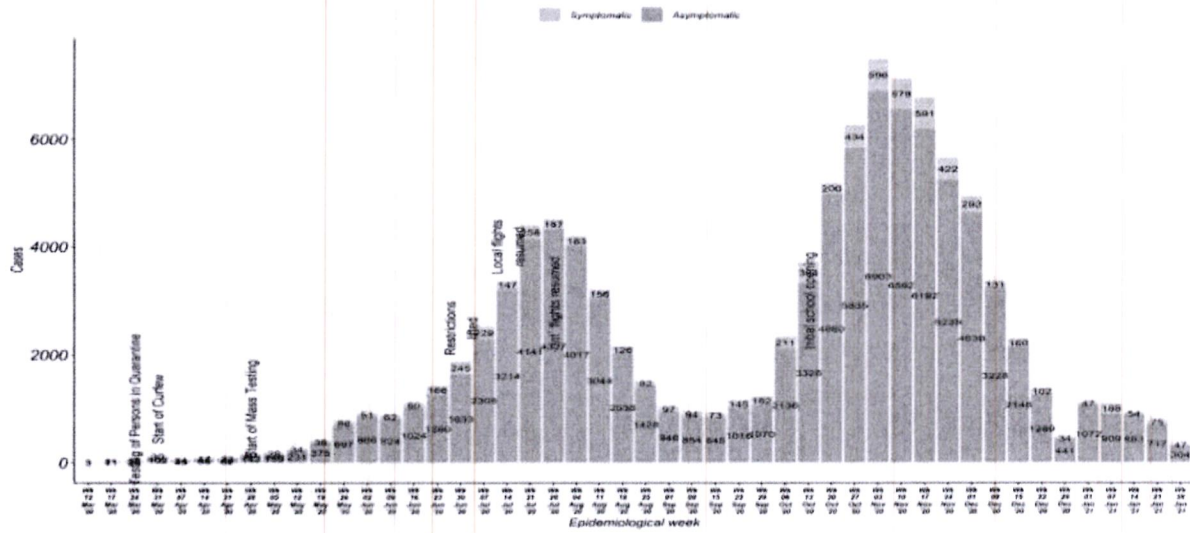
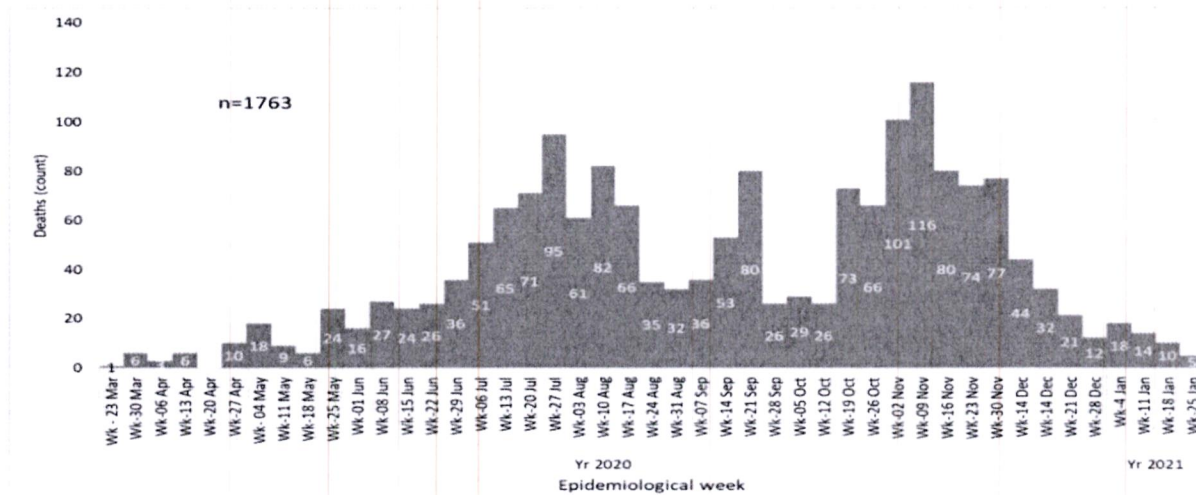
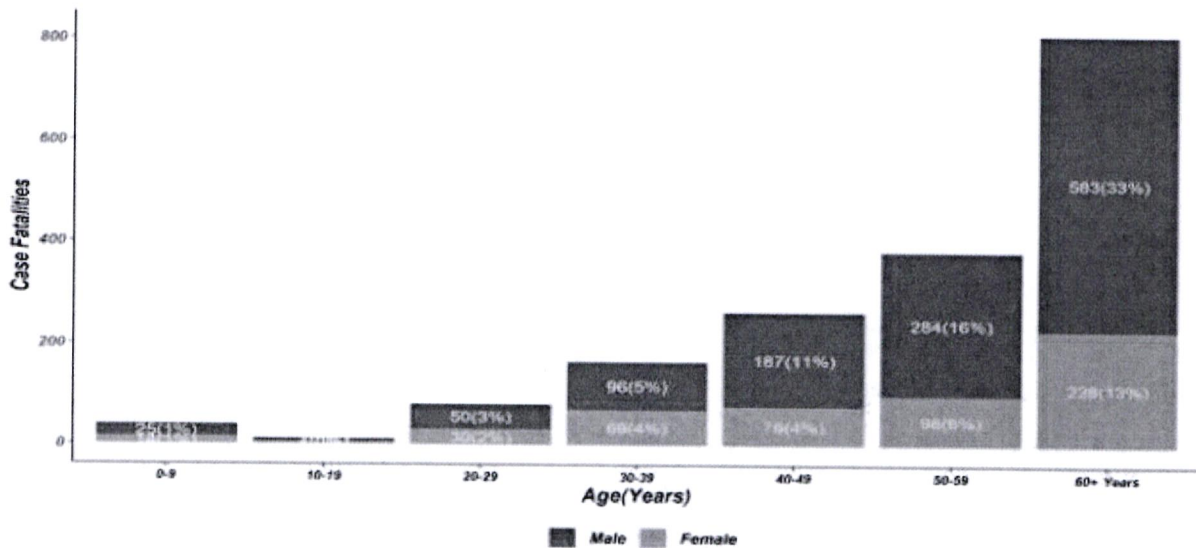


Figure 1: Trends of Fatalities by week, Kenya



A total of 1,586 deaths have been reported so far, 1,123 (71%) being males and 463 (29%) were females (Figure 8).

Age and sex distribution of COVID-19 Case Fatalities, Kenya



The country is witnessing a community level transmission of the COVID Disease. Nairobi County has the highest attack rate of 885.5 per 100,000 population followed by Mombasa County at 682.2 per 100,000 population as below:

## Background

Kenya is a lower middle-income country (LMIC) with the third largest economy in Sub-Saharan Africa [3] (GDP per capita USD 2,008). In 2019/2020 total health expenditure was KES 230.4 billion (USD 2.3 billion).

Kenya is a signatory to the Addis declaration on immunization, that required counties to attain Universal Access to Immunization. In 2019, immunization coverage was 82% (target >90%). In the last ten years, eight new vaccines have been successfully introduced into the national immunization program. Currently, it costs the country KES 6.0 Billion to procure and distribute vaccines for routine Immunization and maintain depots of which GAVI contributes KES 3.8 Billion and the Government 1.4 Billion, leaving a gap of KES 0.8 Billion. The country risks outbreaks of diseases e.g. Measles, in the face of inadequate funding for operations. Kenya having become a LMIC is expected to be self-financing for immunization by 2027.

*Covid -19 Vaccine rollout*

The National Emergency Response Committee and the Kenya National Immunization Technical Advisory Group endorsed the introduction of COVID-19 vaccine in Kenya. This will be done in the context of the National Routine Vaccines and Immunization Program.

The coordination of the immunization program is supported by the N-ICC Immunization Interagency Coordinating Committee, the KENITAG (Kenya National Immunization Technical Advisory Group), and the NVSAC (National Vaccine Safety Advisory Committee). They provide overall technical and policy advisory on Immunization, as per their Terms of Reference. They report to the Cabinet Secretary Health, and National Steering Committee, for purposes of the COVID Vaccine introduction.

#### COVID-19 vaccines

The World Health Organization (WHO) has to date approved three vaccines for deployment, namely: Pfizer BioNTech, Moderna and AstraZeneca while a few other vaccines are finalizing trials and will be reviewed for registration soon.

The above vaccines require two doses for optimal immunogenicity and efficacy. There are vaccines based on at least six vaccine platforms being deployed against the coronavirus:

#### Vaccines Landscape

<b>Name of Vaccine</b>	<b>WHO prequalification or SRA's</b>	<b>Countries Using</b>	<b>Cost</b>	<b>Price under COVAX</b>
Pfizer/BioNTech	Yes (WHO, USFDA, MHRA, EMA, Swissmedic)	US ? UK, Belgium Canada Costa Rica Czech Republic Greece Germany	USD 20/dose in the US	USD 7

		Sweden Switzerland		
Moderna	Yes ( MHRA, EMA and USFDA)	USA Germany Canada Netherlands Spain	USD 32-37 /dose	USD 7
Astrazeneca/Oxford	Yes (MHRA)	UK Scotland Northern Ireland	USD	USD 7
Sinopharm	No	Brazil Bahrain China UAE	Less than USD 88 for 2 doses	TBD
Johnson	No	USA UK Philippines S. Africa Brazil Columbia	USD	TBD
Novavax	No	USA S.Africa Australia	USD	TBD
Sinovac	No	Brazil Turkey Bangladesh Indonesia	USD 3- 10 (Indonesia)	TBD

Various vaccine candidates use different technology platforms and will likely have different characteristics, including immunogenicity, dosing schedules, safety profiles, cold chain requirements, and manufacturing time. These factors have implications for how each vaccine can be used.

*Lessons learnt from influenza A H1N1 and other vaccine introductions.*

Kenya has been implementing an influenza vaccination demonstration project among children aged 6-23 months in two Counties (Mombasa and Nakuru) in Kenya since January 2019. Data from this demonstration project is expected to inform help the Ministry of Health understand the Programmatic Implications of introducing the COVID-19 vaccines.

Lessons Learned	Actions
<p><b>Coverage:</b></p> <ul style="list-style-type: none"> <li>A campaign strategy yields high coverage. However, adopting this as the primary strategy is costly and could be difficult to sustain. The estimated financial and economic costs amounting to US\$ 20.67 and US\$ 44.77 respectively (inclusive of vaccine costs, in the case of HPV).</li> </ul>	<ul style="list-style-type: none"> <li>Revise the primary strategy/ mode of delivery to a more sustainable approach i.e. facility-based approach</li> <li>Complement the facility-based approach with accelerated immunization activities (Immunization Days) outreach approach varied depending on country context</li> <li>Rump up advocacy and social mobilization efforts to ensure that the target population receives the message and seeks the vaccine at the facility</li> </ul>
<p><b>Microplanning</b></p> <ul style="list-style-type: none"> <li>Inaccurate target numbers of individuals to be vaccinated during new vaccine introductions, causing miscalculation of the required number of vaccines, with subsequent stockouts and/or un-realistic coverages</li> </ul>	<ul style="list-style-type: none"> <li>Ensure accurate and timely micro-planning and mapping of the target population in liaison with Counties and KNBS</li> <li>Ensure timely and adequate vaccine supply,</li> <li>Use appropriate advocacy and social mobilization using the disease specific platform</li> </ul>
<p><b>Staff Training</b></p> <ul style="list-style-type: none"> <li>Importance of having adequate training materials developed and distributed to all service points on time</li> </ul>	<ul style="list-style-type: none"> <li>Ensure technical guidelines and job aides are available at all levels including service points</li> <li>Technical guidelines and other materials should be bundled and delivered early in advance</li> </ul>
<p><b>Cold chain / storage capacity</b></p> <ul style="list-style-type: none"> <li>Following previous Vaccine introduction, counties reported increased cost of operation, especially costs related to the transportation of vaccines due to increase in the frequency of vaccine collection. This is due to inadequate storage/ transportation space.</li> <li>Need to address gaps in temperature monitoring</li> </ul>	<ul style="list-style-type: none"> <li>Ensure adequate planning and mapping of sites with adequate CCE</li> <li>Ensure continuous temperature monitoring devices (FT2) at all levels are available and working correctly</li> <li>Various investments (e.g. Gavi, KFW) have increased the cold chain capacity NVIP has developed a 5-year Cold Chain Expansion and Rehabilitation Plan (CCERP) that will guide investment in cold chain. To finance the plan, the MOH will enhance its advocacy activities with county leadership and immunization partners, as well as mobilize resources for CCE through Gavi HSS and CCEOP</li> </ul>

<p><b>Vaccine acceptability and dropout rates</b></p> <ul style="list-style-type: none"> <li>• Due to intensive collaboration with relevant stakeholders and packaging of messages, minimal hesitancy and refusals have been encountered.</li> <li>• Use of SMS and other reminders to clientele resulted in great penetration and demand generation for vaccination</li> </ul>	<ul style="list-style-type: none"> <li>• Increased engagement with stakeholders, especially religious leaders, and immunization champions, to reduce vaccine hesitancy and dropout rates.</li> <li>• Packaging the vaccines as a COVID Control strategy</li> <li>• Collaboration with other ministries e.g., Education, interior will lead to the success of the roll out.</li> <li>• Apply strategies that have worked in the past to increase demand for the vaccine e.g., use of SMS</li> </ul>
<p><b>Others</b></p> <ul style="list-style-type: none"> <li>• Concerns regarding virus mutation among Health workers.</li> <li>• concerns as to why only specific groups were being vaccinated and not all other populations.</li> <li>• Concerns about the short expiry nature of the vaccine.</li> <li>• Some health care workers linked the Influenza vaccination drives to a COVID-19 trial vaccine.</li> <li>• Most health care workers requested for influenza vaccine notification cards as proof of immunization and requested for annual vaccination.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure technical guidelines and job aides are available at all levels including service points, ahead of the introduction.</li> <li>• Conduct an audience segmentation and adapt messages to specific audiences targeting the concerns raised.</li> <li>• Engage relevant experts to continuously engage and regularly provide updates to health workers on the COVID Vaccines</li> </ul>

## 2. Regulatory preparedness

Kenya has an established National Drug Regulatory Authority (The Kenya Pharmacy and Poisons Board (PPB), established in 1957 by an Act of Parliament, the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya.

The Pharmacy and Poisons Board is charged with the responsibility of regulating the practice of pharmacy and trade in health products and technologies. The PPB's core mandate is to ensure the provision of quality, safe and efficacious

medical products and health technologies in Kenya. All drugs and vaccines must receive prior approval before use in Kenya.

### *Covid-19 Vaccine Regulatory Approval*

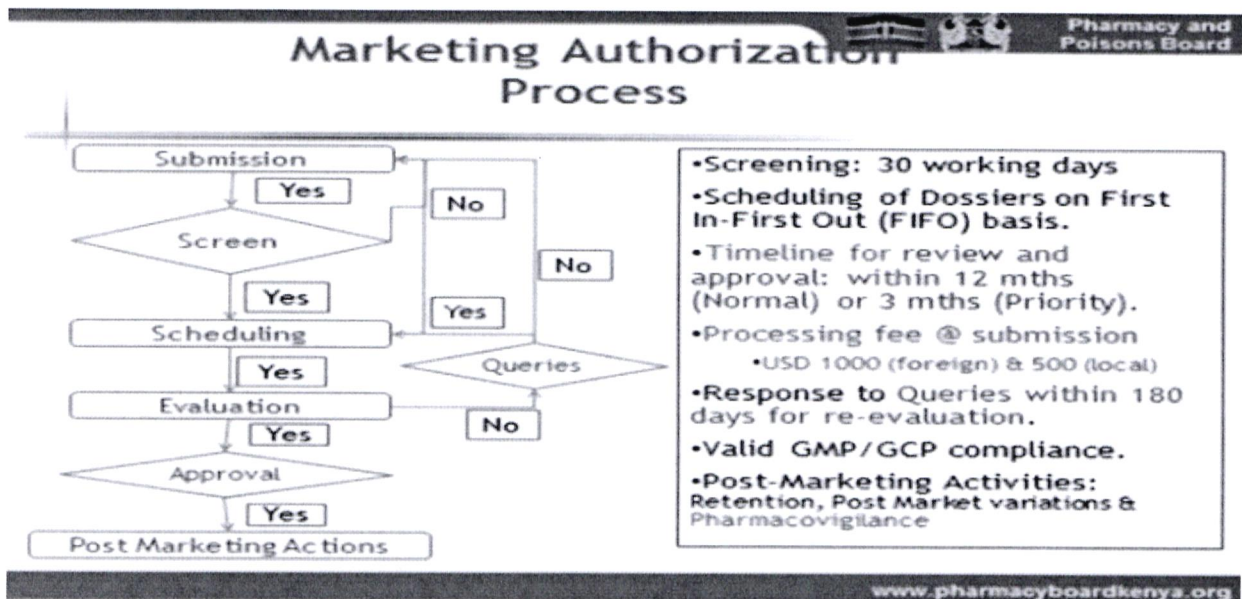
COVID 19 vaccines must receive PPB authorization before use in Kenya. The review process will involve evaluating submitted data on the quality, safety and efficacy of the COVID 19 vaccines.

COVID 19 vaccines must receive PPB authorization before use in Kenya. The review process will involve evaluating submitted data on the quality, safety and efficacy of the COVID 19 vaccines.

COVID-19 vaccines that have already received approval from stringent regulatory authorities (SRAs) or WHO will be expedited for approval within seven (7) days, upon application by the manufacturing company or their agent. The PPB recognizes regulatory decisions (marketing authorization or emergency approval) of Stringent Regulatory Authorities (SRAs) e.g. USFDA, MHRA, EMA, Swissmedic and WHO.

The diagram below shows the steps involved.

*Steps involved in licensure of medicines and biological products*



The following key parameters must be met for COVID 19 vaccines approval (adopted from EMA)

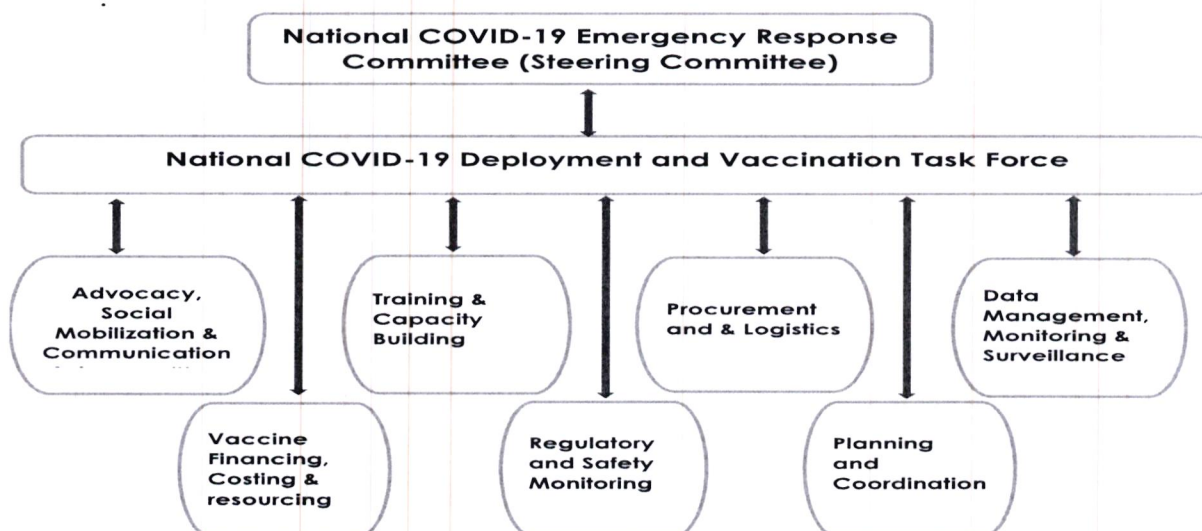
i. Primary endpoint: prevention against symptomatic COVID-19 disease of any severity
ii. Secondary endpoint: Prevention of severe disease or infection
iii. Point estimate vaccine efficacy of 50-60%, lower bound of 95% CI between 20-30% preferably above 30%, as per literature all COVID-19 vaccines have an efficacy of > 70%
iv. Clinical safety database (3000 subjects) followed for at least 6 weeks
v. Preclinical data: toxicology studies and challenge model tests tailored against a vaccine construct, if available.
vi. Primary assays of immunogenicity e.g. neutralizing antibodies assay should be established.
vii. Correlates of protection should be explored

### 3. Planning and coordination of the vaccine introduction

The COVID Vaccine introduction is through a strong country-led, multi-stakeholder and evidence-based decision-making process. The introduction is envisaged to be fast tracked under the direction of the Ministry of Health, with the support of other stakeholders.

A coordination structure, coordinated at three levels has been set up as below:

#### Summary of National Level Coordination Structures



## **National COVID-19 Vaccine Deployment and Vaccination Steering Committee (NSC)**

### **Members:**

**Hon. Sen. Mutahi Kagwe;** Cabinet Secretary Health (Chairman)

**Dr. Fred Matiangi;** Cabinet Secretary Interior and Coordination of National Government/ Designated Representative,

**Hon. Amb. Ukur Yatani;** Cabinet Secretary National Treasury/ Designated Representative,

**Prof. George Magoha;** Cabinet Secretary Education/ Designated Representative,

**H.E Hon. FCPA Wycliffe Ambetsa Oparanya;** Chairman, Council of Governors/ Designated Representative,

**Dr. Ruddi Eggers;** WHO Kenya Country Representative

**Dr. Maniza Zaman;** UNICEF Kenya Country Representative

**Dr. Jane Chuma;** World Bank Kenya Country Representative

**Dr. Gerald Macharia;** Country Director, CHAI Kenya

**Dr Marc Bulterys;** Country Director, CDC Kenya

**Rt. Rev. Peter Mbatia;** Catholic Health Commission

**Dr. Samuel Mwenda;** General Secretary, CHAK

**Mr. Ole Nado;** Representative, SUPKEM

**Prof. Fred Were;** Chair, KENITAG

**Dr. Fred Siyoi;** CEO, Pharmacy and Poisons Board

### **Terms of Reference of the Steering Committees**

1. To provide oversight for the planning and implementation of the COVID-19 Vaccine introductions, through review of recommendations of the technical working groups and provide appropriate guidance
2. To moderate on any impediments to the implementation of the COVID-19 vaccine introduction
3. Advocate for, guide & facilitate the implementation of COVID-19 vaccine introductions: Resource mobilization: Funds (Including disbursement modalities

and accountability); Technical support; Expediting any legal formalities; High Level engagement

4. Review the recommendations of the technical committee and give guidance on implementation of the vaccine introduction
5. Participate in the launch of the COVID-19 vaccine introduction

### **National COVID-19 Vaccine Deployment and Vaccination Task Force**

*Mandate:* Provide overall technical leadership for the vaccine deployment planning and implementation.

*Members of National Taskforce on Covid-19 Vaccines Deployment*

<i>National Taskforce on Covid-19 Vaccines Deployment.</i>		
Chair	Dr. Willis Akhwale	Disease control specialist/ Senior Advisor MOH
Member	Dr. Pacifica Onyancha	Head, Directorate Preventive and promotive Health Services
Member	Dr. Githinji Gitahi	AMREF
Member	Dr. Nazila Ganatra	Head Strategic Public health Programs
Member	Dr. Collins Tabu	Convenor/ Head, Division of national Vaccines and Immunization Program/ convener
Member	Mr. Mburugu Gikunda	MoH Advisor, Communications (Task Lead, Advocacy, Communication and Community Mobilization)
Member	Mr. Benson Murimi	MoH Kenya, Finance (Task Lead, Vaccine Financing, Costing & Resourcing)
Member	Dr. Ayub Manyà	Task lead- Data management, monitoring and surveillance
Member	Dr. Linda Makayotto	MoH, Surveillance
Member	Dr. Peter Mbwiri	Pharmacy and Poisons Board
Member	Mr. Onesmus Kamau	Data Management
Member	Dr. Peter Okoth	Immunization Specialist, UNICEF
Member	Dr. Kibet Sergon	WHO
Member	Dr. Richard Ayah	University of Nairobi
Member	Prof. Bernhards Ogutu	KEMRI
Member	Mr. Anthony Ngatia	CHAI
Member	Mr. Kenneth Munge	World Bank
Member	Edwine Barasa	Kemri Wellcome Trust

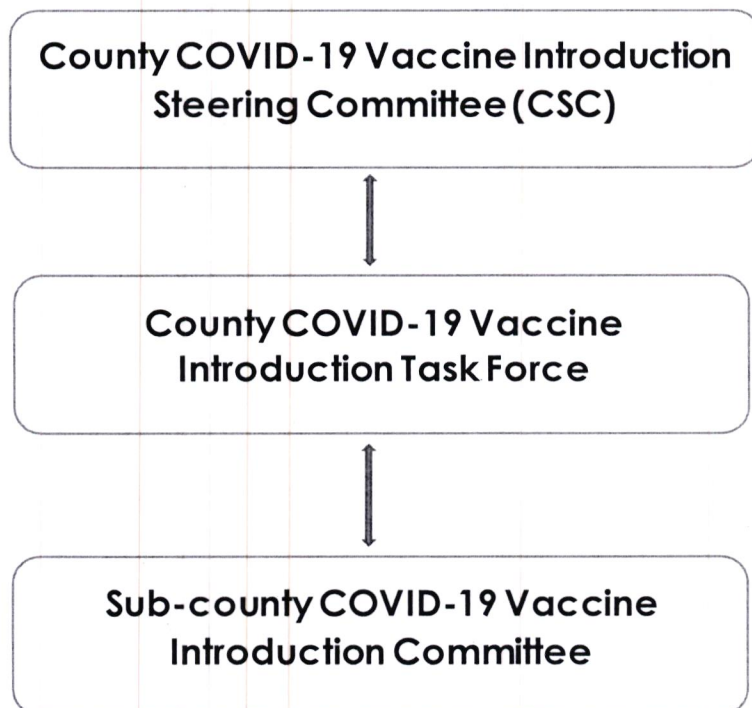
Member	Dr. Edward Abwao	USP
Member	Health Committee, CoG	Representative, Council of Governors
Member	Dr. Cosmas Mugambi	MOH
Member	Dr. Victoria Kanana	MoH, Secretariat
Member	Dr. Stephen Muleshe	MoH Kenya (Task Lead, Planning and Coordination)
Member	Mr. John Kabuchi	MoH, (Task Lead, Procurement and Logistics)
Member	Dr. Salim Hussein	MoH, Head, Department of primary Health

**Terms of reference of the Task Forces:**

1. Identify resource needs, and make recommendations for inclusion in the COVID-19 Deployment and Vaccination Plan
2. Guide technical sub-committees in the planning and implementation of the COVID-19 vaccine introduction
3. Review the work plans of the COVID-19 vaccine introduction technical sub-committees, guide as appropriate and monitor their implementation.
4. Review and approve the technical COVID-19 vaccine introduction materials including Print, electronic, vaccine logistics, training, tools among other vaccine introductions materials
5. Guide the technical communication, training, supervision, and monitoring of the COVID Vaccine introduction
6. Advise and report to the National Steering Committee regularly on the progress of the COVID Vaccine introduction and undertake any other duties as may be assigned by the NSC

Health is a devolved function and hence the need to have strong and well-coordinated structures at both the county and sub-county levels. At the County Level, there will be established the **COVID-19 Vaccine Deployment and Vaccination Steering Committee and Taskforce**. The County Emergency Covid-19 Response Committee could be adopted to form the Steering Committee.

## Summary of County Level Coordination Structures



### County COVID-19 Vaccine Deployment and Vaccination Steering Committee (CSC)

1. County Governor (Chairperson)/ or a designate
2. County Commissioner
3. County Secretary
4. ALL County Executive Committee Members
5. Representatives of National Government Departments within the County
6. Any other member as may be co-opted by the Chair.

### County COVID-19 Vaccine Deployment and Vaccination Taskforce

1. County Director for Health (Chairperson)
2. County Nursing Officer
3. County EPI Logistician
4. County Disease Surveillance Coordinator
5. County Health Records and Information Officer
6. County Health promotion Officer
7. County Community Health Services Officer

8. County Health Accountant
9. County Referral Hospital Medical Superintendents

The specific Tasks to be undertaken are:

*Preparatory phase:*

Monitor progress of database of beneficiaries on COVID-19 Vaccine.

Ensure training of all concerned HR on COVID-19 Vaccine into a training database.

Monitor progress on key activities such as microplanning, communication planning, cold chain and vaccine logistics planning. Accountability to be fixed for each activity at all levels.

Planning and mapping of vaccination sessions where HCWs and priority sector workers and other Priority Groups will be vaccinated during the initial phase of COVID-19 vaccine roll-out.

Involve other relevant departments and partners. Involve the local and religious leaders.

Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing COVID-19 vaccine.

Anyone legally authorized to give injection may be considered as potential vaccinator.

Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site.

*Implementation phase (upon availability of vaccine):*

Monitor the roll-out of COVID-19 vaccine in the county for progress made and resolving bottlenecks.

Requisition of required human resource and infrastructure including vehicles if needed from other departments for implementation and monitoring.

Ensure minimal disruption of other routine health services during rollout of COVID-19 vaccine.

Ensure identification and accountability of senior officers in sub-counties. They should visit these sub-counties and provide oversight to activities for rollout of COVID-19 vaccine, including participation in training, monitoring etc.

Ensure safe storage, transportation and delivery of vaccine doses with sufficient police arrangements so that there are no leakages in the delivery system.

Robust communication planning at all levels to address rumor mongering as well as vaccine eagerness. Ensure adequate number of printed IEC materials (as per prototypes) are printed and disseminated to blocks/planning units in time. Ensure that these materials are discussed and used in the sensitization workshops.

Track sub-counties and facilities for adherence to timelines for various activities required for introduction of COVID-19 vaccine.

Share key qualitative and quantitative feedback at county level for review.

Monitor meetings of County AEFI Committee for expedited investigation of AEFI.

### **Sub-county COVID-19 Vaccine Introduction Committee**

1. Subcounty Medical Officer for Health
2. Sub-county Public Health Nurse
3. Subcounty EPI Logistician
4. Subcounty Disease Surveillance Coordinator
5. Subcounty Health Records and Information Officer
6. Subcounty Health promotion Officer
7. Subcounty Hospital Medical Superintendent

The specific Tasks to be undertaken are:

#### *Preparatory phase:*

Monitor progress of database of beneficiaries to be shared with county and uploading to database.

Ensure training of all concerned HRH.

Monitor progress on key activities such as microplanning, communication planning, cold chain and vaccine logistics planning. Accountability to be fixed for each activity.

Planning and mapping of vaccination sessions where HCWs and other Priority Groups will be vaccinated during the initial phase of COVID-19 vaccine roll-out.

Involve all relevant departments and partners.

Identify vaccinators across government and private sectors to minimize disruption of Routine Immunization services while introducing COVID-19 vaccine. Anyone legally authorized to give injection may be considered as potential vaccinator.

Mapping human resources across departments that could be deployed for vaccination sessions for verification of beneficiaries, crowd management and overall coordination at session site.

*Implementation phase (upon availability of vaccine):*

Monitor the roll-out of COVID-19 vaccine in the sub-county for progress made and resolving bottle-necks.

Requisition of required human resource and infrastructure including vehicles if needed from county and/or other department for implementation and monitoring.

Ensure minimal disruption of other routine health services during rollout of COVID-19 vaccine.

Ensure supervision of vaccination sessions being conducted for COVID-19 vaccine.

Implementation of communication plan while addressing the local context and needs to address rumor mongering as well as vaccine eagerness. Maximize use of local influencers (including religious leaders) for countering misinformation.

Ensure adequate number of IEC material pertaining to COVID-19 vaccination is displayed at prominent places and at session site.

Ensure adherence to timelines for various activities required for introduction of COVID-19 vaccine.

Share key qualitative and quantitative feedback at county level for review.

### **FBOs, CSOs and Private Sector Engagement**

The FBOs, CSOs and Private Sector are represented at the National Covid-19 Vaccine Deployment Steering Committee and will play a pivotal role in the following areas;

Identification and registration of clients

Provision of facilities and vaccination services

Public awareness creation

Training & Capacity Building of the Health Care Workers

Safety monitoring and reporting

Logistical support including provision of vaccine storage facilities and maintenance.

#### **4. Resources and funding (costing tool under development)**

The resource requirements for the introduction of the COVID-19 vaccine were estimated based on the following approach presented in more detail in Section 5 - 11 of this plan:

The vaccine introduction will occur over the period Jan 2021 to December 2023 straddling three Kenya government financial years FY 2020/21; FY 2021/22 and FY 2022/23

The population coverage by the end of that period is aimed at 30%.

Vaccines will be sourced mainly from the COVAX facility though other options for purchase will be considered.

Vaccine introduction will be in phases designed based on priority populations, supply availability and health system capacity to deploy the vaccine.

Other activities planned for successful introduction include: capacity building of health workers, information management, surveillance, communication, advocacy and community engagement

The estimation of resource requirements is also informed by the following assumptions:

- Kenya plans to vaccinate 30% (or 15.8 Million) of a total population of 49,070,876 by the end of June 2023 in 3 phases
- Kenya will receive vaccine support from Gavi to vaccinate 20% of the population and self-procure vaccine for 10% of the population
- The vaccination will be rolled out in three phases, to progressively cover all target groups, based on vaccine availability- Phases may overlap
- Early vaccination to focus on administration sites that can reach prioritized populations with as much throughput as possible- Levels IV, V and VI hospitals estimated at 5% of the total facilities

- Positive storage temperature vaccines will be prioritized during Phase I while Negative Storage Temperature Vaccines, if available, will be considered during Phase II & III.
- Individuals will need to receive at least 2 doses of vaccine; During the Rollout, the MoH will hold a second dose reserve.

#### *Vaccine costing, financing and resourcing*

GAVI supports Kenya with vaccines through a co-financing approach to promote country ownership and financial sustainability of the routine immunization programme.

The country is set to access safe and effective COVID-19 vaccines to cover approximately 20% of the population through the GAVI COVAX Facility and additional doses to cover an additional 10% of the population. The GAVI indicative prices for vaccines ALL vaccines available through the COVAX facility is USD 7 (Kshs.770) per dose.

The total budget required to implement the sub-activities in the above indicated thematic areas is Kshs.34.02 billion. GAVI through COVID-19 Vaccine Global Access (COVAX) Facility will provide in-kind support equivalent to Kshs.19.71 billion by procuring vaccines and injection devices to vaccinate 20% of the population (approx. 11 million people). The GoK is expected to provide budgetary resources totaling Kshs.14.31 billion to vaccinate additional 10% of the population (approx. 4.9 million people) and all related operational costs.

The two tables below provide a summary of National COVID-19 Vaccine Deployment Budget.

#### *Summary of COVID-19 Vaccine Deployment Budget*

Main Activity Description	Financing		Total
	GoK	GAVI	
	Kshs.		
Procurement of Vaccines and Injection Devices (Covering 30% Population), Warehousing and Distribution	11,137,133,621	19,711,056,609	30,848,190,230
Cold Chain Equipment Capacity Expansion	1,446,529,104	0	1,446,529,104
Trainings & Capacity Building	175,834,854	0	175,834,854
Planning & Coordination	102,728,334	0	102,728,334

Data Management, Monitoring & Surveillance	564,517,418	0	564,517,418
Advocacy, Communication and Community Mobilization Initiatives	879,824,000	0	879,824,000
<b>Total</b>	<b>14,306,567,330</b>	<b>19,711,056,609</b>	<b>34,017,623,939</b>

*COVID-19 Vaccine Deployment Budget per Financial Year (Kshs.)*

Main Activity	FY 2020/21		FY 2021/22		FY 2022/23
	GAVI	GoK	GAVI	GoK	GoK
Procurement of Vaccines and Injection Devices (Covering 30% Population), Warehousing and Distribution	2,248,423,476	857,491,715	17,462,633,133	1,440,937,455	8,838,704,451
Cold Chain Equipment Capacity Expansion	-	-	-	1,446,529,104	-
Trainings & Capacity Building	-	156,405,054	-	19,429,800	-
Planning & Coordination	-	53,492,084	-	49,236,250	-
Data Management, Monitoring & Surveillance	-	292,605,478	-	215,149,440	56,762,500
Advocacy, Communication and Community Mobilization Initiatives	-	295,608,000	-	584,216,000	-
<b>Total</b>	<b>2,248,423,476</b>	<b>1,655,602,330</b>	<b>17,462,633,133</b>	<b>3,755,498,049</b>	<b>8,895,466,951</b>

GAVI through the COVAX mechanism has committed to supply 4.1 million doses of the AstraZeneca vaccine. While the Government has availed a budget of Kshs

933.2 million for Phase I of the introduction. Summary of the budget is shown in the table below but must be noted that currently there are limited vaccines stocks globally but are projected to increase during Phase II&III.

*Introductory Vaccines GoK Budget (Kshs.)*

<b>No.</b>	<b>Main Activity</b>	<b>GoK</b>
1	Procurement of Vaccines and Injection Devices (Covering 280,000 of the targeted Population), Warehousing, Distribution, Taxes & Clearance	592,617,352
2	Trainings & Capacity Building	70,802,082
3	Planning & Coordination	17,166,340
4	Data Management, Monitoring & Surveillance	20,573,740
5	Advocacy, Communication and Community Mobilization Initiatives	232,008,000
	<b>Total</b>	<b>933,167,514</b>

During phase I, the Ministry of Health intends to finance the total budget of Kshs.933.2 million from its own budgetary resources.

## **5. Target populations and vaccination strategies**

The rationale for the priority target populations, is aligned with the WHO Strategic Advisory Group of Experts (SAGE) recommendations, in the context of limited supply and values framework for the allocation and prioritization of COVID-19 vaccination and adapted to country context through consideration of Local COVID-19 Epidemiology data.

Further, consideration has been given to the community level transmission of the disease that's ongoing and the vaccine availability constraints.

The objective of the introduction is to reduce morbidity and mortality due to COVID-19, through maintaining the most critical essential services, protecting individuals most vulnerable to severe disease and death from COVID-19, and subsequently achieving equity and reducing transmission of COVID-19.

### **Approach to vaccination of target groups**

Kenya plans to vaccinate 30% (or 15.8Million) of a total population of 49,070,876 by the end of June 2023 in 3 phases.

During Phase 1, the initial COVID-19 vaccine supply will be limited; Significantly more COVID-19 vaccine will become available for distribution during Phases 2 and 3. The phases are not exclusive and may overlap. There are plans to increase coverage to 40% of the population (20 million) once more supplies become available.

Early vaccination will focus on administration sites that can reach prioritized populations with as much throughput as possible- Levels IV, V and VI hospitals estimated at 5% of the total facilities (Approx. 284 GoK and 195 Private HFs); Phase II will focus on administration sites most effectively able to assess comorbidities- Level III and above (Approx. 1,302 GoK and 2,582 Private HFs); Phase III will focus on all immunizing facilities (Approx. 4,338 GoK and 3,539 Private HFs) to achieve equity.

Negative Storage Temperature Vaccines to only be considered during phase II and III.

Individuals will need to receive at least 2 doses of vaccine; During the Rollout, the MoH will hold a second dose reserve to ensure that the individual receives the same vaccine.

The COVID-19 vaccine rollout is envisaged in phases as below:

**Phase I (Q3 &  
Q4, FY  
2020/2021)**

- **Vaccine supply limited**
- **Focus:** Rapidly reaching critical target populations
- **Priority Group:** Front line Health Care Workers (HCWs- Including CHWs) Critical/ Essential Workers
- **Target Population:** 1.25 Million

**Phase II (FY  
2021/2022)**

- **Larger number of vaccine doses available**
- **Focus:** Rapidly reaching target populations most vulnerable to severe disease and death
- **Priority Group:** Persons >50 years and those >18 years with co-morbidities
- **Target population:** 9.76 Million

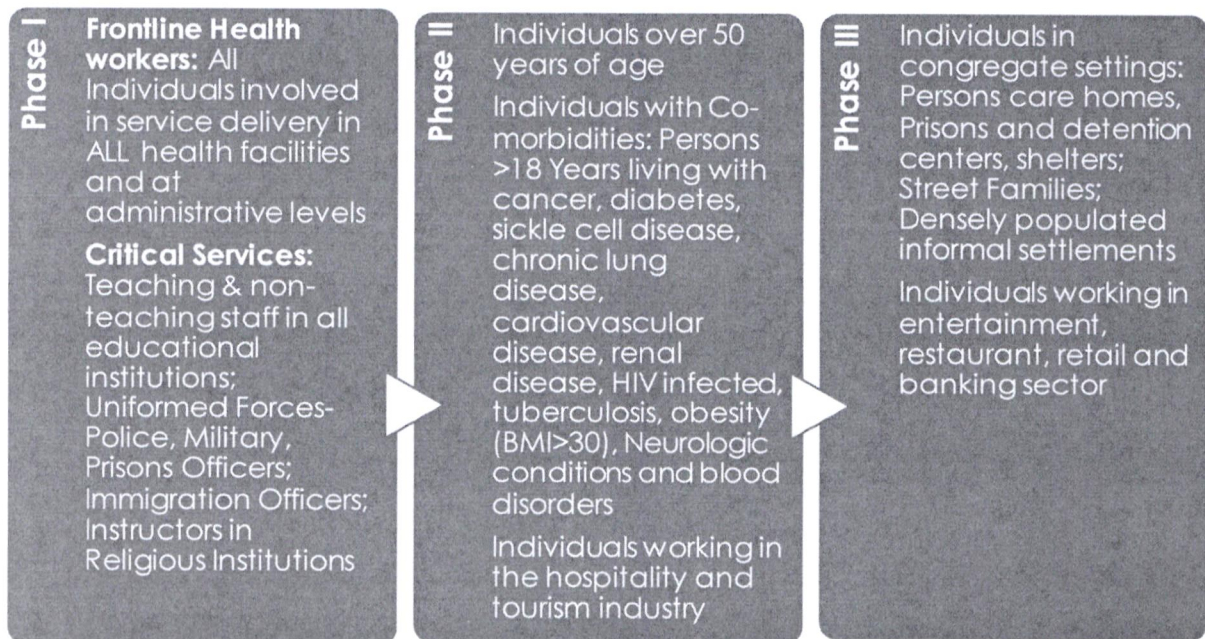
**Phase III (FY  
2022/2023)**

- **Sufficient supply of vaccine doses**
- **Focus:** Ensuring equitable vaccination of other vulnerable groups
- **Priority Groups:** Persons > 18 years in congregate settings, Hospitality and tourism industry
- **Target Population:** 9.8 Million

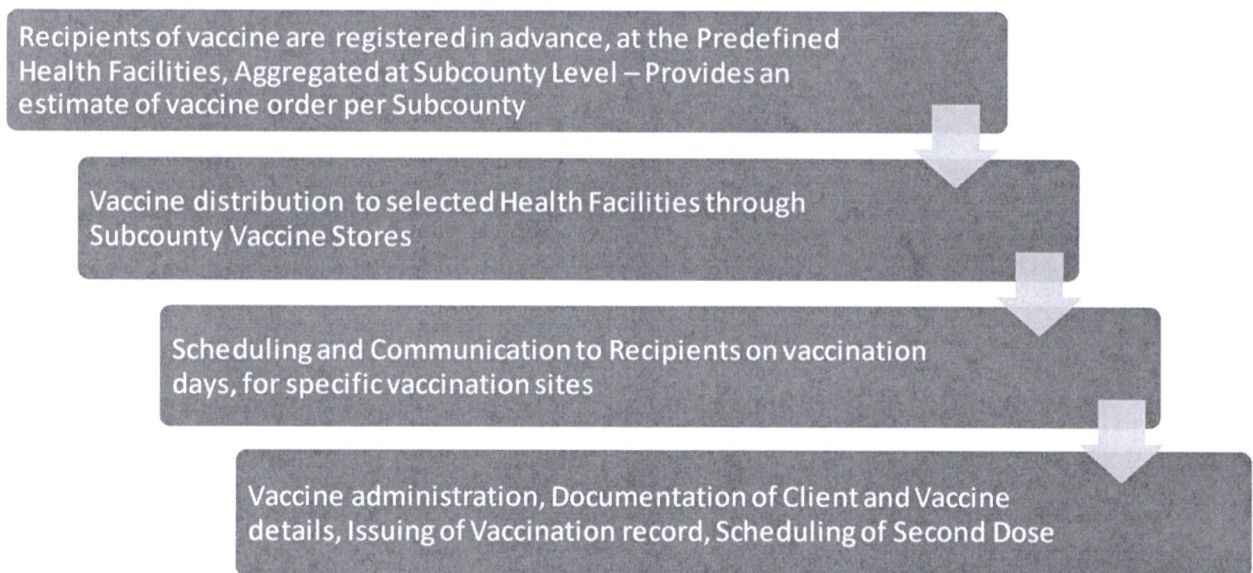
The phases are aligned to GOK financial years; Phase 1- January-June 2021, Phase II- July 2021-June 2022, Phase III- July 2022-June 2023.

### **Identification of and prioritization of target populations**

The priority target populations are defined as below:



The country will identify and Map vaccine providers to administer vaccines in Public, Private, Faith based NGOs run facilities to target populations following the schema below:



The Facilities to conduct targeted outreaches in phase III will be identified at county level, depending on the county context and mapping of targeted populations, with the frequency varied based on informed county needs.

COVID-19 vaccine will provide Kenya with opportunities to extend immunization services across the life course and improve integration of immunization with other health services. Furthermore, the contact with the vaccine recipients will be used to identify any missed opportunity of routine infant vaccination and to build public confidence on vaccines.

### **Site of vaccine administration**

The National Vaccines and Immunization Program policies in vaccine administration will be adopted and only a qualified clinician will administer the vaccine.

the site of injection for the COVID Vaccine will be the **left deltoid region** as an intramuscular injection. This is standardized to enable individuals and clinicians monitor the vaccine delivery and any adverse events following immunization. However, if there are new vaccines with different vaccine administration methods, the guidance to vaccinators will be updated accordingly.

### **Eligibility for vaccination**

Individuals will be eligible for vaccination if they:

1. Present to an immunizing health facility within the selected sub-county, where they have been registered for vaccination, or any other health facility and present evidence of registration for vaccination.
2. Are among the target groups identified for vaccination at the time when they present to the immunizing health facility and had not been vaccinated against COVID before
3. Have no fever (temperature currently  $\geq 38^{\circ}\text{C}$ ) and no reported allergies for eggs or chicken, (Individuals who present with fever (temperature currently  $\geq 38^{\circ}\text{C}$ ) will be asked to return for vaccination once the fever has subsided)
4. Have not suffered COVID Infection within the last 6 Months preceding the day they present for vaccination.
5. They are not pregnant or breastfeeding at the time of vaccination- However, pregnancy test will not be required before vaccination
6. They provide verbal/ written consent for them to be vaccinated.

Being a novel vaccine, with recommendations for initial target population; Kenya will explore non-traditional vaccine delivery approaches to ensure maximum reach for especially the target populations e.g. the utilization of special clinics for vaccination of people with comorbidities.

### ***Health facility adjustments for COVID-19 Vaccine delivery***

The following adjustments will be made to accommodate COVID Vaccines:

1. Designate a specific area/ tent away from the MCH clinics for COVID Vaccination.
2. Follow the existing guidelines on COVID-19 infection prevention measures during immunization sessions.
3. Avoid crowding in waiting rooms by advanced scheduling/ staggering of immunization visits in the day.
4. Allocate ventilated areas and ensure social distancing for clients and dedicate separate specific rooms for sick visits, away from the well visits and immunization.
5. Assess and triage immunization clients for acute respiratory symptoms and risk factors for COVID-19 first to minimize chances of exposure.
6. Observe aseptic techniques during the vaccination sessions and Perform hand hygiene with alcohol-based hand rub before and after all client contact with potentially infectious material. Use soap and water if hands are visibly soiled.
7. Routine cleaning and disinfection procedures to be carried out as appropriate in immunization clinics
8. Anticipate increased risk of coincidental AEFIs with COVID Vaccines, Report and investigate ALL serious AEFIs as per existing protocols

### ***Infection prevention measures to be undertaken.***

To ensure safety of vaccination teams and caregivers, the following measures will be undertaken:

- o Each vaccination site will be supplied with hand sanitizers to be used by clients and team members.
- o Soap for Handwashing for fixed sites
- o Surgical face masks (1 face masks for each member of the team per day)

- Crowd control to ensure physical distancing, including vaccination in open spaces.
- Clear communication to communities by community volunteers and leaders on vaccination sites, date of visit and guidance to clients on observing safety measures (face masks and physical distancing)
- Clients will be encouraged to visit vaccination sites wearing face masks as per national guidance. No one will be turned away for not having a mask.

It is expected that both national and county level will leverage on the existing routine immunization systems including internal resource mobilization to bridge any gaps arising, in addition to the funding from the National level mobilized from domestic resources and the World Bank

Engagement of National and county leadership for oversight, accountability, and ownership

Microplanning and mapping of health facilities that will offer COVID Vaccines (Level 3 upwards) and areas with highest number of individuals in target priority groups

Determination of the start dates for vaccination

Development of county specific tailored approach to reach the targeted priority groups

Undertake intensified communication and social mobilization activities to create demand:

- Engage local Community leadership through Health Facility management Boards to mobilize communities for COVID Vaccination
- Engage Community Health Volunteers to pass messages and follow up vaccines
- Use local mass media to mobilize individuals to seek for vaccination services

Enhanced immunization at static facilities and outreaches:

- Contact all individuals from Immunization registers and other sources who will have received the first dose of COVID Vaccines to ensure they receive the second dose
- Share messages during COVID vaccination sessions on COVID Prevention

- Ensure all health facilities (Level 3 and above), Public, Private, Faith Based and NGO offer COVID Vaccinations daily
- Identify facilities that will conduct COVID Vaccination targeted outreaches focusing on areas with highest number of individuals in target priority groups
- Ensure uninterrupted availability of COVID vaccines and other supplies at the immunizing health facilities

Being a novel vaccine, with recommendations for initial target population; Kenya will explore non-traditional vaccine delivery approaches to ensure maximum reach for especially the target populations e.g. the utilization of special clinics for vaccination of people with comorbidities.

## 6. Supply chain management

### *Vaccine Preference*

The following country preferences have been selected in the vaccine request to Gavi.

- Vaccine Platform: **Viral Vector**
- Regulatory process: **Vaccines that have been Prequalified by WHO**
- Vaccine Storage/ Cold chain requirements: **Vaccines with traditional cold chain requirements 2-8°C and or -20°C**
- Price: **Lowest Price**

### *Licensure and Importation*

The Kenya Ministry of Health, Pharmacy and Poisons Board, will grant a special approval, and expedite market authorization, and lot release waiver to facilitate the importation and use of the COVID 19 Vaccines in the country. In addition, approval will also be granted for the COVID Vaccines continued evaluations in the context of community deployment.

### *Logistics and Supply chain Management*

The Ministry of Health will leverage on UNICEF Mechanisms under the Vaccine Independence Initiative Agreement. The outsourcing of vaccine clearance at ports of entry and delivery to National and Regional stores, has eliminated delays

at the port of entry. The amount of time taken to clear vaccine consignments held at ports of entry currently does not exceed 48hrs.

From the Regional depots, a mixed approach will be employed to deliver vaccines to the counties- Some Counties will pick vaccines from the nearest Regional Depots while others will have the vaccines delivered to them by air freight.

The vaccine distribution is expected to follow the existing distribution patterns, from National to Subcounty Levels.

The 'Chanjo' electronic logistics management information system (eLMIS) will be used to manage vaccine stocks, vaccine cold chain management and to provide an immunization data dashboard that presents the vaccine coverage, stock levels and integrated indicators for immunization performance.

The program will continue to require that the Sub Counties update their records by the 15th of every month.

#### *Cold Chain capacities*

The National Vaccine store has a total of 8 cold rooms with net capacity of 130M<sup>3</sup> for positive temperature cold storage (2-8°C) and 2 freezer rooms with net capacity for negative temperature cold storage (-20°C) of 14 M<sup>3</sup>.

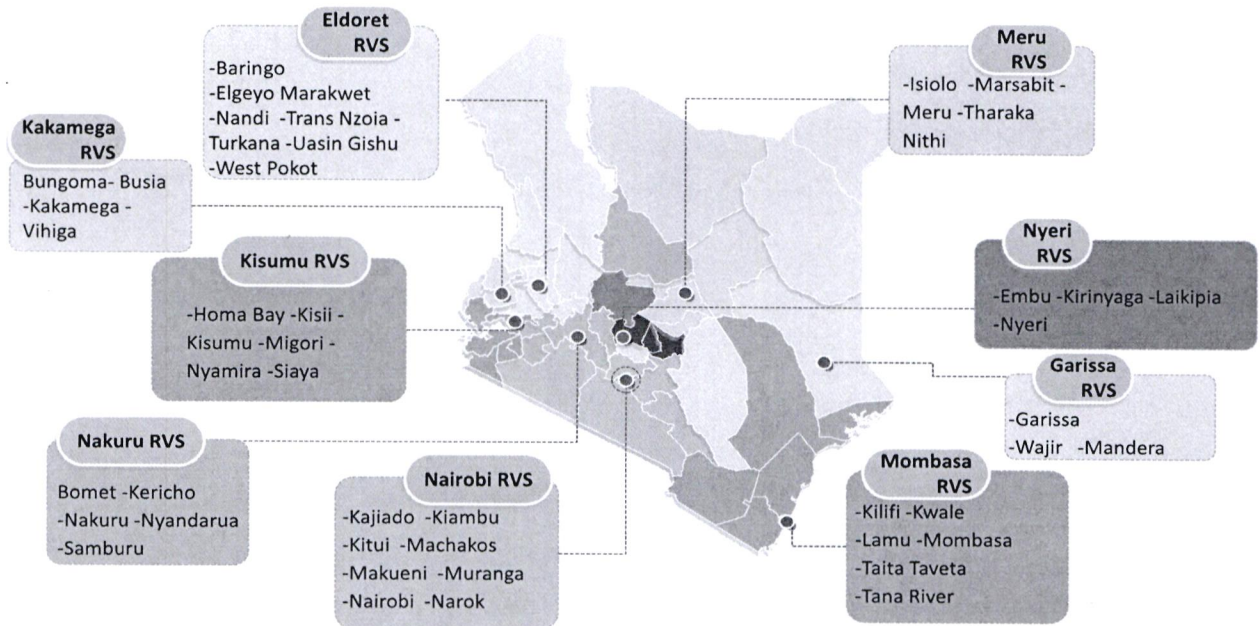
The capacity at the new National cold rooms is sufficient for deployment of vaccines requiring the +2°C to 8°C / -20°C of cold storage; with a quarterly vaccine delivery schedule to the national and regional vaccine stores. Minimal expansion will be required to provide for less frequent shipment schedules and introduction of other vaccines in future.

For vaccines requiring -70°C, storage temperatures, the country will need to procure additional cold chain storage capacity to comply with the storage needs of these vaccines.

Storage capacity for both positive and negative temperature storage at all the 9 Regional stores is adequate with introduction of COVID-19 as confirmed through the 2013 EVMA and vaccine forecasting using WHO EPI Logistics Forecasting tool (2014).

Storage capacity for both positive and negative temperature storage at all the 9 Regional stores is adequate with introduction of COVID-19 as confirmed through the 2013 EVMA and vaccine forecasting using WHO EPI Logistics Forecasting tool (2014).

Below is a schema showing the location of the National and Regional vaccine depots and the counties served:



Kenya National and Regional vaccine cold store capacities estimates.

STORE	NET REFRIGERATION VOLUME (Ltrs)	NET FREEZING VOLUME (Ltrs)	OWNERSHIP	RESPONSIBILITY	STAFF	STATUS
1 KITENGELA CENTRAL VACCINE STORE	130,000	14,000	MOH/NVIP	MOH/NVIP	2 MOH	FUNCTIONAL
2 NYERI REGIONAL VACCINE STORE	20,000	813	KEMSA	MOH/NVIP	1 MOH + 1KEMSA	FUNCTIONAL
3 MERU REGIONAL VACCINE STORE	10,150	542	MOH/NVIP	MOH/NVIP	1 MOH	FUNCTIONAL
4 MOMBASA REGIONAL VACCINE STORE	20,150	813	KEMSA	MOH/NVIP	1 KEMSA	NON-FUNCTIONAL
5 NAIROBI REGIONAL VACCINE STORE	23,000	7,000	MOH/NVIP	MOH/NVIP	2 MOH	FUNCTIONAL
6 NAKURU REGIONAL VACCINE STORE	20,000	1,355	KEMSA	MOH/NVIP	1 MOH + 1 KEMSA	FUNCTIONAL
7 ELDORET REGIONAL VACCINE STORE	20,000	1,626	KEMSA	MOH/NVIP	1 MOH + 1 KEMSA	FUNCTIONAL
8 KAKAMEGA REGIONAL VACCINE STORE	10,300	542	MOH/NVIP	MOH/NVIP	2 MOH	FUNCTIONAL
9 KISUMU REGIONAL VACCINE STORE	23,000	542	KEMSA	MOH/NVIP	1 MOH + 1 KEMSA	FUNCTIONAL
10 GARISSA REGIONAL VACCINE STORE	13,330	450	MOH/NVIP	MOH/NVIP	1 MOH	FUNCTIONAL
<b>NEWLY ESTABLISHED COUNTY VACCINE COLD STORAGE POINTS</b>						
STORE	NET REFRIGERATION VOLUME (Ltrs)	NET FREEZING VOLUME (Ltrs)	OWNERSHIP	RESPONSIBILITY	STAFF	STATUS
1 TURKANA COUNTY	13,330	542	MOH/NVIP	MOH/NVIP	1 MOH	FUNCTIONAL
2 WAJIR COUNTY	13,330	813	MOH/NVIP	MOH/NVIP	1 MOH	FUNCTIONAL
3 MANDERA COUNTY	13,330	813	MOH/NVIP	MOH/NVIP	1 MOH	FUNCTIONAL

Overall, total cold chain capacity at National and Regional level is sufficient to hold COVID vaccines. However, there exists significant inequity in cold chain capacity distribution among and within counties. With a monthly supply cycle, less than 75% have sufficient capacity to accommodate the COVID Vaccines and all the other routine vaccines.

*Below is a schema showing the distribution of Sub-county stores*



The Program plans to bridge the cold chain capacity gaps through:

1. Procurement and installation of additional Cold chain equipment through the Gavi and World Bank support
2. Implementation of year 2 & 3 of the Cold Chain Equipment Optimization Platform Project
3. Review of the delivery cycles and
4. Redistribution of cold chain equipment will be able to bridge these gaps.
5. Explore the possibility of coordination with private sector, for cold chain storage

All old cold rooms and Refrigerators in depots and health facilities countrywide are equipped with continuous electronic temperature monitoring devices, that record the temperature status continuously.

All Regional Depots and Subcounty stores have Remote Temperature monitoring devices to ensure real time monitoring of temperature and response to temperature excursions. This is to maintain viability of the vaccines stored.

*Cold Chain Equipment (CCE) Needs Estimates and Scenarios*

From the analysis of CCE Estimates, the estimates presented herein are based on pre-selected equipment models using template provided for the Cold Chain Equipment Optimization Platform (CCEOP) by Gavi.

Also included is an analysis based on the current capacity gaps existing in storage, even prior to selection of a Covid vaccine.

*The Country elects to receive 6 months' supply interval for other routine vaccines, and 3 months for Covid. This would yield the cold chain requirements as estimated below:*

No	Item Description	Quantity/ Number
1	Installation of 13 Walk-In Cold Rooms 40CBM with a Surge Protector for central vaccine store and RVS	13
2	Installation of 1 Walk-In Freezer Rooms 20CBM with a Surge Protector for central vaccines store	1
3	Installation of 44 Walk-In Cold Rooms 40CBM with a Surge Protector for county depots	44
4	1 KVA Single Phase Extended Range Voltage Regulator	2,401
5	On-grid Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for <b>Health Facilities</b> , under a 10 year warranty	1,502
6	Off-grid Solar Direct Drive Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for <b>Health Facilities</b> , under a 10 year warranty	150
7	On-grid Cold Chain Equipment, without freezer compartment and capacity for remote temperature monitoring for <b>Health Facilities</b> , under a 10 year warranty	300

8	Off-grid Solar Direct Drive Cold Chain Equipment, with freezer compartment and capacity for remote temperature monitoring for Health Facilities, under a 10 year warranty	100
9	On-grid Cold Chain Equipment without freezer compartment for <b>Sub-counties</b> , under a 10 year warranty	145
10	On-grid Cold Chain Equipment -freezers for <b>subcounty and regional depots</b> , under a 10 year warranty	154
11	Standard 5L Vaccine Carriers for <b>Health Facilities</b>	38,600
12	Standard 5-25 L Cold Boxes for <b>sub county stores</b>	600
13	Assorted Spareparts for ILRs, number of kits-TCW 2000 AC	181
14	Assorted Spareparts for SDDs, number of kits-HTCD 90 SDD	15
15	Assorted Spareparts for ILRs, number of kits-TCW 40R AC	30
16	Assorted Spareparts for SDDs, number of kits-TCW 15 SDD	10
17	Assorted Spareparts for ILRs, number of kits-TCW 4000 AC	15
18	Assorted Spareparts for Freezers, number of kits-HBD 286	16
19	Temperature Monitoring Devices (TMD) for Fridges-FT2E	9,000
20	10 KVA Three Phase Voltage Regulator, for WICRs and WIFRs-Sollatek, AVR3LE20	58
21	Modification of Designated Existing Rooms at county levels to accommodate Walk In Cold Rooms and other Cold Chain Equipment at County Level	47

#### *Waste management and injection safety*

The country plans to procure Auto-Disable syringes as a measure for infection prevention and adequate safety boxes for proper storage and disposal of used syringes

The COVID vaccine waste materials will be managed through the current injection safety and medical waste management policy, adapted to the COVID contexts. Extra precautions will be observed in the management of waste related to COVID vaccination. Safety boxes for disposal of sharps, followed by incineration and deep burial, will be used to dispose of used injection equipment in the program.

The waste management plan will be in line with the national healthcare waste management plan and will include:

- Identification of waste disposal site and personnel responsible for waste management
- Estimation of the number of safety boxes needed
- Bundling of waste disposal boxes with vaccines and syringes during delivery

- Plan for the waste disposal sites and procedures for the disposal of all wastes generated irrespective of vaccination site
- Special attention will be made to ensure healthcare waste management in schools and other outreach sites are carried out according to best practices
- Plans for transportation and disposal of the waste from outreach posts such as schools.
- Include waste management in the training material and documentation
- Monitoring and evaluation of waste management to ensure waste management is carried out to a high standard

Specifically, to ensure safety of vaccinating health workers and caregivers, the following measures will be undertaken:

- Each vaccinating site will be supplied with hand sanitizers to be used by caregivers and team members
- Soap for Handwashing for fixed vaccinating sites
- Surgical face masks (1 face masks for each member of the team per day)
- Crowd control to ensure physical distancing, including vaccination in open spaces, in designated areas away from the MCH Clinic
- Clear communication to communities by health workers, community volunteers and leaders on vaccination site, date of visit and guidance to caregivers on observing safety measures (face masks and physical distancing)
- Caregivers will be encouraged to visit vaccination sites wearing face masks as per national guidance. However, no one will be turned away for not having a mask

## **7. Human resources management and training**

Kenya still faces an absolute shortage of human resources for health in general and disparity in health workforce distribution across counties, which is influenced by demographics, number of health care facilities and epidemiological profile of individual counties. Available health workers are pressed for time, must meet regulatory and accreditation standards, while working continuously to document and improve health outcomes. This calls for training that is rigorous but flexible to

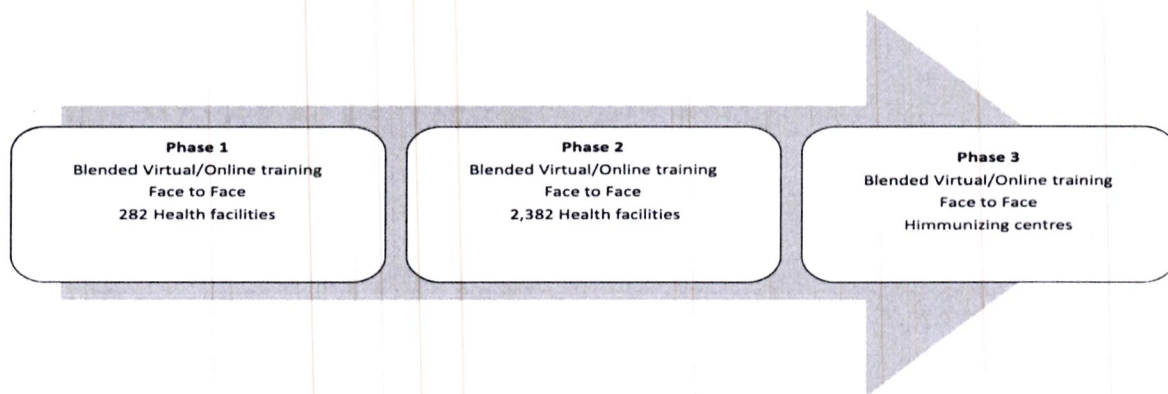
allow the shortest possible time to achieve vaccine deployment competency for the individual health worker and the program.

Current health facilities' staff establishments especially at National and Subnational levels will be adequate to roll out the COVID Vaccine especially in phase 1. The COVID Vaccine deployment will leverage staff in Public, Private, NGO and Faith-based health facilities. Where necessary, redistribution of health-workers at implementation levels will be done to bridge any gaps that exist. No additional human resources will need to be hired, besides the TA at central levels.

Building human resource capacity to deliver covid-19 vaccine will need health workers trained and competent on; knowledge on COVID 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, communication, waste management, mental health, multi-disciplinary team work.

The COVID-19 Vaccine introduction will draw experience in lessons learnt from past introduction of new vaccines and experiences in online training. The training opportunity will also be used to update health workers on the revised National Immunization Policy Guidelines, address gaps noted in the 2020 Effective Vaccine Management Assessment and the Immunization data Quality Assessment.

The training will be organized around the 3 phases. Phase 1 for level 4-6 health facilities will be done through blended online/virtual training and face to face/peer demonstration. These will also be recorded for later use in phase 2 and 3 and used to TOT training.



*Healthcare Worker COVID vaccine delivery Training*

For every phase, a training guide for health workers containing information on COVID disease, the vaccine characteristics, and the immunization procedures will be developed to ensure standardization and smooth implementation of training activities. The training guide will be developed based on WHO generic training modules and contextualized to phase (target population) and county specific situation.

This will involve the following steps:

**Step 1:** Planning, development of online and face to face training and IEC materials, to be used across various training platforms including webinars, social media. Conducting baseline assessment.

**Step 2:** Preparation of a training plan comprising of activity timelines, sources of support, target audience, budget, training platforms, monitoring and evaluation and other training logistics.

**Step 3:** Training will include orientation of stakeholders at national level, training of the national TOTs cascaded to the County level then Sub-county and finally the service delivery point (immunizing health facility public and private).

Each of these steps will be reviewed for Phase 1, 2 and 3 of vaccine administration.

#### *Implementation of COVID Vaccine Introduction training*

Blended Training of health workers (HW) will be organized to cover the whole country in a cascaded manner, following the 3 phases and incorporating both face to face and online/virtual training. An initial pilot training will be done, followed by development of training didactics, demonstration videos, quizzes allowing self-paced learning and certification. Different training modules will be developed for the different groups from vaccinators, other clinicians, data management to administrators. The training material will be reviewed at national level which will also be a Training of Trainers (TOT) course.

#### *Online Training Registration Platform*

An online platform for registration will be used to ensure certification and be used to monitor progress of training. This is critical because of the evolving knowledge

and will allow health workers to update their skills and knowledge over the program period. CPD points will be awarded to motivate participation in the COVID-19 vaccine program by all health workers, not just those selected as vaccinators.

This approach will allow a rapid and horizontal approach to training ensuring equity, effectiveness and overcoming some of the HRH limitations outlined above.

The specific approach followed will be:

- 1) Simulation or dry run to validate the content and evaluate the trainers ( National level TOT, for staff from NVIP & Partners)
- 2) Development of online platform including HW registration, social media discussion platforms, quizzes and certification
- 3) Recording of online materials and uploading online platform
- 4) Phase 1: Sensitization of HW, support supervision by County level (CHMT) drawn from 47 counties incorporating the 284 health facilities.
- 5) M&E support supervision, identify training gaps, update training materials
- 6) Phase 2 and 3 further sensitizations of HW from each sub-county and health facilities. Sub county training of 5 SCHMT members from each sub-county. All immunizing facilities in the counties, 2 health facility staff
- 7) M&E support supervision
- 8) Training of the Community Health Volunteers (CHVs) at community unit

The training content will cover the following:

Epidemiology of COVID-19 pandemic	<ul style="list-style-type: none"><li>o Overview of COVID-19 pandemic</li><li>o Etiology and clinical presentation of COVID-19</li><li>o Clinical management, surveillance and reporting of confirmed cases and suspected cases</li></ul>
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<p>Description of the vaccine</p> <p>Recommended schedule and target population</p> <p>Mode of Administration</p>	<ul style="list-style-type: none"> <li>o The vaccines will be described &amp; their administration demonstrated –NB: COVID-19 vaccine to be injected IM on the upper outer quadrant of the left arm and how to counsel about the vaccine</li> <li>o The schedule for administration and how they will be integrated in the routine EPI schedules.</li> <li>o Case studies</li> </ul> <p>Managing the patient (side/adverse)</p>
<p>Cold Chain issues</p>	<ul style="list-style-type: none"> <li>o General cold chain aspects of EPI will be discussed, emphasizing COVID-19 vaccine cold storage requirements.</li> <li>o Introduction of new distinctly colored vaccines trays, and how to tackle storage challenges of high output facilities.</li> </ul>
<p>Documentation and record keeping</p>	<ul style="list-style-type: none"> <li>o Trainees will be introduced to the revised reporting forms, stock monitoring tools and other monitoring tools, including electronic platforms</li> <li>o Health facility staff will be trained on how to document and report any adverse events following immunization (AEFIs)</li> </ul> <p>Basics on monitoring key indicators , SOPs, wastage,</p>
<p>Injection Safety</p>	<ul style="list-style-type: none"> <li>o General review of injection safety measures regarding injectable vaccines and other injection waste.</li> </ul>
<p>IPC</p>	<ul style="list-style-type: none"> <li>o PPE use, Hand Hygiene, Hand Hygiene resources</li> <li>o Standard precautions for IPC</li> <li>o Social distancing</li> </ul> <p>Waste management (facility and community)</p>

Demand generation and communication	o Health workers will be trained on approaches for creating awareness on the COVID-19 vaccines, risk communication and interpersonal communication
Team building	multi - cadre teamwork, recognizing mental health issues, Referral system, micro-planning
E-learning	Accessing online training materials, evaluating information sources, social media use

### *Supportive supervision*

Supportive supervision visits will be provided to the National and County teams to provide technical assistance, and mentorship, to complement existing efforts by the County governments. This will be deployed through virtual platforms from National level but will include field visits at county level.

These will be conducted periodically with a predefined checklist. The checklist will be developed during planning for introduction and supervisory visits to monitor the process of introduction at all levels, observe implementation and assure maintenance of quality and standards in the vaccine roll out.

### *Key Risks in HW Training Roll Out*

Risks that need to be mitigated include HW industrial discord, lack of staff engagement, ethnic biasness, different organizational cultures and risks of unintended consequences. A risk mitigation plan specific to counties will have to be developed.

## **8. Vaccine acceptance and uptake (demand generation)**

Whereas adherence to the containment measures is critical, the introduction of the vaccine in the market provides another level of protection that introduces greater confidence in daily lives amongst the people. This means that the country will be required to manage the process of community demand creation through awareness and managing vaccine hesitancy as well as creating channels for risk communication - exchange of timely information and advice between the public

and the experts to enable Kenyans make informed decisions to protect their lives and those of other people.

The buy-in of key stakeholders will be crucial in creating the demand of the vaccine and address hesitancy issues. These key stakeholders will include:

- 1) Political and religious leaders at both national and county government levels.
- 2) Health workers through professional Associations,
- 3) Civil society Organizations
- 4) Media practitioners and social media influencers
- 5) Community leaders

From the experience gained with other new vaccine introductions, and influenza vaccinations, vaccine acceptance has been high in Kenya. However, for the COVID19 vaccine surveys indicate a 15% hesitancy level and this may increase due to misinformation, rumors and conspiracy theories.

To best define local communication needs, a communication needs assessment will be conducted by MoH in select Counties prior to the deployment of the vaccines and the findings will inform the communication plan strategies and risk communication.

Sensitization for COVID vaccine introduction will begin well in advance of introduction. To achieve this, the following will be developed:

- 1) A communication plan incorporating risk and crisis communication aspects.
- 2) Key messaging and visualization including artwork, audio and video production with focus on determined primary and secondary audience groups
- 3) Message delivery plan to include the use of Key Opinion Leaders, key media channels including TV, Radio, posters and banners, SMS, Twitter, Facebook and Instagram as well as a plan for Frequently Asked Questions through a hotline and a WhatsApp bot
- 4) Post deployment message and channel evaluation and adaptation of plans based on feedback.

In addition, the vaccine will be ceremonially launched at national and county level involving high profile personalities in order to drum up support for the vaccine and the vaccination exercise while adhering to the principles of equity.

At the community level, opinion leaders such as chiefs, ward administrators, ward education officers, head teachers, village elders and community health volunteers will be sensitized on COVID vaccination.

*Development of a communication strategy, Risk Communication, and a crisis communication plan*

The MOH will develop a communication plan that includes risk communication.

A crisis communication plan will be integrated within the communication strategy so as to address any potential adverse events, myths, misconceptions and hesitancy that may arise associated with either COVID disease or the vaccine. The crisis communication plan will outline activities for all levels addressing:

- risk communication on vaccine safety
- communicating with individuals and addressing concerns real-time
- vaccine hesitancy and response to misconceptions and rumors in the media including social media.

The Ministry of Health will seek to effectively communicate on COVID-19 disease prevention, with an emphasis on vaccination alongside other primary prevention strategies.

The communication plan will also outline other possible strategies that COVID vaccine advocacy can be integrated with for example screening for NCDs. Further, because the deployment plan is intended to be rolled out in a phased manner, the communication plan will also need to be supportive of this phased approach.

The communication plan will include:

- 1) Key stakeholders to be engaged at each level and time e.g. Policy makers and key opinion leaders, health workers, local and national leaders, religious leaders, civil society organizations private sector etc
- 2) Key messaging for each stakeholder
- 3) Key channels to be used for each stakeholder e.g One on one meetings, public meetings, traditional media, social media, bulk messaging, promotional materials etc

The specific activities for the communication strategy will include:

- 1) Development of Communication Plan
- 2) Development of Key Messages
- 3) Communication assets development including training tools.
  - a) Development of Radio & Tv shows including content influencing on existing entertainment and current affairs programs.
  - b) Production of short training video(s) to support capacity building for training of trainers.
  - c) Creation of media assets including graphics, texts and short videos for engagement on digital platforms.
  - d) Development of Public Service Announcements and advertisements
  - e) Print media pull outs and native content production.
  - f) IEC materials; Seed material for sites and Billboards at county border points
- 4) Media Events.
  - a) Media training
  - b) Media launch, National and County
  - c) Regular media field visits
- 5) Identification and facilitation of county-based champions
- 6) Community engagement.
  - a) Listenership/viewership groups
  - b) Opinion leaders
- 7) Distribution of communication assets
  - a) Broadcasting (TV & Radio)
  - b) Print media publication including opinion pieces, pull outs, advertisements.
- 8) Bulk messaging to target facilitators and internal stakeholders' mobilization.
- 9) 24-Hour Hotline manned by health workers to answer vaccination related questions from access, to administration and adverse events.

The communication plans will be informed by local data and outline tailored strategies, segmented per audience and per area of activity.

MOH will identify capacity building gaps and challenges for vaccine acceptance and uptake early in the process and ensure that they are fully addressed during the training of frontline health workers, social workers and community influencers and mobilizers.

There shall be in place a monitoring framework as an essential part of the communication plan, including media monitoring and a rumor log system.

*Key considerations that will be made to support risk communication and community engagement activities to address vaccine hesitancy:*

- listening to communities and gathering social data to understand their concerns and beliefs and addressing them through timely and targeted communication and other strategies.
- Use of channels, including media and social media, to proactively share information about vaccination in general, the COVID-19 vaccine development process, determination of best vaccine for Kenya, key risks and challenges, to build public awareness on and trust in the development and roll-out process.
- Sharing of information from trusted sources in local languages about eligibility and roll-out plans, with details on populations that are initially prioritized for vaccination.
- partnering with national and community civil society organizations, faith-based organizations, NGOs, etc., and include training of journalists and content producers as key advocates in the response.
- working with community, religious and influential leaders to dialogue and deliver messaging; community leaders will also be empowered with access to more detailed information on the vaccines and roll-out plans.
- engaging local medical providers to ensure they support vaccination activities; and transparent and routine reporting on the progress and effectiveness of roll-out plans.

#### *Empowering frontline health workers*

We shall develop a vaccine deployment strategy that ensures health workers have positive experiences as early beneficiaries of COVID-19 vaccine. This will be essential, given their influential role as vaccinators, advocates and change agents in the community, including communication skills training to support them in dealing with rumours, misinformation, and vaccine hesitancy.

Capacity building for Health workers will be done in advance of the vaccine roll-out. They will be equipped with decision-making and job aids to support them in prioritizing eligible vaccine recipients, and tailored messaging to reach diverse community contexts. There shall be training sessions to build their skills in listening, interpersonal communications and community dialogue that will help to equip them to hold difficult conversations both in the face of demand from those not eligible to receive the vaccine in the first phases, and those who are hesitant

about receiving the vaccine. Listening and collating early experiences, concerns, successes, etc. from health workers will help inform ongoing vaccine delivery.

Key objectives will be to educate health workers on the COVID-19 vaccine; increase health worker uptake and satisfaction with the vaccine as early, priority recipients; and improve health workers' ability to communicate and engage with priority groups and caregivers and endorse COVID-19 vaccination.

Since health workers (in addition to community members) are susceptible to misinformation and vaccine hesitancy; guiding principles and high-level actions will be taken at national and county levels to support health worker capacity to increase COVID-19 vaccine demand and uptake. Demand activities shall initially focus on health workers and other high-risk groups (e.g. older adults) that have been prioritized by the country.

#### *Crisis communications*

Because of the scope of vaccination, adverse events are likely, whether related to the vaccine or not, and may be misattributed to the vaccine, suppressing vaccination uptake if not addressed swiftly and competently, with clear messages and actions. To prepare for this, we shall develop crisis communications plans that include actions to take before, during and after the crisis.

Crisis communication will ensure that the country is prepared to respond first, fast and in a coordinated manner to any rumors and adverse events following COVID19 immunization. Crisis communication management plans will be informed by social listening, community feedback and other relevant data and will be in place prior to deployment of the vaccine. Existing coordination mechanisms for planning and response to events will also be harnessed, so that in the case of an event, communications take place rapidly, with transparency and empathy, and that there are not multiple conflicting voices.

A core team will be responsible for coordinating and managing crisis communication and for the following key functions:

- SOPs for managing crisis communication.
- development of content and guidance to detect and respond to rumors, misinformation, and disinformation with a real-time rapid response, especially online.
- development and dissemination of key messages; ensuring that immunization programs and stakeholders speak with one voice.
- training of media and spokespersons.

- social mobilization and communication activities; and
- communicating with affected populations and other target audiences in case of adverse events following COVID19 immunization.

## **9. Vaccine safety monitoring and management of AEFI and injection safety**

The country will deploy a robust monitoring system to identify, report, and investigate all adverse events following immunization (AEFIs) leveraging heavily on the current immunization AEFI reporting structure.

AEFI reporting, investigation and monitoring will be implemented using:

- 1) The routine pharmacovigilance and AEFI Reporting through the NVIP AND PPB, as per the National AEFI Guidelines
- 2) Sentinel hospital monitoring and tracking of safety data.
- 3) Global AEFI monitoring and review of clinical trial data for safety profile data.

The National Immunization Program and the Pharmacy and Poisons Board have a harmonized system for AEFI reporting. Health workers will report any AEFI through the Sub county and County Focal persons to the Head NVIP, who shares the reports with the Pharmacy and Poisons Board (PPB), in addition to online self-reporting systems deployed by the PPB.

The NVIP and PPB will collaborate to implement a vaccine safety strategy in strengthening the country's COVID-19 AEFI surveillance. The Ministry of Health aims to reach a reporting rate of 10 or more AEFI per 100,000 population. To further strengthen AEFI surveillance, the following activities are planned:

- 1) Sensitization of health workers on vaccine safety reporting (including vaccine pharmacovigilance) prior to the COVID Vaccine roll out to provide baseline information on AEFI
- 2) Training and sensitization of the Kenya National Vaccines Safety and Advisory Committee (KNVSAC) expert committee
- 3) Printing and dissemination of copies of the AEFI guidelines
- 4) Printing and distribution of AEFI forms

- 5) Field AEFI investigation simulation exercises for County Health Management Team and Sub-County Health Management Teams, as part of the COVID vaccine training

The country will develop a list of Adverse Events of Special Interest (AESI) for which active surveillance methods will be employed in sentinel hospitals.

Market authorization holders (MAHs) shall also submit AEFI reports as per the existing guidelines on the vigilance of vaccines including having a pharmacovigilance and risk management plans.

#### *Causality Assessment and the National Vaccines Safety Advisory Committee*

The country has a National Vaccine Safety Advisory Committee (NVSAC) in place composed of experts from different professional backgrounds to provide advice to the ministry on matters regarding vaccine safety. It consists of Pediatricians, Vaccinology experts, Epidemiologists, Pharmacologist, Physicians, Pharmacists, Pharmacovigilance experts, Infectious disease specialists, Pathologist and others. The NVSAC operates as per their terms of reference.

AEFI reports once received will be analyzed at county level and by PPB and NVIP. The line lists from PPB and NVIP will be examined and merged into a National AEFI database by the National Vaccine Safety Advisory Committee (NVSAC) secretariat. The NVSAC secretariat consisting of PPB and NVIP will meet periodically to share and analyze AEFI reports and guide on appropriate action to be taken, and also present to the NVSAC for further analysis.

Selected Serious COVID vaccine AEFI will further be presented to the National Vaccine Safety Advisory Committee for expert causality assessment.

The following steps undertaken to ensure vaccine safety include:

1. Communicate to parents, community and public at large about AEFI's and reassure them about immunization safety.
2. Train all concerned persons as a corrective measure for any operational challenges such as knowledge and skills gap.
3. Conduct regular supportive supervision, to institutionalize vaccine management practices and give feedback.

4. Improve availability of supplies and the working condition of the equipment to minimize immunization errors.

The roles and responsibilities of the various stakeholders in assuring the COVID Vaccine safety are outlined in the table below:

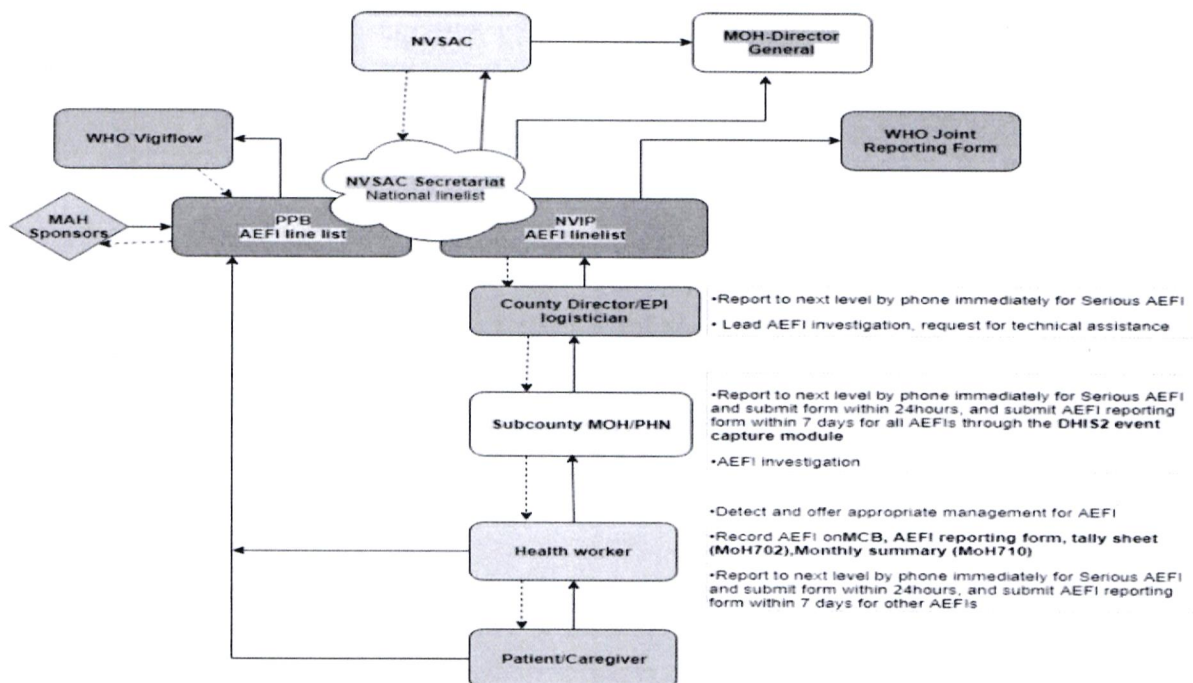
No	Stakeholder	Responsibility
1.	Ministry of Health	<ul style="list-style-type: none"> <li>· Policy formulation</li> <li>· System and database maintenance (DHIS)</li> <li>· Resource mobilization</li> </ul>
2.	National Vaccines and Immunization Program	<ul style="list-style-type: none"> <li>· Provision of vaccines</li> <li>· Training of health workers</li> <li>· Feedback and information sharing</li> <li>· Share Information with PPB immediately for Serious AEFI</li> <li>· NVSAC secretariat</li> <li>· Participating in investigation</li> <li>· Provision of reporting tools</li> <li>· Participate in Post-market surveillance</li> <li>· Reporting through Joint Reporting Form</li> <li>· Signal detection</li> <li>· Causality assessment</li> <li>· Training of health workers</li> <li>· Maintenance of database and AEFI line list</li> </ul>

3.	Pharmacy and Poisons Board	<ul style="list-style-type: none"> <li>· Licensing of vaccines</li> <li>Regulatory action</li> <li>· Issue import permit for vaccines</li> <li>Feedback and information sharing</li> <li>· Share Information with NVIP immediately for Serious AEFI</li> <li>· NVSAC secretariat</li> <li>· Participating in AEFI investigation</li> <li>· Post-market surveillance</li> <li>· Reporting through Vigiflow®</li> <li>· Signal detection</li> <li>· Causality assessment</li> <li>· Provision of reporting tools</li> <li>· Training of health workers</li> <li>· Maintenance of database and AEFI line-list</li> </ul>
4.	County Government	<ul style="list-style-type: none"> <li>· Provision of vaccination services</li> <li>· Training of health workers</li> <li>· Feedback and information sharing to lower level</li> <li>· Lead AEFI investigation, request Technical Assistance</li> <li>· Participate in Post-market surveillance and pharmacovigilance activities</li> <li>· Reporting of AEFI</li> <li>· Maintenance of AEFI line-list</li> <li>· Resource mobilization</li> </ul>

5.	Sub-county health management team	<ul style="list-style-type: none"> <li>· Provision of vaccination services</li> <li>· Training of health workers</li> <li>· Feedback and information sharing to lower level</li> <li>· Initiate AEFI investigation</li> <li>· Participate in Post-market surveillance and pharmacovigilance activities</li> <li>· Reporting of AEFI</li> <li>· Maintenance of AEFI line list</li> <li>· Resource mobilization</li> <li>· Entering of AEFI reports into DHIS 2 by HRIO</li> </ul>
6.	Health Care worker	<ul style="list-style-type: none"> <li>· Detection, management and timely reporting of AEFI</li> <li>· Provision of vaccination services</li> <li>· Providing information on vaccines to clients</li> <li>· Feedback to caregivers</li> </ul>
7.	Development partners	<ul style="list-style-type: none"> <li>· Resource mobilization</li> <li>· Technical assistance</li> </ul>
8.	World Health Organization	<ul style="list-style-type: none"> <li>· Technical assistance</li> <li>· Providing information/guidance documents</li> </ul>
9.	Media	<ul style="list-style-type: none"> <li>· Responsible reporting</li> <li>· Support awareness creation</li> </ul>
10.	Caregiver/client	<ul style="list-style-type: none"> <li>· Report AEFI</li> <li>· Adhere to guidance of health worker</li> </ul>

11.	Laboratories: NQCL, Government Chemist, NPHLS	<ul style="list-style-type: none"> <li>Timely testing of specimen</li> <li>Provide advice</li> </ul>
12.	NVSAC	<ul style="list-style-type: none"> <li>Advisory role- Refer to NVSAC Terms of Reference</li> </ul>
13.	NVSAC secretariat	<ul style="list-style-type: none"> <li>Merge and update the joint NVIP &amp; PPB national line list</li> <li>Select cases for NVSAC to review, summarize findings from NVSAC deliberations</li> <li>Share recommendations of NVSAC to NVIP and PPB</li> <li>Coordinate investigations</li> </ul>

### Kenya AEFI Reporting Pathway



### *AEFI management and reporting*

1. AEFI reporting forms will be provided to all health facilities which is the first port of call for all AEFI and AESI.
2. Each facility will provide a contact person to be informed following an AEFI and this will be clearly outlined in each facility
3. Each county will have an overall safety point person to coordinate all AEFI and AESI within the county and this point person will interface and coordinate with the national Vaccine safety committee. The point person will also manage information flow within the county stakeholder ecosystem.
4. Reporting of ALL AEFI and AESI will be through the PPB self-reporting portal and through DHIS for AEFI reporting forms completed in facilities
5. The NVCS will develop monthly summaries to be shared to the MoH Director General, national COVID19 vaccine deployment task force and other stakeholders to guide the vaccine deployment strategy.

## **10. Immunization monitoring system & Evaluations**

The Monitoring and Evaluation of the COVID vaccine introduction will begin prior to the launch and will continue through the established reporting systems which will be enhanced to take into account Covid-19 vaccine approvals.

The Covid-19 vaccine data management, deployment monitoring and evaluation will ensure that there is:

1. Stock tracking of the COVID-19 vaccines;
2. Supply and demand forecasting and matching;
3. Individual patient registration and management of records;
4. Management of priority groups and special groups;
5. Data capture and reporting;
6. Data for decision making and decision making matrix;
7. Data for impact assessment and evaluation;
8. Data for analytics and visualization and;
9. Data for communication and demand generation.

### Details of Data Management Procedures and Activities

#### Stock tracking of the COVID-19 vaccines

COVID vaccine stock monitoring will be done via the *Chanjo* ELMIS for the stores and through DHIS for facility level stock data.

The primary data capture tool will be;

1. Vaccine ledger book- Vaccine ledger book captures vaccines received and issued at the immunization facility and vaccine stores
2. Temperature monitoring sheet- Vaccine temperature will be monitored twice a day everyday through the temperature monitoring sheet. A copy of the temperature monitoring sheet will be shared with the supervising manager.
3. Bin cards, Issue vouchers such as S11 will be utilized as required.

Data from the vaccine ledger will be summarized in the *Chanjo* ELMIS system for aggregation and national reporting. The *Chanjo* ELMIS system will capture batches, daily, weekly and monthly vaccine stock balances, and VVM statuses of all vaccines.

Temperature monitoring sheets will also be supported with remote temperature monitoring systems where available to provide real time temperature data for example the national vaccine store real time temperature monitoring system.

#### Supply and demand forecasting and matching

To achieve the ambitious task of immunizing 40% of the population the Government will ensure that demand forecasting and the supply are matched. To determine the expected demand the program will develop and monitor detailed plans on target population by county/ sub county and ward. The targets will be informed by the phase of the vaccination program.

Demand monitoring will also be guided by social media tracking of public sentiment to ensure demand is being tracked adequately and appropriate responses and actions being implemented.

#### Individual patient registration and management of records

COVID-19 vaccination status will be a critical data point to track due to future needs to be able to establish immunization status for employment, travel and to provide reliable proof of vaccination where it would be required.

To ensure that reliable status individual tracking of people vaccinated is required as well as personal proof of documentation will also be required by the population. To achieve this objective the Government will develop electronic and paper-based forms to ensure that tracking is possible. This will include patient card, patient immunization certificate, linkage of patient ID number or other identification number in a national immunization registry managed by the Government will be developed and deployed.

#### Management of priority groups and special groups

The COVID 19 vaccine introduction will be introduced in phases with different phases targeting different priority sectors and groups. The deployment plan will identify national priority groups and with support from the county the different counties will identify and develop their pre registration records of the different groups prior to vaccination.

The priority groups vaccination prioritization will also be managed considering available vaccine supplies, state of the COVID-19 epidemic in Kenya and other country priorities.

#### Data capture and reporting

Monitoring of COVID-19 vaccine performance will be monthly through the routine immunization system and the immunization reporting tools will be utilized will be

1. Permanent Register Book- Captures comprehensive patient level data.
2. COVID-19 Vaccine Tally sheet - Tally sheet used by vaccinators to track immunization and doses
3. COVID -19 Immunization summary sheet- This summary sheet captures daily immunization summary as captured by the tally sheet and summarizes data into a monthly format
4. COVID patient vaccination card- Card utilized by patient to show the vaccine received, batch numbers and provides information on next due data
5. AEFI reporting sheets- Used to capture AEFI and AESI at facility level.

Data Management will utilize the existing DHIS 2 system for aggregate reporting from the summary sheet. A digital vaccine registry platform with a mobile

application and aggregation system that tracks longitudinal information on targeted vaccination will also be utilized.

The digital platform will be accessible from a browser, mobile phone, tablet /iPad thus every vaccination centre will be able to vaccinate and report to the centralized server which will be set up at a centralized location either at County or at National Level

Specifically, the platform aims to support the electronic registration of population to be vaccinated at each vaccination point to capture vaccination data, provide clinical decision support, track vaccinations at multiple facilities in a single location and produce reports that support public health decisions at the facility, sub-county, County and National Level.

The system will also have capability to generate digital health certificates linked with the vaccine registry platform and where possible integrate it with digital vaccination cards that we intend to embed within the system for the purposes of identifying those who have received the vaccine and to eliminate fraudulent certificates. This is being done in collaboration with our stakeholders such as ITECK-K, University of Oslo, CDC, KEMRI, UON, JKUAT, UNICEF, USAID,WHO among other partners.

All mobile devices will automatically synchronize the information to this central repository when an internet connection is available. This central repository will be used as the primary data repository for client identification, aggregate reporting and management.

The Feedback mechanisms for COVID-19 vaccine delivery performance will be done through monthly and quarterly bulletins as well as through an integrated visualization dashboard. The program will also leverage on quarterly data review meetings to monitor performance and give feedback.

The coverage of both the first and second dose of COVID vaccine will be monitored through regular data analysis and evaluation of performances across the country as well as dash-boards for monitoring vaccination delivery which includes drop-out rates and AEFIs. This will ensure that individuals are monitored for the full course of vaccine dose regime.

We will also evaluate the possibility of adopting the full DHIS 2 COVID -19 vaccine delivery system which easily integrates into the DHIS2 system which provides us with a data driven deployment approach of vaccine delivery.

Data security, privacy and security of individual data will be provided by ensuring that the digital system to be adopted is role based and therefore only accessible through system login based on the user's role in the facility thus ensuring that only authorized personnel access the client's data. The system will be hosted in a secure centralized environment that ensures even the data shall at rest is secure and stable at all times to avoid loss of data integrity.

Data for decision making and decision-making matrix

The Government of Kenya will be the primary owner of all data on COVID -19 vaccination. The Government will provide the tools, systems and infrastructure to capture all relevant data related to COVID-19 vaccination.

This data will be availed to relevant health managers, health institutions, other Government institutions and other bodies as deemed fit by the Government.

	Description	Users/ decision
Primary data capture forms	This is data captured at immunization centres and will include data on vaccine provide, batch numbers, expiry data, patient identifiable data, expected date of return etc.	Full access: Health facility/ Facility and sub county health managers  Limited access: Other than primary facility staff express permission is required from the County health director for access to primary data forms
Secondary aggregate	Summary facility data	Online access to

<p>data/ online systems</p>	<p>will be captured through several online systems such as KHIS, Chanjo and the national electronic database system</p>	<p>aggregated data will be managed by the KHIS program through password access.</p> <p>Access to online data repositories will be managed by the Ministry of Health in line with Kenya data laws.</p>
<p>National aggregate data from other Government sources</p>	<p>Data will be required from other Government departments and ministries for example data on employment status, cadres, location data will be required for prioritization of vaccine provision</p>	<p>Data from other Government departments required for COVID-19 vaccinations will be accessed and managed by the national Ministry of Health in collaboration with the other Government departments providing the data.</p>
<p>Non-Government data</p>	<p>Other data sources not from Government sources but are still required for COVID 19 vaccination will also be captured and managed by the national MOH.</p> <p>These data sets can include survey data on public opinion, social</p>	<p>These data will be aggregated by the national MoH where applicable and linkages with other data sources will be through the national MoH</p>

	media tracking of public sentiment etc.	
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### Data for impact assessment and evaluation

Monitoring of vaccine introductory activities will be done through the Checklist & Timeline of activities. In addition, each subcommittee will prepare a Gantt chart that will be aggregated as the National Task Force level. This will provide accountability and visibility to co-dependent processes being performed by different working groups.

To track and monitor the overall vaccination program as well as support the reporting of the impact of the vaccine to meet international reporting standards the program will carry out

1. Annual reporting to the WHO/UNICEF through the joint reporting forms
2. Implement post introduction evaluation of the different vaccination phases
3. EPI program review
4. Vaccination coverage survey
5. Impact surveys

#### *Annual reporting to the WHO/ UNICEF Joint reporting form*

The country annually reports on the WHO/ UNICEF joint reporting form on the performance of antigens. The need for reporting may be heightened with the introduction of the COVID Vaccine. The country will regularly report on COVID after introduction.

#### *Post introduction evaluation (PIE) of Phase 1-3*

A Post Introduction evaluation will be conducted six months after introduction to identify challenges and lessons learnt during the implementation period. This will evaluate the process of introduction, implementation, coverage and strategy. It is expected that the results will translate to more focused and targeted technical support to the subnational levels.

WHO PIE tools will be adapted to the country context followed by visits to implementation sites and analysis of data and report writing.

#### *EPI program reviews*

The COVID vaccine introduction will leverage on other planned NVIP program reviews to assess the impact of the vaccine introduction into the routine system. The EPI review will highlight sector wide challenges the program is facing and areas for further interventions.

#### *Vaccination coverage surveys*

The program will also work closely with the Kenya National Bureau of Statistic (KNBS) to include COVID vaccination status in the demographic health survey. This will also provide a measure of effectiveness of the program is reaching its goal.

#### *Impact Studies*

Impact studies will be conducted in select counties, leveraging consortia of partners involved in local COVID Studies- Universities, KEMRI, CDC/Wellcome Trust in central, western and coastal parts of Kenya. National Research Fund will be engaged to fund multi-disciplinary research.

Existing longitudinal population-based surveillance systems will be utilized, to evaluate the decline in incidence of COVID Disease attributable to the vaccine introduction.

#### Data analytics and Dissemination

There will be huge volumes of data being generated during the COVID-19 vaccination. The data will be managed through

1. Data analytics.

The Ministry of Health will implement appropriate data analytics process to pool and aggregate data and apply advanced data analytics procedures such as forecasting and regression, machine learning and artificial intelligence analytics to provide critical insight to support the COVID 19 vaccination process.

The data analytics will be critical for the procurement and logistics of COVID 19 vaccines and other related supplies, prioritization and management of the overall epidemic.

2. Analytic dashboards

Analytical dashboards will be developed to inform decision makers at Sub county, county and national level both within the Ministry of Health and outside the Ministry of Health.

Data dashboards will be critical and simple visualization to support decision making,

3. Data stories and infographics

Data stories and infographics will also be developed to provide the general public with summarized information of the progress of the overall COVID-19 vaccination.

Data for communication and demand generation

Data for communication and demand generation will be developed and collected by the Ministry of Health through public data sources and Ministry of Health sources.

**Risk Matrix For the COVID-19 Vaccines Deployment and Vaccination**

Group	Assumptions	Risk	High/Medium/Low	Mitigation
<b>Pre-deployment phase</b>	Vaccine approved	Delays in deployment	Medium	Process of vaccine approval timelines clear/key DM engaged
	Budget approved	Delays in deployment	High	Budget process timelines clear/key DM engaged
	Key stakeholders (COG,	Delayed/ Skewed	High	Stakeholder communication

<b>Group</b>	<b>Assumptions</b>	<b>Risk</b>	<b>High/Medium/Low</b>	<b>Mitigation</b>
	counties, private sector, priority sectors)	vaccine deployment		plan implemented
<b>The disease/virus</b>	Covid is not present	Low vaccine uptake	Medium	Promote Vaccine as preventive measure
	Covid19 wave	Vaccine appears to be ineffective	Medium	Communication of role of vaccine vs other covid19 measures
	New Covid19 strain	High or Low vaccine uptake	High	Continuous monitoring of vaccine efficacy and communication
<b>The vaccine</b>	Vaccine not available or insufficient doses	Slow vaccine deployment	Medium	Planned roll out well communicated (eligibility) and pre-registration
	Vaccine found to be defective	Low vaccine uptake	Medium	Research, timely release of results (by trusted authority)
	Deaths associated with vaccine	Low vaccine uptake	low	Timely investigation and communication, financial payout
<b>Vaccine deployment</b>	Adequate funding	Slow, inept vaccine deployment	medium	Planned roll out well communicated: Robust monitoring
	Adequate Health system capacity for program	Slow, inept vaccine deployment	high	Additional resource budgeting (2021-2023)

Group	Assumptions	Risk	High/Medium/Low	Mitigation
	HW industrial action	Slow vaccine deployment	high	
	Legal challenges	Slow vaccine deployment, expiry of stock	medium	Clear mandates for deployment
<b>Unintended Consequences</b>	Vaccine deployment does not drain other Health system functions	Low Health indicators	Medium	Regular review of other health system activities, synergies
	Corruption	Low trust	High	Well planned communication, robust procurement
	Other crisis emerges	Reduced funding/focus	low	Uncertainty
	Other countries stop vaccine deployment	Questions on effectiveness of vaccine deployment	low	Monitor key country comparators , engage WHO
	Political change (2022 elections)	Loss of focus on vaccine deployment	Medium	uncertainty
	Kenya LMIC status expires 2022/23	Reduced grants to health	low	Additional resource budgeting (2022-2023)
	No categorization of target population	High vaccine deployment/ vaccine stock out	Medium	
	Vaccine donations (Non-GAVI)		Low	

### COVID-19 Disease surveillance

Public health surveillance is defined as the ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning,

implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control. Because surveillance can directly measure what is going on in the population, it is useful both in measuring the need for interventions and for directly measuring the effects of interventions. The purpose of surveillance is to empower decision makers to lead and manage more effectively by providing timely, useful evidence. In the context of COVID-19 vaccine introduction, surveillance will help to guide the implementation and adjustment of the COVID-19 vaccination program and policies.

The burden of COVID-19 disease will continue being monitored through the existing COVID-19 surveillance systems, managed by the Division of Disease Surveillance and Response (DDSR). The existing data collection and management tools will be modified to include vaccination related data elements. Data will be analyzed and disseminated regularly.

As COVID-19 vaccination is new, the Division will also set up additional surveillance leveraging existing systems e.g., Influenza sentinel sites, Acute Febrile Illness (AFI) sentinel sites etc. to aid in measuring and understanding the effects and impact of vaccination. Additionally, considering that the vaccine will be deployed in phases and also targeting specific sub populations then specific surveillance systems will be established to collect critical data from selected sub populations. To accomplish the aforementioned objectives, rigorous planning, methodical designing, standardization of procedures and collection of quality data will be crucial in generating credible scientifically sound information. This Information will be timely disseminated to policy makers for decision making, and moreover, shared with WHO to allow for a global perspective on vaccine effectiveness and impact.

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## MINISTRY OF HEALTH

### **RESPONSE TO THE SENATE STANDING COMMITTEE ON HEALTH REGARDING THE NATIONWIDE COVID-19 VACCINE ROLL-OUT**

The Ministry received a letter, Ref. SEN/DCO/CORR/SCH/02/003/2021 (1), dated 11<sup>th</sup> March, 2021, inviting the Cabinet Secretary to a virtual meeting on Thursday, 18<sup>th</sup> March, 2021, to apprise the Committee on the following;

1. Details of the safety profile, efficacy and known side effects of the COVID-19 vaccine
2. Any reports of adverse side effects and/or deaths that have been attributed to the vaccine so far.
3. Details of financial and budgetary implications of the COVID-19 vaccine roll-out (including cold chain, storage, logistics etc);
4. Measures that the Ministry has put in place to facilitate the seamless roll-out of the vaccine to all Kenyans;
5. Capacity of Kenya's cold chain system and vaccine storage facilities in relation to the COVID-19 vaccine roll-out; and
6. Details of the measures that the Ministry has taken to ensure effective involvement and engagement of County Governments and other stakeholders in the vaccine roll-out.

#### **1. Details of the safety profile, efficacy and known side effects of the COVID-19 vaccine**

#### **Response**

Chair and honourable members, Kenya has rolled out the COVID-19 vaccine AstraZeneca which is an adenovirus vector vaccine whose efficacy in clinical trials has been reported to range between 62%- 70% for disease prevention and at 100% for reduction in hospitalization and death prevention. The common reported side effects are pain at injection site, headache, tiredness and muscle ache.

During clinical trials there were no major severe adverse effects reported and hence its receipt of Emergency Use Authorization by the World Health Organisation (WHO).

**2. Any reports of adverse side effects and/or deaths that have been attributed to the vaccine so far.**

**Response**

Chair and Honourable Members, although a number of Countries have suspended the use of AstraZeneca to allow for investigations regarding its linkage to formation of clots, no direct link or causality has been established. It is noteworthy that a number of Countries such as Canada, Spain, Italy and France and Belgium have resumed its use.

Chair and Honourable Members, Kenya, through the Ministry of Health, supported by the Pharmacy and Poisons Board is monitoring for reported side effects and so far, no significant side effects that would warrant investigations and/or deaths have been reported.

Kenya has already vaccinated 20,000 people and so far, the adverse effects reported include

- Injection site pain/swelling
- Muscle pain
- Headache
- Low grade fever

**3. Details of financial and budgetary implications of the COVID-19 vaccine roll-out (including cold chain, storage, logistics etc);**

Chair and Honourable Members, the Government of Kenya is currently mobilising resources to support the COVID-19 vaccine roll out as outlined in the tables below.

*Table 1. Summary of activities and financing through Government of Kenya and GAVI*

Main Activity Description	Financing (KSH)		Total (KSH)
	GoK	GAVI	
Procurement of Vaccines and Injection Devices (Covering 30% Population), Warehousing and Distribution	11,137,133,621	19,711,056,609	30,848,190,230
Operational costs including capacity building, communication, community mobilization and cold chain storage	3,169,433,710	0	3,169,433,710
<b>Total</b>	<b>14,306,567,330</b>	<b>19,711,056,609</b>	<b>34,017,623,939</b>

Table 2. Financial allocations and activities from 2020/2021 to 2022/2023

Main Activity	FY 2020/21		FY 2021/22		FY 2022/23
	GoK	GAVI	GoK	GAVI	GoK
Procurement of Vaccines and Injection Devices (Covering 30% Population), Warehousing and Distribution	857,491,715	2,248,423,476	1,440,937,455	17,462,633,133	8,838,704,451
Operational costs including capacity building, data management, advocacy, communication, mobilization initiatives and cold chain storage	798,110,616		231,456,059	-	56,762,500
<b>Total</b>	<b>1,655,602,331</b>	<b>2,248,423,476</b>	<b>3,755,498,049</b>	<b>17,462,633,133</b>	<b>8,895,466,951</b>

**4. Measures the Ministry of Health has put in place to facilitate the seamless rollout of the vaccine to all Kenyans.**

Chair and Honourable Members, the following measures have been undertaken by the Ministry to facilitate the vaccine deployment:

- a. The Ministry developed and is currently implementing the National Vaccine Deployment Plan (NVDP) whose objective is to facilitate the deployment, implementation, and monitoring of the COVID-19 vaccine(s) in Kenya and ensure the plan and related financing is well aligned to the overall national COVID-19 recovery and response plans.
- b. The Ministry has mapped out vaccine storage capacity for both positive and negative temperature storage vaccines at the central regional vaccine stores, employing a mixed approach to deliver vaccines to the counties – some counties will pick vaccines from the nearest regional depots while the hard-

to-reach ones have the vaccines delivered to them by air freight (Turkana, Mandera, Wajir).

The Country has identified and mapped vaccine providers to administer vaccines in Public, Private, Faith-based NGOs run facilities, at no cost, by their level of health service delivery for each phase. During phase 1 which runs up to 30<sup>th</sup> June, 2021, we have listed 622 facilities across the Country. These include public, private and faith based facilities.

- c. The Ministry has deployed a robust engagement exercise with counties in a microplanning process to map and validate the target groups, to guide vaccine allocation, adopting a phased approach to vaccine deployment focusing on priority populations by County, populations most at risk of death or severe disease from COVID-19 and other vulnerable populations.
- d. Undertaken training of health workers, organized around three phases aligned with the vaccination phases, and done through blended online/virtual training and face to face/peer demonstration. A training guide for health workers containing information on the COVID-19 disease, the vaccine characteristics, and the immunization procedures has been developed to ensure standardization and smooth implementation of vaccination activities. The Ministry has already supported the training of 35 National Master Trainers, 235 county TOTs and 110 health workers. More trainings at regional level targeting over 2000 health workers is planned to start next week. This will include ICT officers to support the digital platform (Chanjo KE).
- e. The Ministry has developed a communication plan that includes risk communication to ensure buy-in of key stakeholders in creating demand for the vaccine and address hesitancy issues. The crisis communication plan will address any potential adverse events, myths, misconceptions, and hesitancy that may arise associated with either COVID-19 or the vaccine.
- f. Close monitoring of the vaccine rollout is being undertaken and will continue through the established ICT platform – Chanjo Management Information Systems (CMIS) to inform action. We plan to monitor each phase to document the impact of the vaccinations on the disease burden and transmission.

## **5. The capacity of Kenya's cold chains system and vaccine storage facilities in relation to the COVID-19 Vaccine rollout**

Chair and Honourable Members, the Ministry will deploy the vaccines through the following network of depots and vaccine stores/ centres:

- a. The National Vaccine Depot, located in Kitengela.
- b. Nine (9) Regional Depots located in Kakamega, Kisumu, Nakuru, Eldoret, Meru, Mombasa, Garissa, Nyeri, Nairobi and three (3) County Depots in Mandera, Wajir and Turkana.
- c. 290 Sub-county Vaccine stores, in subcounty headquarters.
- d. Approximately 7,877 Immunizing Health Facilities across the Country.

Storage capacity for both positive and negative temperature storage at the National and all the nine (9) regional stores is adequate for introduction of COVID-19 vaccines.

The National Vaccine store has a total of eight (8) cold rooms with a net capacity of 130M<sup>3</sup> for positive temperature cold storage (2-8°C) and 2 freezer rooms with a net capacity of 14 M<sup>3</sup> for negative temperature cold storage (-20°C).

Chair and Honourable Members, the capacity at the national cold rooms is sufficient for deployment of vaccines requiring the +2°C to 8°C / -20°C of cold storage, with a quarterly vaccine delivery schedule to the national and regional vaccine stores. Minimal expansion will be required to provide for less frequent shipment schedules and introduction of other vaccines in future.

There exists significant inequity in cold chain capacity distribution among and within counties, considering a monthly supply cycle.

The Ministry plans to bridge the cold chain capacity gaps through:

1. Procurement and installation of additional cold chain equipment from Gavi the Vaccine Alliance and World Bank support.
2. Implementation of year 2 & 3 of the ongoing Cold Chain Equipment Optimization Platform Project, supported by Gavi the Vaccine Alliance.
3. Redistribution of cold chain equipment within counties.
4. Collaboration with the private sector for cold chain storage.

All the old cold rooms and refrigerators in depots and health facilities countrywide are equipped with continuous electronic temperature monitoring devices that record the temperature status continuously.

**6. Details of the measures that the Ministry has taken to ensure effective involvement and engagement of County Governments and other stakeholders in the vaccine roll-out.**

Chair and Honourable Members, the County Governments and other stakeholders have been engaged through establishment of a multistakeholder coordination structure, coordinated at three levels- National, County and Subcounty Levels.

The National level coordination, at which National, County, Private sector, Civil and Religious society members are represented.

The National Level Steering and planning committees provide overall policy, oversight and technical leadership for vaccine deployment planning and implementation, while the county and subcounty levels undertake the execution of the policies and service delivery. At the county and subcounty levels, an engagement plan is being implemented covering the following key components:

- a. Key stakeholders to be engaged at each level and time e.g. policy makers and key opinion leaders, health workers, local and national leaders, religious leaders, civil society organizations, private sector etc.
- b. Key messaging for each stakeholder
- c. Key channels to be used for each stakeholder e.g. one-on-one meetings, public meetings, traditional media, social media, bulk messaging, promotional materials etc.

In conclusion, Chair and Honourable Members, the Ministry intends to implement the National Vaccine Deployment Plan to ensure voluntary access of the COVID-19 vaccine.

I hereby wish to submit the above responses.



**SEN. MUTAHI KAGWE, EGH,**  
**CABINET SECRETARY.**

18 March, 2021



## MINISTRY OF HEALTH

### **RESPONSES TO THE SENATE STANDING COMMITTEE ON HEALTH, ON THE CANCELLATION OF LICENCES TO PRIVATE SECTOR ENTITIES IN THE IMPORTATION, DISTRIBUTION AND ADMINISTRATION OF COVID-19 VACCINES INTO KENYA**

The Ministry refers to a communication from the Senate vide letter Ref. No. SEC/DCO/CORR/SCH/02/012/2021/ (1) dated 6<sup>th</sup> April, 2021, requesting for a response on the cancellation of licenses to private sector entities in the importation, distribution and administration of Covid-19 vaccines into Kenya.

Please find comprehensive responses on the issues raised:

**Question 1. Explain what has led to the changing positions of the Ministry of Health 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 18<sup>th</sup> March, 2021 and 29<sup>th</sup> March, 2021 (copies attached), the oral submissions by the Cabinet Secretary of Health at the meeting held on Thursday, 1<sup>st</sup> April, 2021 (Hansard transcript attached), and the aforementioned public statement issued by the Cabinet Secretary of Health on 2<sup>nd</sup> April, 2021.**

The Ministry of Health is part of a Multi-Agency National Emergency Response Committee (NERC), constituted by the President through the Executive Order No. 2 of 2020, issued at State House, Nairobi on 28<sup>th</sup> February, 2020. Part of the mandate of the NERC is to;

Given its mandate of coordinating the supply of testing-kits, critical medical products/supplies, pharmaceuticals, masks and other protective gear within the Republic, of which the COVID-19 vaccine is part, the NERC put on hold the private sector's importation, distribution and administration of said imported vaccine, until such a time when greater transparency and accountability in the entire process was assured in the interest of public health safety.

**Question 2. Explain the Ethical considerations that went into cancelling the importation, distribution and administration of the Russian-manufactured Sputnik V vaccine in light of the Government's assurance to members of public who had already received the vaccine that they will duly receive the second dose.**

Matters of public health safety are a priority of the Government of Kenya. NERC was informed that vaccinations were taking place at posts that were not accredited and designated by the Kenya Medical Practitioners and Dentists Council, including individual people's homes.

Since mixing of vaccines is not recommended by both WHO and 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 2<sup>nd</sup> dose after 3 weeks are assured of receiving their dose to complete the vaccination. This criterion will only apply to the 527 vaccination cases which had been reported in the Chanjo-KE System at the time of the ban.

**Question 3. State whether the private entities concerned in the importation and distribution of the Russian-manufactured Sputnik V vaccine will 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;**

The plan is to have this framework in place by end of June this year, so that the private sector joins the roll-out plan in July this year, when we fully actualize Phase II of the deployment.

Chair and Honorable members, I hereby wish to submit the above responses.



for **SEN. MUTAHI KAGWE, EGH,**  
**CABINET SECRETARY.**



## MINISTRY OF HEALTH

### RESPONSES TO THE SENATE STANDING COMMITTEE ON HEALTH ON CANCELLATION OF LICENCES TO PRIVATE SECTOR ENTITIES IN THE IMPORTATION, DISTRIBUTION AND ADMINISTRATION OF COVID-19 VACCINES INTO KENYA AND STATUS OF VACCINE ROLL-OUT

#### A. INTRODUCTION

The Ministry refers to a communication vide letter Ref No. SEN/DCO/CORR/SCH/02/012/2021(2) and SEN/DCO/CORR/SCH/02/018/2021(1) dated 16<sup>th</sup> April, 2021, and 23<sup>rd</sup> April, 2021, respectively, from the Clerk of the Senate, requesting the Ministry to provide responses for;

**Question 1. To clarify 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.**

1. The National Government through the Ministry of Health (MoH) is responsible for health policy under the Fourth Schedule of the Constitution of Kenya, 2010, and is obligated to implement the principles in Articles 10 and 232, Chapter 6 and Chapter 12 of the Constitution.
2. The Pharmacy and Poisons Board (PPB), under the Ministry of Health, is the National Medicines Regulatory Authority, established under the Pharmacy and Poisons Act (Cap 244), responsible for regulation of health products, technologies and the profession of pharmacy inter alia;
  - a. grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;

- b. ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy; and
  - c. 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.
3. According to the Pharmacy and Poisons Rules, appeals of the decisions from the Pharmacy and Poisons Board lie with the Cabinet Secretary for Health.
4. In relation to vaccines specifically, the Cabinet Secretary for Health, under Section 158(1) of the Public Health Act, is empowered 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”.*
5. The National Emergency Response Committee (NERC) on Coronavirus Disease was established by H.E. The President on 28<sup>th</sup> February, 2020, vide Executive Order No. 2 of 2020, with among other terms of reference to *“coordinate Kenya’s preparedness, prevention and response to the threat of Coronavirus Disease”.*
6. Ordinarily, the Ministry of Health routinely issues and guides policy direction on how the PPB undertakes its legal mandate as stipulated above. Health products and technologies is a key policy orientation under the Kenya Health Policy (2014-2030). This policy provides for the strategy of ensuring the availability of affordable, good quality health products and technologies. This is to be done through application of all options and public health safeguards relating to health products & technologies, through multisectoral interventions on trade and related sectors.
7. Under the Health Policy, vaccines for epidemics are categorized as “Strategic” health products and technologies, and the National Government is required to acquire and maintain adequate stocks of the Strategic categories of products.

8. Therefore, under the unprecedented emergency, regulatory emergency responses, including emergency use authorization, import licence of products under emergency authorization, and Good Distribution Practices (GDP), inspections preceded specific policy directions on the same. This was with a view to complying with the existing general policy of ensuring availability of strategic health products for management of the pandemic.

At the advent of this unprecedented global emergency/pandemic, the NERC was tasked to coordinate Kenya's preparedness, prevention and response to the threat of Coronavirus disease, and therefore this influences policy relating to management of the pandemic. The above informed the change in policy to restrict import, distribution and administration of Covid-19 vaccines to the Government only as a policy decision that PPB as the implementing agency is expected to enforce, hence the decision by the Ministry of Health to cancel and revoke licenses to private entities for the importation, distribution and administration of health products, including vaccines.

**Question 2. Status update on the national COVID-19 vaccine deployment exercise, reported shortages in the AstraZeneca vaccine and the measures that the Government has taken to ensure that all eligible persons receive their first and booster vaccinations in a timely manner.**

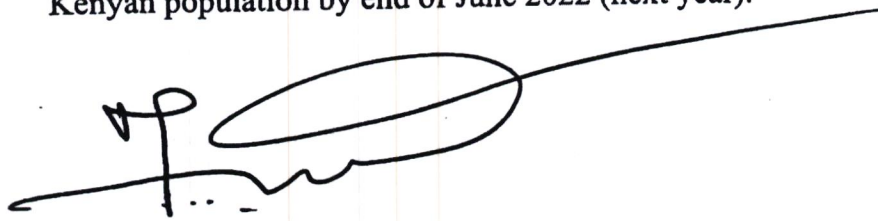
Kenya received 1,020,000 doses of AstraZeneca vaccine from Covax as an in-kind contribution on 3<sup>rd</sup> March, 2021. These vaccines were distributed to all 47 counties and vaccination started on 5<sup>th</sup> March, 2021. In addition, the Government received a donation of 100,000 doses of the same vaccine from the Government of India. Total doses dispatched to regional stores as at 26<sup>th</sup> April, 2021, was 1,080,000 with a balance of 40,000 doses at the Kitengela Central Vaccines Stores.

The total number of persons vaccinated stands at 853,081. 56% of these are males while 44% are females. Among those vaccinated as of 27<sup>th</sup> April, 2021 include 154,031 health workers, 70,467 security personnel, 129,527 teachers, 259, 961 persons above 58 years of age while 226,089 constitute other categories. 74% of targeted health workers have been vaccinated, 39% of targeted teachers and 10% of persons above 58 years.

In regards to the issuance of the 2<sup>nd</sup> dose of AstraZeneca, Members may be aware of the global supply constraints occasioned by the decision by the Government of India to prioritize the vaccination for its own population and inability of the Serum Institute of India, which is the largest vaccine manufacturer in the world to meet the global demand. Covax informed Kenya of the delay in the shipment of 2.5 million out of the 3.5 million doses of AstraZeneca vaccines that have been allocated to Kenya for the period February to May 2021. The Ministry is in constant touch with Covax and they have informed the Ministry that the shipment to Kenya should be received during the month of May 2021.

It's important to note that the global vaccine shortages are beyond Kenya and indeed Covax. There is however an international effort to address these challenges. In the meantime, the Ministry of Health has taken into consideration guidance from WHO and current evidence, which shows that taking the second dose at 12 weeks provides a higher immune response and better protection while considering the global shortages, the MOH has revised the duration between the administration of the first dose and the second dose from 8 to 12 weeks.

The first recipients of the second dose are therefore expected to receive their booster, during the first week of June 2021, by which time the supplies from Covax should have been received. In addition, the MOH has engaged the African Union with a view to procure 7 million doses of Pfizer and 10 million vaccine doses of Johnson and Johnson to vaccinate additional 13.5 million Kenyans even as we expect a donation of a further 20 million doses from Covax and plans to procure 11 million doses from the same facility. This will ensure that we fully vaccinate the entire adult Kenyan population by end of June 2022 (next year).



**SEN. MUTAHI KAGWE, EGH,  
CABINET SECRETARY.**

30<sup>th</sup> April, 2021

cc. Principal Secretary  
Ministry of Health



**MINISTRY OF HEALTH**  
**UPDATES ON COVID-19 VACCINATION EXERCISE**

**Background**

- Vaccines Received- 1,120,000 (Inclusive of 100,000 donations by Government of India)
- Vaccinations began on 5<sup>th</sup> March 2021, Countrywide vaccinations started on the week of 8<sup>th</sup> March 2021
- Total Doses Issued **1,099,000** at 9<sup>th</sup> May 2021
- **Balance at Kitengela Central Vaccines store 21,000 doses** at 9<sup>th</sup> May 2021
- Total number of persons vaccinated to date **917,068**, 56% are male while 44% are female.

<b>Sunday 9<sup>th</sup> May 2021</b>						
<b>Total Vaccinated</b>	<b>Cumulative Persons</b>	<b>Vaccinations per Gender</b>				<b>AEFI Reported</b>
Today	Vaccinated to date	Male	Female	Intersex	Trans	
221	917,068	513,296	403,225	461	86	479

**Table 1: Covid 19 Vaccination Data: Cumulative at 9<sup>th</sup> May 2021**

No.	County	Vaccinated	Proportion	No	County	Vaccinated	Proportion
1	Nairobi	277,321	30.2%	26	Nyamira	9,212	1.0%
2	Nakuru	63,191	6.9%	27	Busia	9,181	1.0%
3	Kiambu	45,599	5.0%	28	Siaya	9,020	1.0%
4	Uasin Gishu	42,415	4.6%	29	Bomet	8,107	0.9%
5	Nyeri	34,759	3.8%	30	Baringo	7,425	0.8%
6	Meru	25,169	2.7%	31	Tharaka Nithi	7,118	0.8%
7	Mombasa	25,045	2.7%	32	Elgeyo Marakwet	7,018	0.8%
8	Muranga	25,035	2.7%	33	Makueni	6,421	0.7%
9	Kisumu	24,359	2.7%	34	Narok	6,053	0.7%
10	Kajiado	22,468	2.4%	35	Kilifi	5,912	0.6%
11	Kakamega	22,168	2.4%	36	Taita Taveta	4,750	0.5%

12	Nyandarua	20,258	2.2%
13	Machakos	19,322	2.1%
14	Trans Nzoia	18,282	2.0%
15	Bungoma	16,684	1.8%
16	Embu	16,681	1.8%
17	Laikipia	16,552	1.8%
18	Nandi	15,242	1.7%
19	Kirinyaga	15,196	1.7%
20	Kitui	12,251	1.3%
21	Homa Bay	12,166	1.3%
22	Kericho	11,742	1.3%
23	Vihiga	11,217	1.2%
24	Kisii	9,967	1.1%
25	Migori	9,273	1.0%

37	Turkana	3,719	0.4%
38	West Pokot	3,591	0.4%
39	Kwale	3,417	0.4%
40	Samburu	3,198	0.3%
41	Mandera	2,403	0.3%
42	Garissa	2,186	0.2%
43	Wajir	2,101	0.2%
44	Isiolo	1,636	0.2%
45	Tana River	842	0.1%
46	Lamu	728	0.1%
47	Marsabit	668	0.1%
<b>Total</b>		<b>917,068</b>	<b>100%</b>

- The table above shows number of persons vaccinated per county and the percentage of contribution to the total number vaccinated, the top five counties are; Nairobi with 277,321(30.2%) persons vaccinated, Nakuru 63,191(6.9%), Kiambu 45,599(5.0%), Uasin Gishu 42,415(4.6%) and Nyeri with 34,759(3.8%) Persons vaccinated.
- Counties with least vaccination is; Wajir 2,101(0.2%), Isiolo 1,636(0.2%), Tana River 842(0.1%), Lamu 728(0.1%) and Marsabit 668(0.1%) persons vaccinated
- **There has been low vaccination uptake across the country in the week e.g Kiambu county recording Zero Vaccination in the last 5 days, others a small number vaccinated as shown in the graph below**

### TOP 5 COUNTIES IN A WEEK

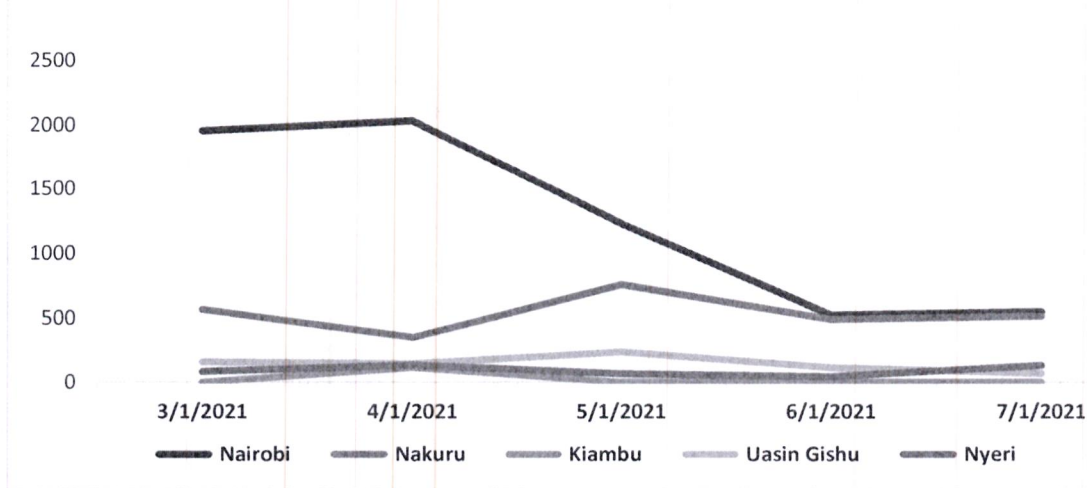


Figure 1: Number of persons vaccinated in the last 5 Days

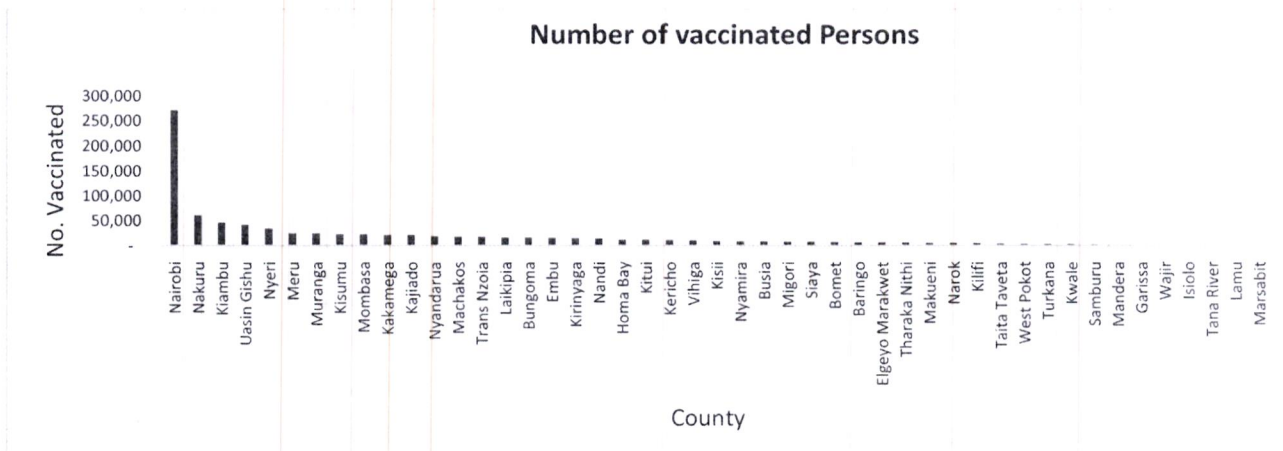


Figure 2: A graph showing number of vaccinated persons per county

Table 2: Vaccination by Occupation

Occupation	No. Vaccinated	Percentage
Health Workers	160,947	17.6%
Security Officers	77,417	8.4%
Teachers	143,684	15.7%
Above 58 years Old	280,876	30.6%
Others	254,144	27.7%
<b>Total</b>	<b>917,068</b>	<b>100.0%</b>

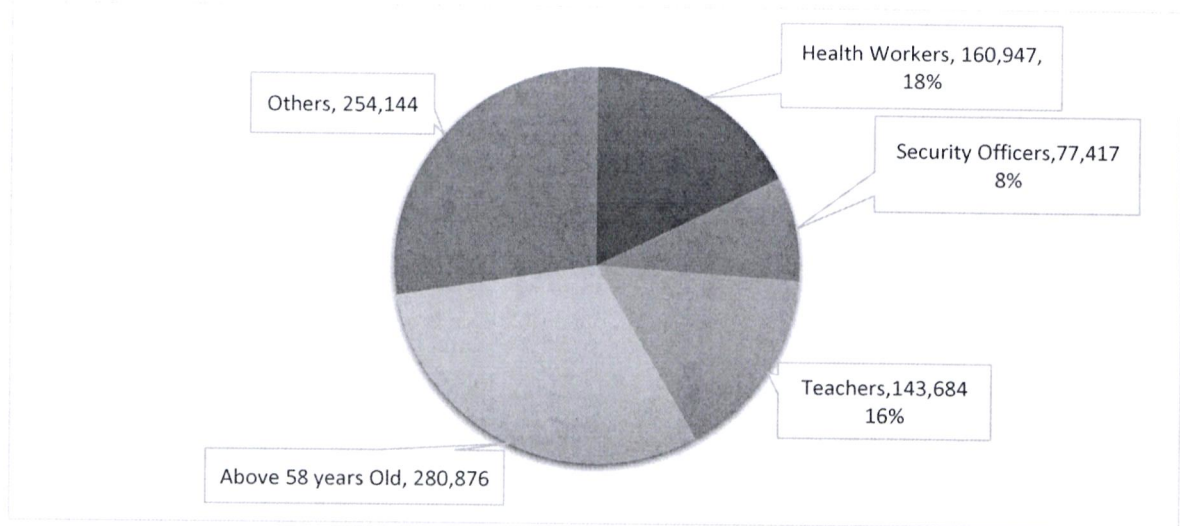


Figure :3 The number vaccinated by occupation

- Figure2; shows that uptake by category (58 yrs and above) is the highest at 31%, Others at 27%, health care workers at 18%, Teachers at 16% and Security at 8%
- Table 4 below, shows that 77.0% of the targeted health care workers have been vaccinated, 43% teachers and above 58years at 11%

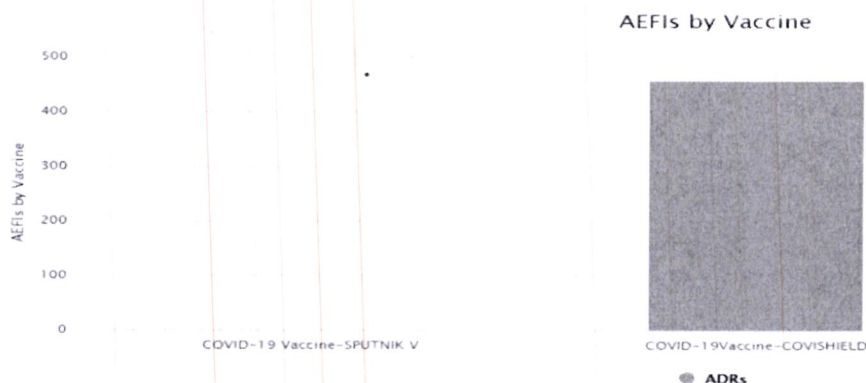
Table 3: Progress towards meeting targets: Kenya, 9<sup>th</sup> May, 2021

Occupation	Vaccinated	Target Population	Progress (% covered)
Health Workers	160,947	208,418	77%
Security Officers	77,417		
Teachers	143,684	330,671	43%
Above 58 years Old	280,876	2,594,585	11%
Others	254,144		
<b>Total</b>	<b>917,068</b>	<b>3,133,674</b>	<b>29%</b>

Table 4: Vaccine Doses Dispensed as at 9<sup>th</sup> May, 2021

Vaccine	Total doses Administered
AstraZeneca	917,068
Sputnik	527
<b>Total</b>	<b>917,595</b>

## Adverse Events Followings Immunization (AEFIs)



**Figure3: Adverse Events Followings Immunization (AEFIs)**

The Chart show there are 479 cases of AEFIs report on COVID shield Vaccine related through the Pharmacovigilance Electronic reporting system as at 9<sup>th</sup> May 2021

**Table 5: Vaccine Logistics Received**

VACCINE ARRIVAL DATE	BATCH NUMBER	QUANTITY RECEIVED	EXP. DATE	MANUFACTURER
3/3/2021	4120Z029	63,810	27/06/2021	SSI LIVE SCIENCES PVT. INDIA
3/3/2021	4120Z030	956,190	28/06/2021	SSI LIVE SCIENCES PVT. INDIA
11/3/2021	4121Z010	100,000	18/07/2021	SSI LIVE SCIENCES PVT. INDIA
<b>TOTAL RECEIVED</b>		<b>1,120,000</b>		

- The table below shows distribution of COVID 19 vaccine doses across the 9 regional depots since the start of the vaccination exercise to date.
- Nairobi Region receiving 393,000 doses, Eldoret 129,000, Nakuru 117,000, Kisumu 108,000, Nyeri 84,000, Kakamega 81,000, Mombasa 66,000, Meru 39,000, Garissa/ Manderu 25,000, KDF Kahawa 42,000, State house 6000 doses, Afya house 10,000 doses.
- A total of **1,099,000** doses distributed as at 9<sup>th</sup> May 2021 and a balance of **21,000** doses at Kitengela Central store.

Table 7: Distribution at Regional Depots as at 9<sup>th</sup> May, 2021

REGIONAL LEVELS		DISPATCH DATE	BATCH NUMBER	QUANTITY ISSUED
1	NAIROBI	3/3/2021	4120Z029	63,810
		3/3/2021	4120Z030	110,190
		30/3/2021	4120Z030	174,000
		19/4/2021	4121Z010	45,000
Total Dispatched			393,000	
2	MERU	3/3/2021	4120Z030	21,000
		8/4/2021	4120Z030	15,000
		19/4/2021	4120Z030	3,000
Total Dispatched			39,000	
3	NYERI	3/3/2021	4120Z030	21,000
		30/3/2021	4120Z030	42,000
		8/4/2021	4120Z030	3,000
		19/4/2021	4120Z030	18,000
Total Dispatched			84,000	
4	GARISSA / Mandera	3/3/2021	4120Z030	12,000
		3/3/2021	4120Z030	6,000
		8/4/2021	4120Z030	7,000
Total Dispatched			25,000	
5	MOMBASA	3/3/2021	4120Z030	45,000
		8/3/2021	4120Z030	21,000
Total Dispatched			66,000	
6	KAKAMEGA	4/3/2021	4120Z030	42,000
		7/4/2021	4120Z030	39,000
Total Dispatched			81,000	
7	NAKURU	4/3/2021	4120Z030	57,000
		7/4/2021	4120Z030	60,000
Total Dispatched			117,000	
8	ELDORET	4/3/2021	4120Z030	60,000
		31/3/2021	4120Z030	60,000
		20/04/2021	4121Z010	9,000
Total Dispatched			129,000	
9	KISUMU	4/3/2021	4120Z030	54,000
		7/4/2021	4120Z030	48,000
		20/04/2021	4121Z010	6,000
Total Dispatched			108,000	
	STATE HOUSE	5/3/2021	4120Z030	6,000
	KDF KAHAWA	16/3/2021	4120Z030	32,000
		26/04/2021	4121Z010	10,000
Total Dispatched			42,000	
	AFYA HOUSE	27/04/2021	4121Z010	9,000
<b>TOTAL ISSUED</b>			<b>1,099,000</b>	
<b>TOTAL BALANCE</b>			<b>4121Z010</b>	<b>21,000</b>

**Table 8: Vaccine Logistics at County Level**

<b>Vaccine Inventory 9<sup>th</sup> May 2021</b>					
<b>Doses in Stock</b>			<b>Used Vaccines</b>		
277,100			823,493		
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% Used</b>	
Baringo County	9,000	1,804	7,196	80%	
Elgeyo Marakwet County	9,000	2,000	6,998	78%	
Nandi County	19,000	3,800	15,191	80%	
Trans Nzoia County	21,000	2,810	18,186	87%	
Uasin Gishu County	48,850	9,040	39,795	81%	
West Pokot County	5,500	2,400	3,591	65%	
<b>Total</b>	<b>116,850</b>	<b>24,440</b>	<b>92,957</b>	<b>79%</b>	
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% Used</b>	
Bomet County	9,500	2,180	7,314	77%	
Kericho County	12,400	790	11,602	94%	
Nakuru County	62,750	8,990	54,167	86%	
Nyandarua County	16,000	1,780	14,223	89%	
Samburu County	4,500	1,570	2,928	65%	
<b>Total</b>	<b>105,150</b>	<b>15,310</b>	<b>90,235</b>	<b>86%</b>	
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% used</b>	
Bungoma County	17,370	1,700	15,668	90%	
Busia County	12,000	2,800	9,203	77%	
Kakamega County	25,050	5,180	21,061	84%	
Vihiga County	15,200	4,619	10,083	66%	
<b>Total</b>	<b>80,170</b>	<b>24,480</b>	<b>56,015</b>	<b>70%</b>	
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% used</b>	
Embu County	15,500	150	15,436	97%	
Kirinyaga County	15,500	300	15,192	97%	
Laikipia County	16,030	90	15,938	99%	
Nyeri County	30,800	2,030	28,749	93%	
<b>Total</b>	<b>77,830</b>	<b>3,050</b>	<b>75,226</b>	<b>96%</b>	
Garissa County	4,600	2,390	2,207	47%	
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% used</b>	
Homa Bay County	18,000	5,830	12,164	68%	
Kisii County	15,140	5,290	9,809	65%	
Kisumu County	31,300	8,210	23,998	77%	
Migori County	13,590	4,510	9,232	68%	
Nyamira County	15,000	2,020	13,028	87%	
Siaya County	13,500	4,480	9,011	67%	
<b>Total</b>	<b>106,530</b>	<b>30,363</b>	<b>77,242</b>	<b>72%</b>	

<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% used</b>
Isiolo County	3,000	1,360	1,636	55%
Marsabit County	2,760	2,080	674	24%
Meru County	25,100	830	24,263	97%
Tharaka Nithi County	7,800	520	7,278	93%
<b>Total</b>	<b>38,760</b>	<b>4,900</b>	<b>33,851</b>	<b>87%</b>
<b>Level</b>	<b>Total Doses</b>	<b>Doses In Stock</b>	<b>Doses Used</b>	<b>% used</b>
Kajiado County	25,150	3,100	21,995	87%
Kiambu County	40,950	650	40,294	98%
Kitui County	14,390	3,040	11,349	78%
Machakos County	18,840	1,710	17,127	91%
Makueni County	6,780	670	6,202	91%
Muranga County	24,500	2,980	21,517	88%
Nairobi County	319,500	94,180	225,343	70%
Narok County	7,200	2,410	4,784	66%
<b>Total</b>	<b>458,310</b>	<b>109,770</b>	<b>348,611</b>	<b>87%</b>
<b>Level</b>	<b>Total Doses</b>	<b>Doses in Stock</b>	<b>Doses Used</b>	<b>% used</b>
Kilifi County	8,850	2,410	5,787	65%
Kwale County	7,000	3,350	3,653	52%
Lamu County	1,500	770	728	49%
Mombasa County	29,000	5,020	23,988	83%
Taita Taveta County	6,000	1,630	4,683	78%
Tana River County	1,500	670	841	55%
<b>Total</b>	<b>62,000</b>	<b>22,350</b>	<b>39,641</b>	<b>64%</b>
Mandera County	6,000	3,580	2,411	40%
Turkana County	7,900	4,180	3,719	47%
Wajir County	6,000	3,860	2,132	36%
<b>Total at county level</b>	<b>1,099,000</b>	<b>277,100</b>	<b>823,493</b>	<b>75%</b>

The table above shows:

- The number of vaccines distributed to county level 1,099,000
- The number of doses used 823,493
- The balances 277,100 doses
- And 74% of vaccines used as at 9<sup>th</sup> May 2021



## COUNCIL OF GOVERNORS

### REPORT FOR THE SENATE AD HOC COMMITTEE ON THE NATIONALWIDE COVID-19 VACCINE ROLL OUT MEETING ON 18<sup>th</sup> MARCH, 2021

#### 1. Introduction

- 1.1 The Government of Kenya has commenced roll out of the COVID 19 Vaccination Program across the 47 counties with a view to reducing COVID 19 transmission, reducing the burden of disease and deaths from COVID 19. The COVID 19 Vaccine roll out plan targets approximately **15 million** persons (30% of the total population) and is to be undertaken in **three** phases from **March 2021 to June 2023**. The government is investing **KES 14 billion** into this program, with support from the Global Alliance for Vaccines Initiative (GAVI) of **KES 20 billion** which totals **KES 34 billion** and projects to mobilize additional resources from other development partners. In the immediate term, the government has opted for the AstraZeneca Vaccine through COVID-19 Vaccines Global Access (Covax) facility.
- 1.2 At the national level, the COVID-19 Vaccine roll out process is led by the National COVID-19 Vaccine Deployment Task Force with oversight from the National COVID-19 Vaccine Deployment and Vaccination Steering Committee (NSC). COG is represented in the Steering committee by the Chair of COG and the technical lead for the COG Health Committee in the Task Force. The Task Force is supported by seven sub-committees that provide technical guidance on regulation and safety monitoring; Vaccine Financing; Planning & coordination; Procurement and logistics; Trainings and Capacity Building; Advocacy, Communication & social mobilization; and Data management, monitoring & surveillance.
- 1.3 At the county level, the process is overseen by a County COVID-19 Vaccine Deployment and Vaccination Steering Committee (CSC) chaired by the Governor and technical guidance is provided by 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. All 47 County Governments have put in place the necessary governance and management structures for the roll out.

- 1.4 The roll out has been designed in three phases guided by priority target populations as informed by recommendations of the World Health Organization (WHO), country epidemiological data and resource availability. Phase 1 (FY 2020/2021) targets **1.25 million** mainly frontline health workers and other essential workers such as teachers and uniformed forces. Phase 2 (FY 2021/2022) targets **9.76 million** of the population considered more vulnerable, including those with comorbidities (especially of non-communicable diseases) and those above 50 years. This phase also targets those in hospitality and tourism industry. Phase 3 (FY 2022/2023) targets **9.8 million** with a focus on making access to the vaccine more equitable. It will target those over 18 years in congregate settings, hospitality, and tourism industry.
- 1.5 Over 8,000 public and private health facilities across the 47 counties, that have immunization sites and support routine immunization, are expected to be the hubs for this program by 2023. Phase 1 involves 622 health facilities from public, private and faith based sub-sectors.
- 1.6 Phase 1 of the COVID 19 Vaccine Roll out was launched by the H. E. President Uhuru Kenyatta on 4<sup>th</sup> March, 2021 following the procurement and delivery of the first batch of 1,120,000 doses of the AstraZeneca vaccine to the main national vaccines depot at Kitengela, Kajiado County.

## **2. Status of county governments response to the COVID-19 Vaccine roll out.**

- 2.1 All 47 County Governments have established covid-19 vaccine deployment and vaccination taskforces, at both the County and sub-County levels, that are coordinating Covid -19 vaccine roll out activities in the Counties. The task forces are closely monitoring the progress of the roll out activities and facilitating resolution of bottlenecks. Notably, all County Governors are championing the COVID-19 vaccine roll out, in addition to the need for citizens to adhere to the COVID 19 Prevention protocols issued by the Ministry of Health in early 2020.
- 2.2 All 47 counties have 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 are also developing detailed plans (micro-plans) that 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.
- 2.3 So far, counties have received COVID -19 vaccine doses totaling to 318,045. *The schedule of the number of doses of the COVID 19 vaccine received by each county is in the appendix.* Since the roll out program is anchored on the routine immunization system, county

government are expected to make logistical arrangements for picking up of vaccines from the nearest regional vaccines depots and subsequently distributing to their immunization sites.

- 2.4 All Counties are providing regular reports on the progress of COVID-19 Vaccine roll out. Reporting is being undertaken through the 'Chanjo' electronic logistics management information system (eLMIS).
- 2.5 In the preparatory phase for the roll out of the COVID 19 vaccine, the Ministry of Health developed a training program that blends both physical and virtual components for building skills of county health staff on : COVID 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 is ongoing in a cascaded approach at the county level led by a team of **329** Trainers of Trainers (TOT) from all the 47 counties. So far, a total of **2,937** health care workers of various cadres have been trained on Covid 19-vaccine roll out for phase 1. Plans for scaling up of the training to cover all staff involved in the immunization process have been formulated, and counties are mobilizing resources for the same.
- 2.6 In terms of vaccination of target population, a total of **15,305** frontline health care workers from the 47 counties had received the COVID 19 vaccine (1<sup>st</sup> dose) as of 16<sup>th</sup> March 2021. *The breakdown of those vaccinated per county is included in the appendix.*
- 2.7 County governments continue to undertake close monitoring of immunization processes including identification, reporting and investigation of adverse events following immunization (AEFIs) in close collaboration with the National Vaccines Program (NVP) and the Pharmacy and Poisons Board (PPB). All counties have focal point persons for AEFI surveillance at county and sub-county levels who collate incident reports from health workers and other sources. *Based on the reports collated so far, the following have been reported by health workers: 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.* County governments have established systems to complement the national government in identifying and addressing safety concerns (both real and perceived) on a timely basis.
- 2.8 Despite the notable achievements demonstrated by the county governments, there are several significant challenges that county governments are dealing with. Admittedly, the county governments do recognize the challenges as risks in the phased roll out and are employing all the necessary measures to mitigate the associated risks.

- 2.9 The current challenges include the following: slow uptake by health care workers owing to social media information on the side effects of the AstraZeneca vaccine (blood clots) as well as Global misinformation of the vaccine; inadequate funding to support training and vaccine roll out at the counties, stretched logistical and human resource capacity, inadequate reporting tools including AEFI forms and tablets for online registration into the chanjo system, and internet downtime. Since phase 1 is being carried out at level 4 and 5 facilities, staff have to travel to the designated sites increasing the opportunity cost on lost time for service delivery.
- 2.10 County governments are making concerted efforts to address the above challenges through various ways including engaging stakeholders for additional resources both financial and in-kind, promoting sensitization of the public regarding COVID -19 response and demystifying myths and misconceptions about COVID 19 Vaccine.

### **3. Looking Forward**

Appreciating that the COVID 19 Pandemic has disrupted the routine delivery of health services and stretched resources available to county governments, the Council of Governors (COG) appreciates the work of the Adhoc Committee of the Senate in addressing bottlenecks faced by county governments as they seek to uphold the right to highest attainable standard of health for the citizens.

The COG calls upon the Senate to allocate additional resources to county governments towards this roll out.



**MINISTRY OF HEALTH  
PHARMACY AND POISONS BOARD**

**RESPONSES TO THE SENATE ON ALLEGED EMERGENCY  
AUTHORIZATION FOR THE IMPORTATION AND DISTRIBUTION OF THE  
RUSSIAN-MANUFACTURED SPUTNIK COVID-19 VACCINE IN KENYA**

---

Reference is made to the above subject and your letter dated 25<sup>th</sup> March, 2021 addressed to us under reference SEN/DCO/CORR/SCH/02/006/2021 (1).

The Board wishes to respond, as below, to the specific questions raised:

**1. State whether the Russian-manufactured vaccine has received  
Emergency Authorization for use in Kenya;**

The Russian-manufactured Sputnik COVID-19 vaccine has been granted Emergency Use Authorization (EUA) by the Pharmacy and Poisons 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.

**2. Outline the standard procedures and processes for the registration  
and/or authorization of health products in Kenya, particularly  
vaccines**

2.1 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

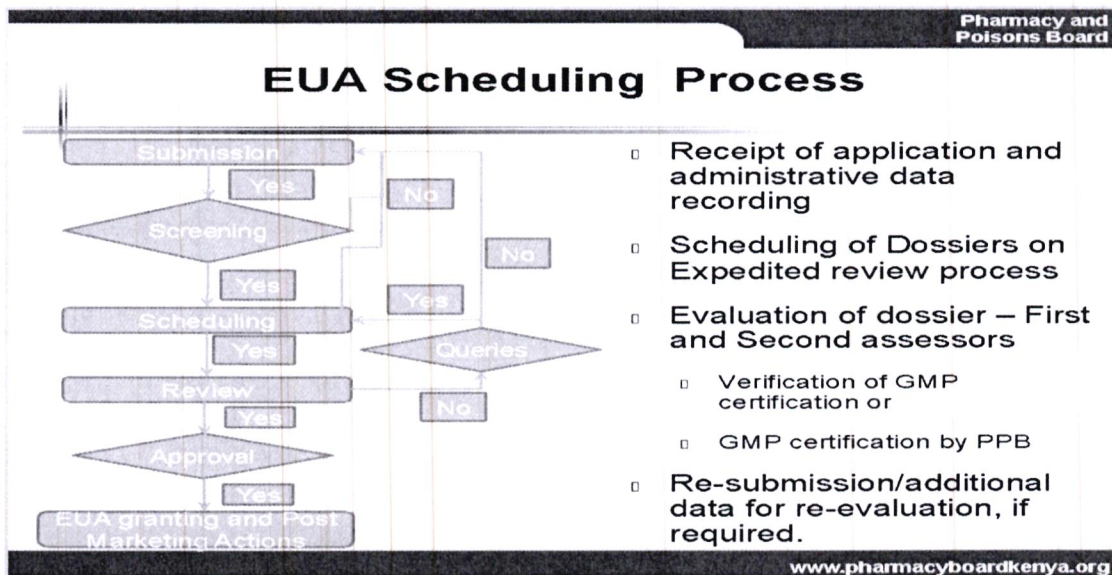
- 2.2 The Board implements several types of registrations/authorizations for medical products and health technologies including full Market Authorizations (MAs), Conditional marketing authorization, Listing and Emergency use Authorizations (EUAs).
- 2.3 In the wake of the COVID-19 pandemic, the Board streamlined its processes to facilitate expedited access and availability of medical products and technologies. This 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. The guidelines provide for the procedure for EUA and are accessible on our website via <https://pharmacyboardkenya.org/covid19-material>.
- 2.4 The COVID-19 Vaccines are thus evaluated in Kenya under the guidelines on ECUA as has been the case worldwide taking into consideration available data on quality, safety and efficacy. The detailed process is as below:

#### **EMERGENCY USE AUTHORIZATION APPLICATION PROCESS**

- 2.5 Vaccine manufacturers through their local technical representatives (LTRs) submit electronic application for Emergency use Authorization or Registration to the Board.
- 2.6 The applicant through the LTR logs into the PPB prims system and submits a Common Technical Document (CTD dossier) in the portal (all the 5 modules must be filled in). Additionally, it is mandatory for the applicant to remit fees as follows: - USD 1000 for EUA application and USD 4000 for GMP certification per Finished Pharmaceutical Product site. This is in line with the fees stipulated under the Act
- 2.7 The applicant has in addition to fill in the section EUA application to ensure that the application queues under “the expedited review process”, Otherwise the application would queue under “the FIFO process”.
- 2.8 Samples should be submitted for review (this is optional for EUA issuance). However, sample submission before vaccine deployment is a condition to be attached to the granted EUA.

2.9 Evaluation and possible approval by the board is to be done within 30 calendar days for NON-SRA approved COVID-19 vaccines while SRA<sup>1</sup> approved vaccines are being expedited for approval within 7 working days.

Please see below a graphical representation of the process flow for EUA applications:-



### **COVID-19 EUA REQUIREMENTS**

2.10 EUA requires less comprehensive data (particularly, clinical data) and is subject to certain obligations. Standards for quality, safety and efficacy are maintained aligned to full marketing authorization (MAs) requirements; only flexibilities are introduced during public health emergencies.

2.11 The applicant is expected to submit the current clinical trials data available, state vigilance issues observed, regulatory processes followed by SRAs to determine acceptability of submitted data.

2.12 The Board may implement Vaccine lot summary protocol review to reduce redundant testing at the time of importation, if deemed critical.

### **3. State whether the Pharmacy and Poisons Board has issued any Commercial Medicines Import Permits to private entities for the**

<sup>1</sup> Currently, the key stringent Regulatory Authorities (SRAs) i.e., EMA, US FDA, Health Canada, Japan and WHO are involved in joint review of COVID-19 vaccines through the platform of “EMA open initiative”

**importation and distribution of any other COVID-19 vaccine other than the Government approved Astrazeneca vaccine;**

The Pharmacy and Poisons Board 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.

**4. If so, identify the private entities that have received approval for the importation and distribution of the vaccines referred to under question (3)**

The authorized importer of the Vaccine is DINLAS Pharma EPZ Ltd, as the local technical representative of the Emergency Use Authorization holder.

As the authorized importer, the company (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.

**5. Where applicable, state what processes and/or procedures the Pharmacy and Poisons Board followed in authorising the importation of any COVID-19 vaccines for private distribution**

The Pharmacy and Poisons Board 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. This document is available on the PPB website via: <https://pharmacyboardkenya.org/covid19-material>.

A summary of the requirements followed in granting import authorization for the vaccine is as below:

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;

**6. Provide details regarding any applications for the importation and distribution of COVID-19 vaccines by private entities that may be awaiting registration/authorisation by the Poisons and Pharmacy Board**

As at 28th March 2021, the Pharmacy and Poisons Board is in receipt of 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 is Simba Pharmaceuticals Ltd.

Prepared By:

Dr. F. M. Siyoi

**CHIEF EXECUTIVE OFFICER**

## RESPONSE TO SENATE

Ref. SEN/DCO/CORR/SCH/02/007/2021 (1)

RE: ALLEGED EMERGENCY AUTHORIZATION FOR THE IMPORTATION AND DISTRIBUTION OF THE RUSSIAN-MANUFACTURED SPUTNIK COVID-19 VACCINE IN KENYA

29/03/2021

HARLEY'S LIMITED AND UNISEL PHARMA (K) LTD

1. Provide copies of your CR-12 certification from the Registrar of Companies;

**Find attached a copy of the CR-12 from the Registrar of companies**

2. State whether the Russian-manufactured Sputnik COVID-19 vaccine has been approved for use by the World Health Organization;

**Sputnik is one of the world's top three coronavirus vaccines in terms of the number of approvals issued by government regulators.**

**Sputnik COVID-19 vaccine has been approved for use in 56 Countries so far including Russia,Belarus,Argentina,Bolivia,Serbia,Algeria,Palestine,Venezuela,Paraguay,Turkmenistan,Hungary,UAE ,Iran,Republic of Guinea,Tunisia,Armenia,Mexico,Nicaragua,Republika Srpska (entity of Bosnia and Herzegovina),Lebanon,Myanmar,Pakistan,Mongolia,Bahrain,Montenegro,Saint Vincent and the Grenadines,Kazakhstan,Uzbekistan,Gabon,SanMarino,Ghana,Syria,Kyrgyzstan,Guyana,Egypt,Honduras,Guatemala,Moldova,Slovakia,Angola,Republic of the Congo,Djibouti,Sri Lanka,Laos,Iraq,North Macedonia,Kenya,Morocco,Jordan,Namibia,Azerbaijan,Philippines,Cameroon,Seychelles,Mauritius and Vietnam.**

**Sputnik COVID-19 vaccine has been approved for Emergency use by the Pharmacy and Poisons Board of Kenya in line with its mandate as the regulatory authority , and as outlined in the Pharmacy and Poisons ( Registration of Drugs ) Rules.**

3. State whether your company has received authorization from the Pharmacy and Poisons Board to distribute the Russian-manufactured Sputnik COVID19 vaccine for use and distribution in Kenya;

**Yes we have .Find attached the Authorization UCR Number : UCR202102594997 issued by the Pharmacy and Poisons Board as the mandated regulatory Authority**

4. Provide copies of all the regulatory permits and approvals your company has received so far for the distribution of COVID-19 vaccines in Kenya;

**Find attached the relevant regulatory permits and approvals received. These permits and approvals have been issued by the Pharmacy and Poisons Board as mandated in the Pharmacy and Poisons Act, CAP 244.**

5. Provide comprehensive details of any COVID-19 vaccine-related consignments that your company has received for distribution into Kenya, including details of the dates, volumes, cost, etc.;

**No, we have not received any consignment from the importer for distribution into Kenya.**

6. Where applicable, provide details of the price/cost at which your company is distributing any COVID-19 vaccine in Kenya; and

**No, we are not as yet distributing the vaccine . In addition, we will only be able to determine the price/cost once we receive the final pricing details from the importer to enable us determine the final price/cost at which we shall distribute the vaccine to the end user.**

7. Where applicable, provide details of the hospitals and/or health facilities to which you have distributed any COVID-19 vaccine in Kenya, including details of the dates, consignment, value, cost etc.

**- We have not distributed any Covid-19 vaccine to any hospital and/or Health Facilities.**

Date: 10<sup>th</sup> March, 2021  
Ref. No: DPL/KEN/HAR/01

**LETTER OF AUTHORIZATION**

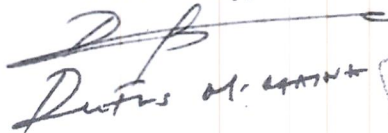
To whomsoever it may concern

**Dinlas Pharma EPZ Limited**, have been granted Emergency Use Authorization (EUA) by the Pharmacy and Poisons Board of the Republic of Kenya, for the drug Gam-COVID-Vac Combined Vector vaccine for the prevention of coronavirus infection caused by the SARS CoV-2 virus. The EUA reference number is **H2021/CTD8457/19767EUA**

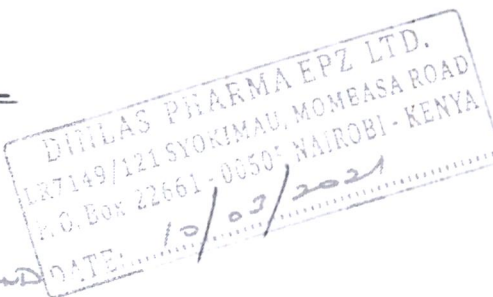
We, **Dinlas Pharma EPZ Limited**, an entity registered in Kenya having its business address at Plot No LR7149/121, Mombasa Road Syokimua, PO BOX 2261—0050, Nairobi Kenya, hereby appoints **Harley's Limited** an entity registered in Kenya having its business address at 63 Westlands Road, Nairobi Kenya and **Unisel Pharma (K) Limited**, an entity registered in Kenya having its business address at Apricot Suites, Nairobi Kenya for distribution of the product Gam-COVID-Vac combined vector vaccine to prevent coronavirus infection caused by SARS-CoV-2 virus ("Gam-COVID-Vac") in Kenya.

Harleys's Limited and Unisel Pharma (K) Limited will be the sole distributors of GamCOVID-Vac in Kenya. Gam-COVID-Vac has been developed by the Gamaleya National Center of Epidemiology and Microbiology of Ministry of Health of Russia ("Gamaleya Center"), 18 Gamalei Street, 123098, Moscow.

Your sincerely,



DIRECTOR - STRATEGIC  
INITIATIVES AND  
LEGAL





BUSINESS REGISTRATION SERVICE  
P. O. BOX 30031  
NAIROBI  
5 JAN 2021

To  
UNISEL PHARMA LIMITED  
P. O. Box 42818  
00100 - G. P. O. NAIROBI

### THE COMPANIES ACT, 2015

Records relating to the below company held by the Companies Registry as at 5 Jan 2021

COMPANY	UNISEL PHARMA LIMITED
COMPANY NUMBER	C 108617
NOMINAL SHARE CAPITAL	100,000.00
NUMBER AND TYPE OF SHARES (VALUE PER SHARE)	ORDINARY: 1000 (KES 100.00 EACH)
DATE OF REGISTRATION	17TH AUG, 2016
REGISTERED OFFICE	P.O BOX 42718 G.P.O NAIROBI TELEPHONE: +254724501401, EMAIL: RUPEN@HARLEYSLTD.COM COUNTY: , DISTRICT: , LOCALITY: STREET: WESTLANDS ROAD, BUILDING: HARLEY'S BUILDING
POSTAL ADDRESS	P.O BOX 42718 G.P.O NAIROBI
ENCUMBRANCES	

Name of Directors and Shareholders of the above company with their particulars are as follows

NAME	DESCRIPTION	ADDRESS	NATIONALITY	SHARES
RUPEN MULCHAND HARIA	DIRECTOR/SHAREHOLDER	P.O BOX 42718 G.P.O NAIROBI	KENYA	ORDINARY: 422
JOSEPH QNA KAMAU	SECRETARY	P.O BOX 42718 G.P.O NAIROBI	KENYA	
ASVIN KUMAR RAISHI HARIA	SHAREHOLDER	P.O BOX 42718 G.P.O NAIROBI	KENYA	ORDINARY: 333
PHADKE SUDHIR SHARAD	DIRECTOR/SHAREHOLDER	P.O BOX 42718 G.P.O NAIROBI	KENYA	ORDINARY: 245
NISHIL ASVIN KUMAR P'ARIA	DIRECTOR	P.O BOX 42718 G.P.O NAIROBI	UNITED KINGDOM	
TOTAL				1000

Yours Faithfully,  
REGISTRAR OF COMPANIES



REF NO: OS-ZDFLYDQ5

DISCLAIMER: THIS IS A SYSTEM GENERATED CERTIFICATE AND DOES NOT REQUIRE A SIGNATURE



REPUBLIC OF KENYA

THE PHARMACY AND POISONS ACT

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

**EMERGENCY USE AUTHORIZATION (EUA) CERTIFICATE**

**EUA Number: H2021/CTD8457/19767EUA**

It is hereby certified that the drug as described hereunder, has been issued emergency use authorization subject to the conditions indicated hereunder:	
<b>Trade name</b>	Gam-Covid-Vaccine (Sputnik V Vaccine)
<b>Approved name</b>	Combined vector vaccine for the prevention of corona virus infection caused by SARs-Cov-2 virus, solution for intramuscular administration; component I: 0.5ml/dose + component II: 0.5ml/dose
<b>Form of preparation (Dosage form)</b>	Solution for Intramuscular Injection
<b>Active ingredients and quantities per unit</b>	Solution for intramuscular injection; component I: 0.5ml/dose + component II: 0.5ml/dose
<b>Condition(s) under which is registered</b>	For Emergency Use Only. Please Refer to Annexure 1 for conditions.
<b>Name and business address of manufacturer (API &amp; FPP)</b>	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).  Russia, 123098, Moscow, Gamalei Street, 18. Tel.: 8 499-193-30-01, Fax: 8 499-193-61-83.
<b>Registered in the name of (EUAH)</b>	Dinlas Pharma EPZ Limited, P.O. Box 22661-00505, Nairobi.
<b>Local Technical Representative (LTR)</b>	Dinlas Pharma EPZ Limited P.O Box 22661-00505, Nairobi.
<b>Date of EUA</b>	9 <sup>th</sup> March, 2021
<b>Date of Issue</b>	9 <sup>th</sup> March, 2021
<b>Expiry date of EUA</b>	The EUA will be effective until declaration of end of covid-19 pandemic by the Government or revocation of the certificate

**Kindly note that this does not constitute a Marketing Authorization (Registration)**

Signed: 

**Dr. Ahmed Mohamed**

**Director, Health Products and Technologies**



### Conditions of Authorization

1. You are required as part of ongoing improvement on product safety that Vaccine Vial Monitor (VVM) be included in future commercial batches.
2. Please ensure that copies of technical agreement between Dinlas Pharma EPZ Ltd and 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) are submitted to Product Evaluation and Registration Department, Pharmacy and Poisons Board (PPB) within one month from date of issue
3. Please ensure that appropriate data on vaccine drug substance (biological substance) and finished product (sputnik V vaccine) is submitted to the Pharmacy and Poisons Board, Product Evaluation and Registration Department within one month from date of issue of the EAU to facilitate completion of the evaluation process.
4. Please ensure that updated stability data for at least three batches is submitted whenever available. Additionally, please note that any out of specifications is to be reported immediately to the Pharmacy and Poisons Board.
5. Please ensure that updated data on toxicity studies is submitted to the Pharmacy and Poisons Board, Product Evaluation and Registration Department within thirty days from date of issue of the EUA.
6. Submit the available Drug Safety Update Reports (DSUR) for evaluation
7. The Emergency Use Authorization Holder (EUAH) shall submit a monthly line list of all AEFIs and AESIs to [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org)
8. The marketing authorization holder shall submit Periodic safety Update Reports (PSURs) within the timelines as prescribed in the Guidelines on the Safety and Vigilance of Medical Products and Health Technologies 2019. The first Periodic Safety Update Reports (PSUR) of this product shall be submitted within 6months following the Emergency Use Authorization (EUA) by PPB.
9. Submit a commitment letter to assure that the EUAH agrees to conduct post authorisation studies in these patient populations; subjects with severe immunodeficiency, those subjects with severe and/or uncontrolled underlying disease and those using other vaccines as this data is not available. Provide the protocols for proactive data collection referred.
10. The EUAH shall submit an updated RMP at the request of the PPB, whenever the risk management system is modified, as the result of new information being received that may lead to a significant change to the risk-benefit balance or as a result of an important pharmacovigilance or risk minimization milestone being reached. (refer to the Guidelines on the Safety and Vigilance of Medical Products and Health Technologies 2019)
11. The EUAH shall also submit all the final Clinical study reports on the additional pharmacovigilance activities required in a timely manner to PPB.
12. The EUAH shall report on all adverse event in accordance to the timelines as prescribed in the Guidelines on the Safety and Vigilance of Medical Products and Health Technologies 2019. The reports shall be sent in E2b format via email at [pv@pharmacyboardkenya.org](mailto:pv@pharmacyboardkenya.org)
13. The EUAH shall maintain a comprehensive pharmacovigilance system for the product. It should be continuously accessible to the appointed QPPV and to PPB on request.
14. The EUAH shall provide details of the ongoing or planned studies in Kenya and globally in the post-authorization development plan. The protocols of the studies shall be submitted to PPB once they are available.

**Conditions Related to Advertising and Promotion**

Please note that all descriptive printed matter, including advertising promotional material relating to the use of GAM-COVID-VACCINE (SPUTNIK V VACCINE) shall be consistent with the authorized labeling as well as terms applicable as per the Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies, Guidelines for Advertisement and Promotions of Medicines and Medical Devices in Kenya and the Pharmacy and Poisons Act (CAP 244).

Pharmacy and Poisons Board Head Office, Lenana Road  
Po Box 27663-00506 Nairobi, Kenya



Serial No: **03190309cbcd7161a426abd4782bdcd2**

Date: March, 9<sup>th</sup> 2021

Emergency Use Authorization - **H2021/CTD8457/19767EUA**



MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT  
(Cap.244, Sub. Leg.)  
(The Pharmacy and Poisons Rules)

**2021 ANNUAL PRACTICE LICENCE FOR PHARMACIST**

**Name: Dr. RUPEN MULCHAND**

**Premise: HARLEYS LTD-NAIROBI**

**ID No: 11498835**

**Plot No.**

**Registration No: 1426**

**P.O. BOX 42718-00100, NAIROBI**

**Town: NAIROBI**

**The above named person is hereby licensed to practise as a Pharmacist in accordance with the Pharmacy and Poisons Act.**

**This Licence is valid upto 2021-12-31, subject to compliance of the provisions of the Act.**

**Fee: KShs. 5000**

**Licence No. P2021D00084**





MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT  
(Cap.244, Sub. Leg.)  
(The Pharmacy and Poisons Rules)

## CERTIFICATE FOR REGISTRATION OF PREMISES

Messrs. **HARLEYS LTD-NAIROBI** .....

of **P.O. BOX 42718-00100, NAIROBI** .....

Plot No. **Plot No.** ..... is registered to carry on  
business of a pharmacist as provided for by section 23.

Registered No. of premises **PPB/H/48** .....

**23-11-2020**  
.....

*Date*

**2021**

Note. (i) This Registration expires on 3<sup>rd</sup> December .....

(ii) No change of premises is permitted without authority of the board.

(iii) This registration shall become void upon expiration of 30 days from any change of ownership of the business.

**Fee: KShs. 10000**

**Licence No. BU202100241**



SR No. 016749/20

FORM 7



MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT  
(Cap.244, Sub. Leg.)  
(The Pharmacy and Poisons Rules)

## WHOLESALE DEALER'S LICENCE

Messrs. **HARLEYS LTD-NAIROBI** ..... of **P.O. BOX 42718-00100, NAIROBI** .....  
carrying on business at **NAIROBI** ....., are hereby authorized to  
sell poisons by way of wholesale dealing.

**23-11-2020**  
.....

*Date*

Note. (i) This licence expires on 31<sup>st</sup> day of December **2021** .....

Fee: KShs. 30000

Licence No. BU202100241





**REPUBLIC OF KENYA  
PHARMACY AND POISONS BOARD**

**Commercial Medicines Import Permit**

Document	321C - Commercial Medicines Import Permit
Document Type	PER - Permits
Process	321C01 - Commercial permit process
Application Reference No : CD2021000PPB321C0002589403	Version No : 1
Master Approval No	Master Approval Version No
UCR Number	UCR202102594997

**Application Status**

Approval Status :AP - Approved	Used Status :	Application Date :20210317160643
Expiry Date :20220319	Amended Date :	Used Date :
Issuance Date :20210326		

**Applicant Details**

Name :HARLEYS LIMITED	Application Code :HLM
PIN :P000626483G	Country :KENYA
Address :42718	Email : imports@harleysltd.com
Contact Person :MukhobiElmius	

**Consignee Details**

Name :Harleys Ltd	OGA Ref No :
PIN :P000626483G	Physical Country :KENYA
Physical Address :42718 - 00100 Westlands Road Nairobi KE	Postal Country :KENYA
Postal Address :42718 - 00100 Westlands Road Nairobi KE	Fax :
Telephone :4261000	Sector of Activity :
Email :imports@harleysltd.com	Warehouse Location :
Warehouse Code :	

**Importer Details**

Name :Harleys Ltd	OGA Ref No :
PIN :P000626483G	Physical Country :KENYA
Physical Address :42718 - 00100 Westlands Road Nairobi KE	Postal Country :KENYA
Postal Address :42718 - 00100 Westlands Road Nairobi KE	Fax :
Telephone :4261000	Sector of Activity :
Email :imports@harleysltd.com	Warehouse Location :
Warehouse Code :	

### Exporter Details

Name :DINLAS PHARMA EPZ LIMITED

PIN :P000000000N

Physical Address :PLOT NO. LR7149/121 MOMBASA ROAD  
SYOKIMAU NAIROBI KENYA

Postal Address :PLOT NO. LR7149/121 MOMBASA ROAD  
SYOKIMAU NAIROBI KENYA

Telephone :0780100035

Email :info@dinlaspharma.com

Warehouse Code :Air Connection Ltd

OGA Ref No :

Physical Country :KENYA

Postal Country :KENYA

Fax :0780100035

Sector of Activity :Trade

Warehouse Location :JKIA

### Consignor Details

Name :DINLAS PHARMA EPZ LIMITED

PIN :P000000000N

Physical Address :PLOT NO. LR7149/121 MOMBASA ROAD  
SYOKIMAU NAIROBI KENYA

Postal Address :PLOT NO. LR7149/121 MOMBASA ROAD  
SYOKIMAU NAIROBI KENYA

Telephone :0780100035

Email :info@dinlaspharma.com

Warehouse Code :Air Connection Ltd

OGA Ref No :

Physical Country :KENYA

Postal Country :KENYA

Fax :0780100035

Sector of Activity :Trade

Warehouse Location :JKIA

### Values - Header Level

Foreign Currency Code :USD

Freight FCY :0.00

CIF FCY :3,825,000.00

Insurance NCY :0.00

Forex Rate :109.75

Insurance FCY :0.00

FOB NCY :419,789,160.00

Other Charges NCY :0.00

FOB FCY :3,825,000.00

Other Charges FCY :0.00

Freight NCY :0.00

CIF NCY :419,789,160.00

### Remarks

OGA Remarks :

1. Ok
2. ok
3. Provide technical agreement between yourself and Dinlas
4. ok

### Conditions Of Approval

1. Ok

### Purpose Of Import/Export

Trading

### Terms and Conditions

1. Wholesale dealer's License
2. Proforma Invoice/Invoice
3. Current product Retention

### Master Document/GMP Reference Number:Version Number

**Item Details****Item No :1**Item Description :Sputnik  
Vaccine Component I

Item HS Code :3002200000

Quantity :50000

Package Quantity :50000

Unit Price NCY :5,597.19

Item Gross Weight :1000 Net  
KilogramHS Description :Vaccines for  
human medicine

Unit Of Quantity :Net Kilogram

Foreign Currency Code :USD

Total Price NCY :279,859,440.00

Applicant Remarks :OK

Supplementary - Quantity :0

Unit Price FCY :51.00

Country Of Origin :RUSSIAN  
FEDERATION

Package Type :Box

Total Price FCY :2,550,000.00

Item Net Weight :1000 Net  
Kilogram**Item Details****Item No :2**Item Description :Sputnik  
Vaccine Component II

Item HS Code :3002200000

Quantity :25000

Package Quantity :25000

Unit Price NCY :5,597.19

Item Gross Weight :1000 Net  
KilogramHS Description :Vaccines for  
human medicine

Unit Of Quantity :Net Kilogram

Foreign Currency Code :USD

Total Price NCY :139,929,720.00

Applicant Remarks :OK

Supplementary - Quantity :0

Unit Price FCY :51.00

Country Of Origin :RUSSIAN  
FEDERATION

Package Type :Box

Total Price FCY :1,275,000.00

Item Net Weight :1000 Net  
Kilogram**Transport Details**

Mode Of Transport :R

Port Of Arrival :Jomo Kenyatta International Airport

Freight Station :JOMO KENYATTA INTERNATIONAL AIRPORT

Mode Of Transport Desc :Road

Customs Office :JKA

Cargo Type Indicator :General Cargo



**Kenya Healthcare**  
Federation

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*Your partner in transforming healthcare*

**Senate Meeting**

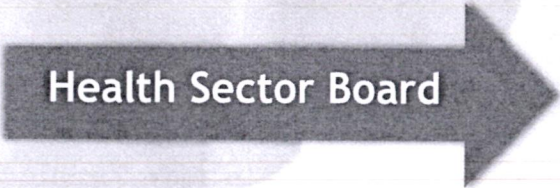
April 19<sup>TH</sup> , 2020 @9AM



## Content

- Introduction to Kenya Healthcare Federation
- Covid19 situation update
- Vaccination Roll out
- Oxygen Supply and ICU/BED Capacity in Private sector

KHF is the Health Sector Board of the Kenya Private Sector Alliance (KEPSA)





REPUBLIC OF KENYA



MINISTRY OF HEALTH

KHF directly works with the Ministry of Health through Ministerial Stakeholder Forums (MSFs), with 13 held so far, and the next to be held before EoY. These MSFs provide insights for the Presidential Roundtable (PRT)

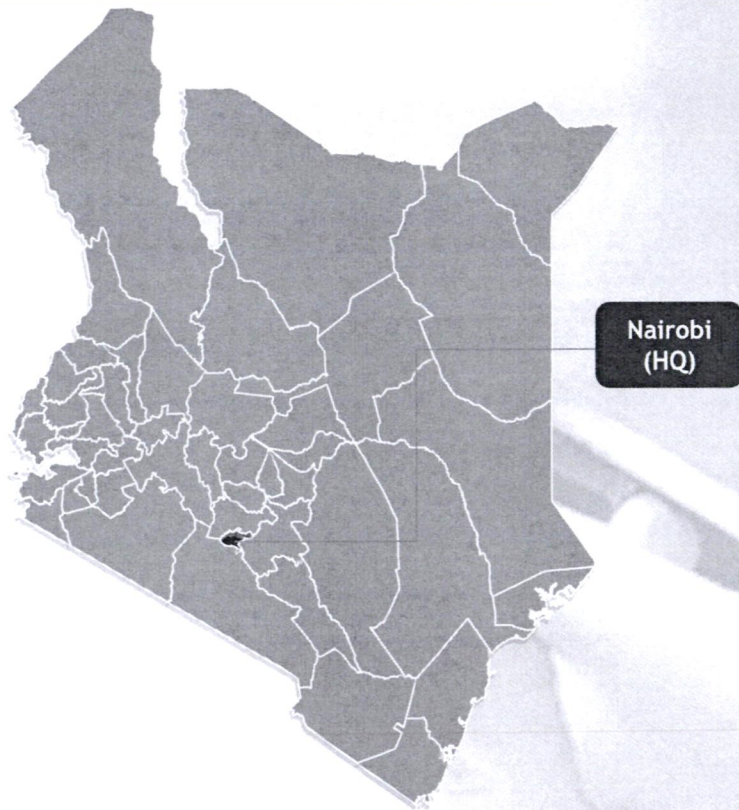


Top: Cabinet Secretary and KHF Leadership Team on August 2019  
Right: CS Mutahi Kagwe accompanied by KHF chairman gives update on Covid-19 situation in Kenya



# Our membership draws from all healthcare sub-sectors, countrywide...

KHF is headquartered in Nairobi, and draws its membership from all 47 counties



## Membership

**180+**  
Total members



**150+**  
Health Organizations\*



**20+**  
Professional Associations



**8+**  
Institutional Associations

## Composition

**180+**  
Total members



Healthcare Financing



Governance Advisory Bodies



Health Technology



Health Service Delivery



Supply Chain



Human Resources for Health

...with leadership provided by an experienced Board of Directors, serving a 3-year term each, and a competent management team

Board of Directors



Dr. Amit Thakker - Chair  
Executive Chairman, Africa  
Healthcare Business



Dr. Elizabeth Wala - Vice Chair  
Programme Director, Health  
Systems Strengthening - Amref



Dr. Walter Obita  
Chief Operations Officer,  
Healthstore East Africa



Dr. Joyce Wanderi  
Chief Executive Officer,  
PS Kenya



Dr. Francis Karanja  
Regulatory Affairs Cluster  
Head for Africa, GSK



Dr. Daniella Munene  
Chief Executive Officer,  
Pharmaceutical Society of Kenya



Dr. Jacqueline Kitulu  
Board Member, Kenya Medical  
Practitioners and Dentists Council



Dr. Faith Muigai  
Regional Director, Safe Care  
Program - PharmAccess Foundation



Dr. Steve Maina  
Managing Director and Principle Officer,  
AfroCentric Health Solutions Limited



Antony Jaccodul  
Founder and C.E.O Keton  
Consulting

Management



Dr. Anastasia Nyalita  
Chief Executive Officer,  
Kenya Healthcare Federation



Leah Odundo  
Administrator and Projects Manager,  
Kenya Healthcare Federation





## Content

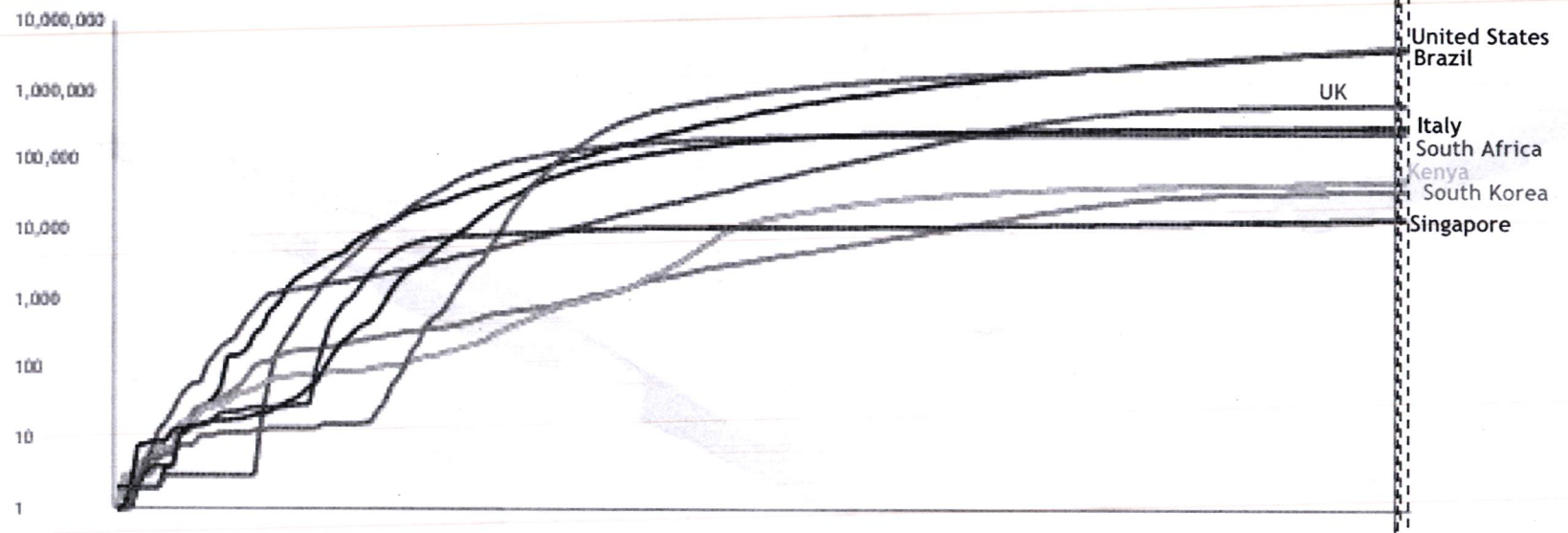
- Introduction to Kenya Healthcare Federation
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# Total confirmed cases in Kenya vs. other countries (log scale)

Data as of 18<sup>th</sup> Apr  
Kenya 19<sup>th</sup> Apr

Top Affected counties worldwide	
USA	32,413,433
India	15,269,626
Brazil	13,943,071
France	5,289,526
Russia	4,710,690
UK	4,390,783

Number of confirmed cases



Day 399 KE 151,894    Day 407 SA: 1.57M    **Day 415 BR: 13.9M**    Day 441 UK: 4.39M    Day 449 IT: 3.87M    Day 450 US: 31.7M    S.K 115k



Source: Johns Hopkins, Github; Kenya more real time from GoK press release, news sources

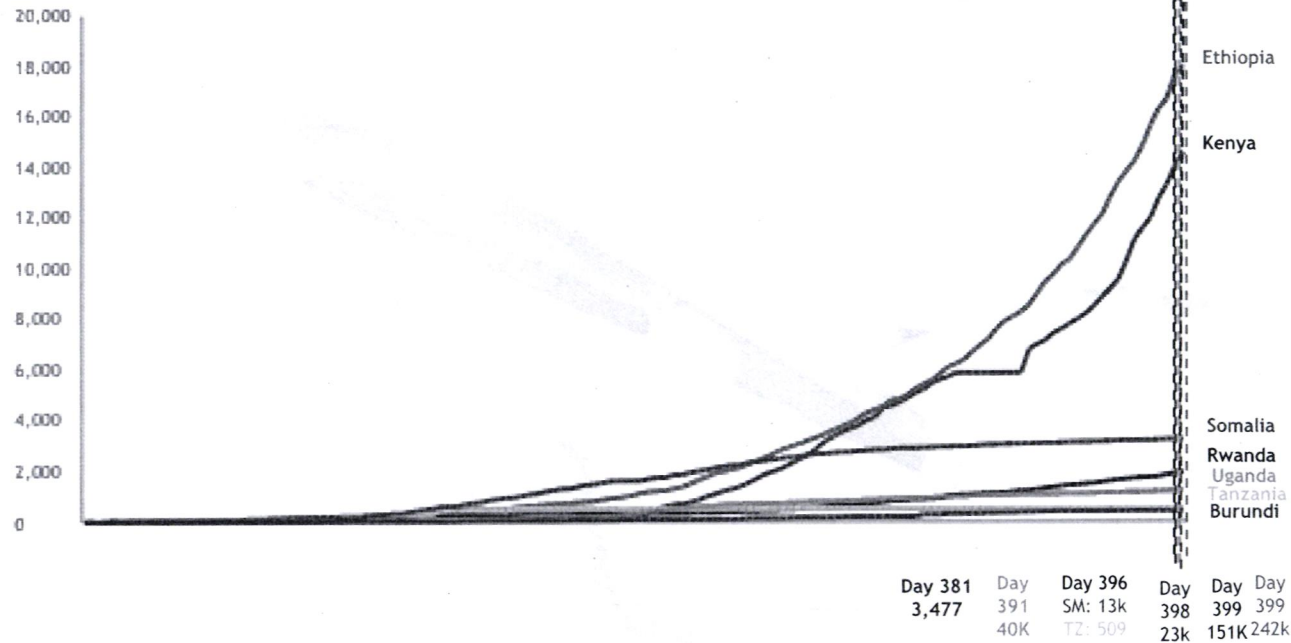


# Cases and testing in East African countries (log scale)

Data as of 18<sup>th</sup> Apr  
Kenya 19<sup>th</sup> Apr

Data as of 18<sup>th</sup> Apr

Number of confirmed cases



	Cases/ M pop	Tests/ M pop	Cum tests	% Pos
South Africa	26,155	172,565	10,337,066	15%
Ghana	2,903	33,149	1,047,048	9%
Morocco	13,580	165,523	6,167,072	8%
Senegal	2,330	27,224	465,317	9%
Kenya	2,776	29,353	1,605,847	9%
Ethiopia	2,065	21,342	2,501,570	10%
Nigeria	781	8,746	1,838,174	9%
South Sudan	927	12,708	143,571	7%
Somalia	805	6,427	104,392	13%
Rwanda	1,809	95,178	1,256,919	2%
Burundi	286	7,397	90,019	4%
Uganda	883	21,050	986,829	4%
Tanzania	8	0	0	0%

Top Cases per 1M population	
Andorra	92,177
Montenegro	63,058
Luxembourg	61,649
French Polynesia	54,442
San Marino	54,002



Source: Johns Hopkins, Github; Kenya more real time from GoK press release



# Total confirmed deaths in Kenya vs. other countries (log scale)

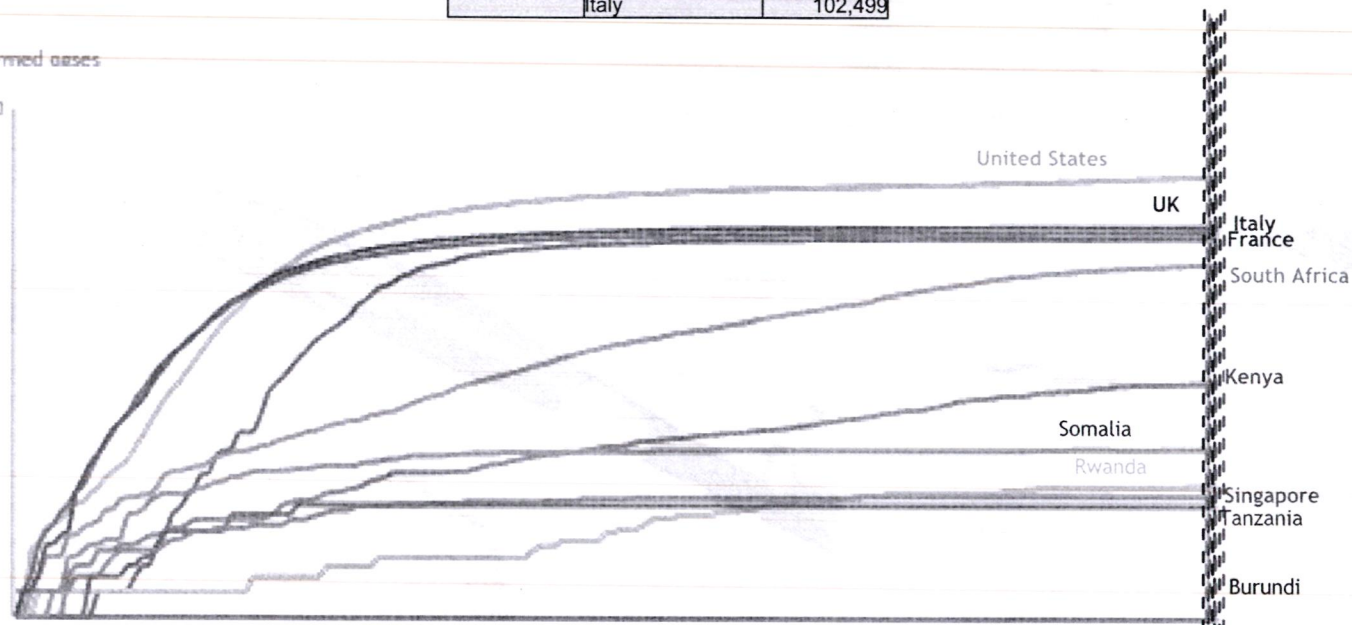
Data as of 18<sup>th</sup> Apr  
Kenya 19<sup>th</sup> Apr

Equivalent deaths at Kenya's stage in other countries		
Day	Kenya	389
Deaths	US	544,268
	Singapore	30
	France	88,811
	Italy	102,499

Data as of 18<sup>th</sup> Apr

Number of confirmed cases

1,000,000  
100,000  
10,000  
1,000  
100  
10  
1



Country	CFR
Italy	3.02%
UK	2.90%
Tanzania	4.13%
USA	1.79%
Somalia	5.12%
Senegal	2.74%
South Africa	3.43%
Nigeria	1.25%
S. Korea	1.57%
South Sudan	1.09%
Ethiopia	1.39%
Kenya	1.65%
Morocco	1.77%
Uganda	0.82%
Ghana	0.84%
Rwanda	1.36%
Botswana	1.52%
Singapore	0.05%

Day 409  
127K  
Rw:Day 324 Bur: Day 371 SomD ay 376 TZ: S.A Day Day Day 409  
Day 325 6 670 384 388 389 30 415 100K 116K  
21 58K 2,481 567K



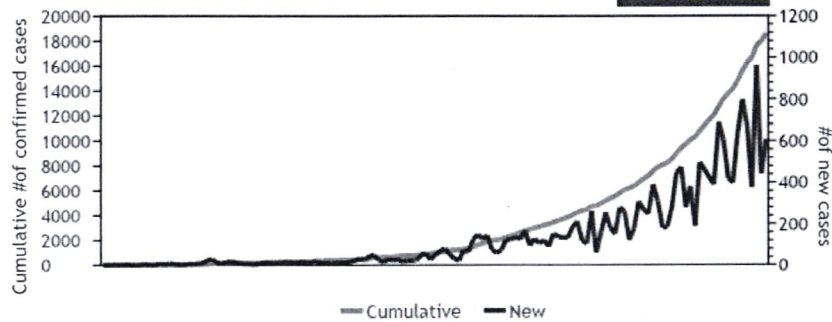
Source: Johns Hopkins, Github; Kenya more real time from GoK press release, news sources



# Cases by geography and testing data for Kenya

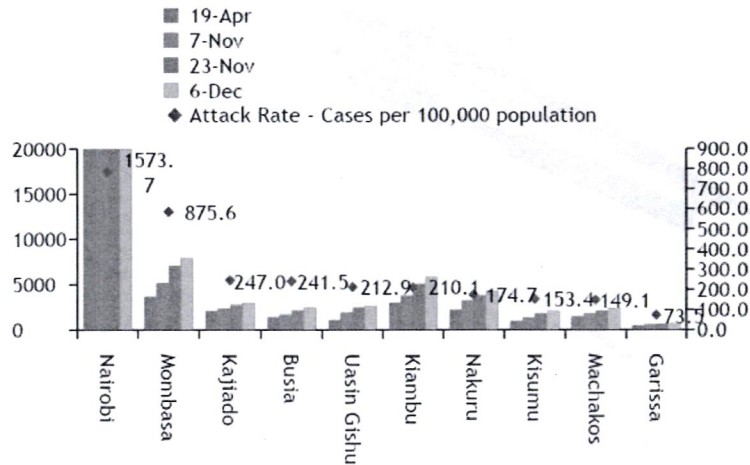
Data as of 18<sup>th</sup> Apr  
Kenya 19<sup>th</sup> Apr

151,894

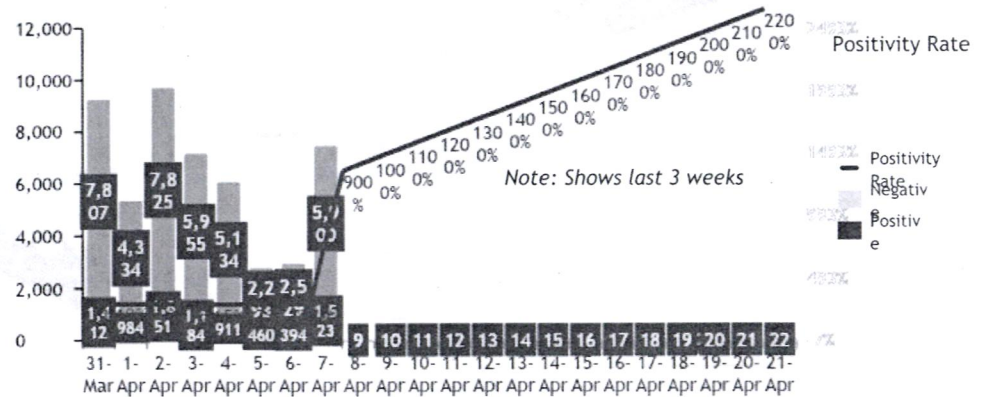


Metric	Cumulative	New	Comments
# confirmed cases	151,894	+241	As of 19 April
# confirmed deaths	2,501	+20	As of 19 April
# recovered	102,278	+636	As of 19 April
# tests completed*	1,605,847	+2515	As of 19 April

\*Lag time between test performed vs. analysed; completed should refer to performed and analysed



## Total tests and positivity rate



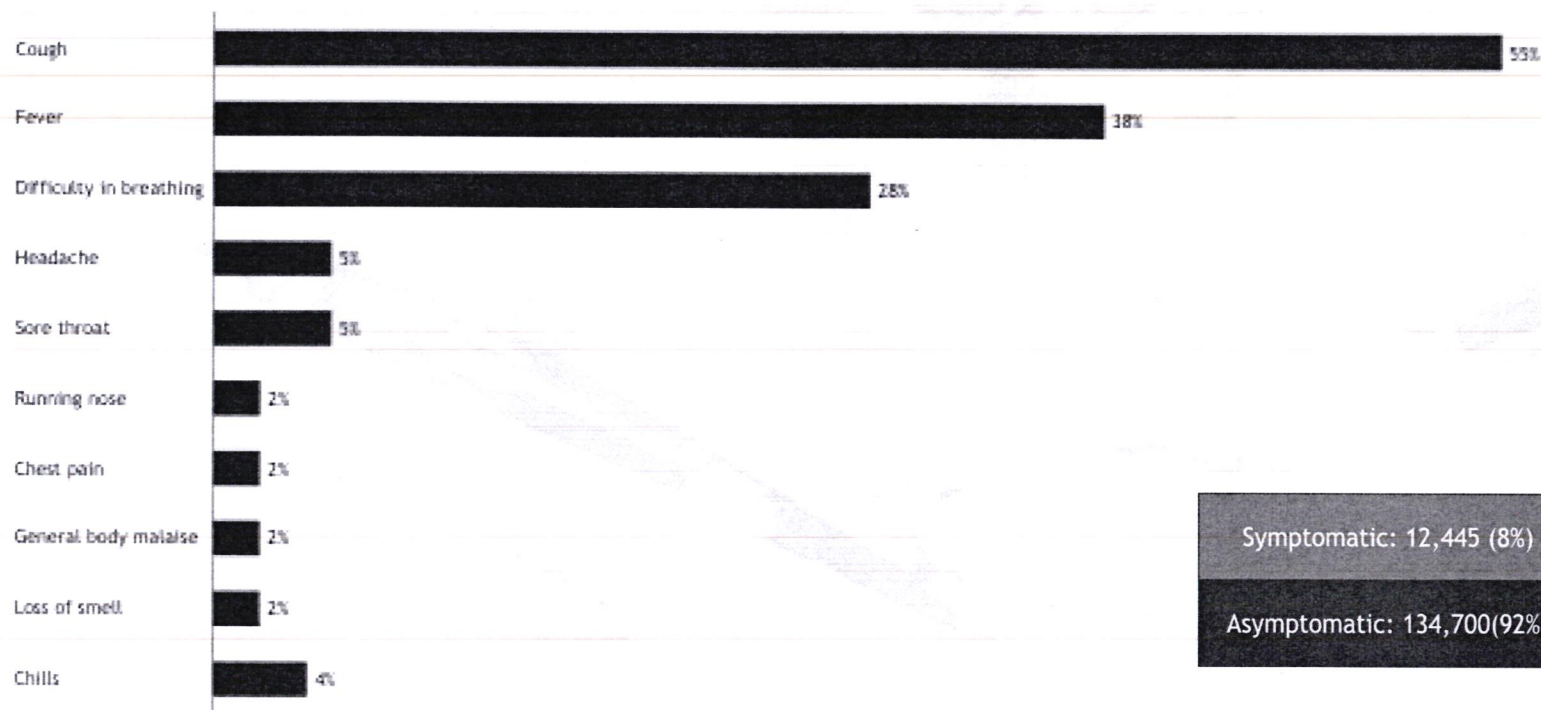
Source: Johns Hopkins, Github, GoK / NERC / MOH press releases



# Distribution of presenting symptoms among symptomatic COVID-19 Cases

Data as of 18<sup>th</sup> Apr

Presenting symptoms

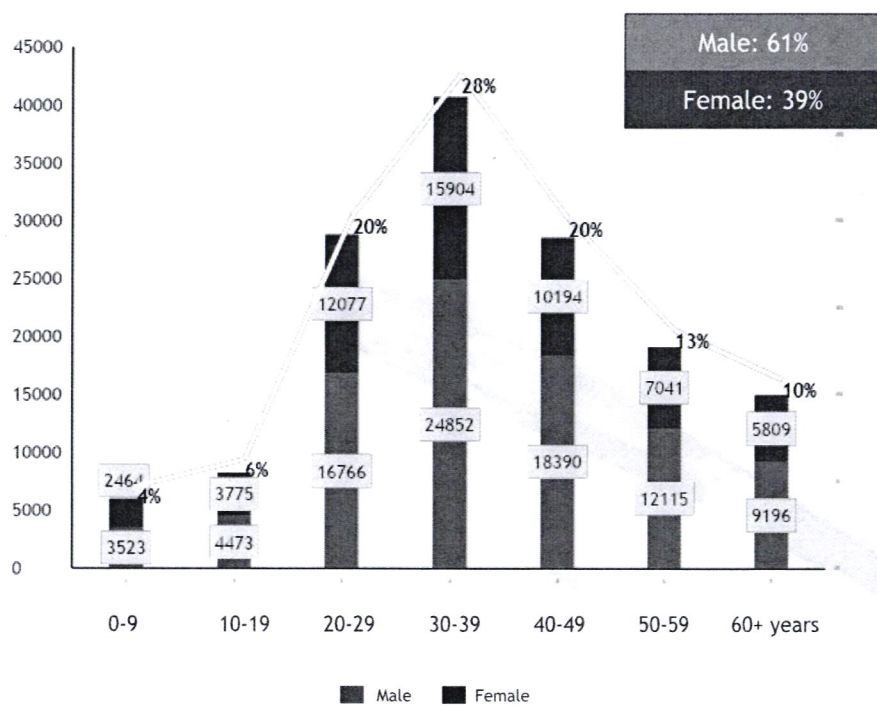


Symptomatic: 12,445 (8%)  
Asymptomatic: 134,700 (92%)

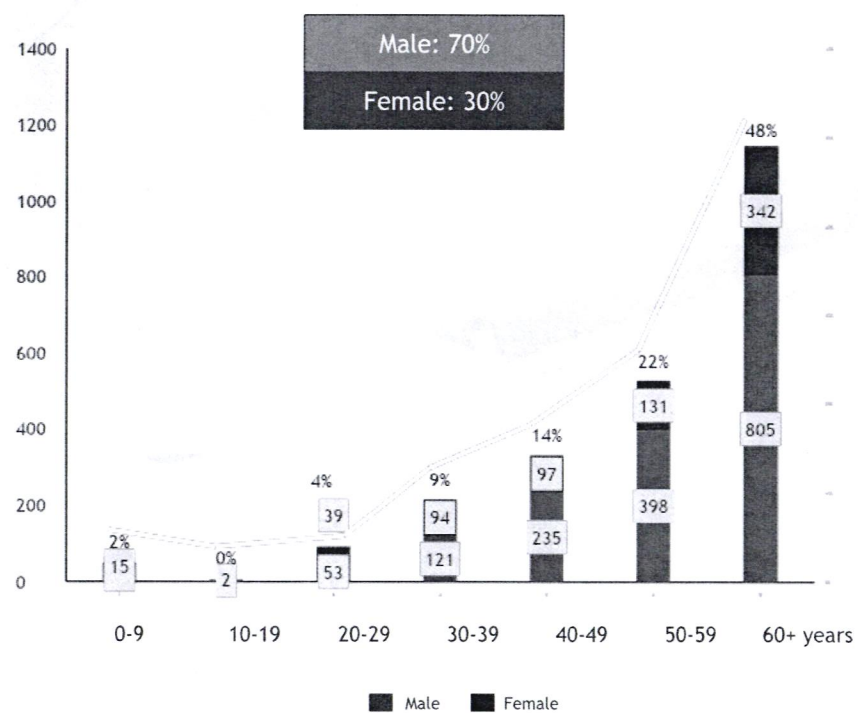
# Distribution of cases and fatalities by age and sex

Data as of 18<sup>th</sup> Apr

Case distribution by age and sex



Fatality distribution by age and sex



Source: GoK press release; KHF analysis

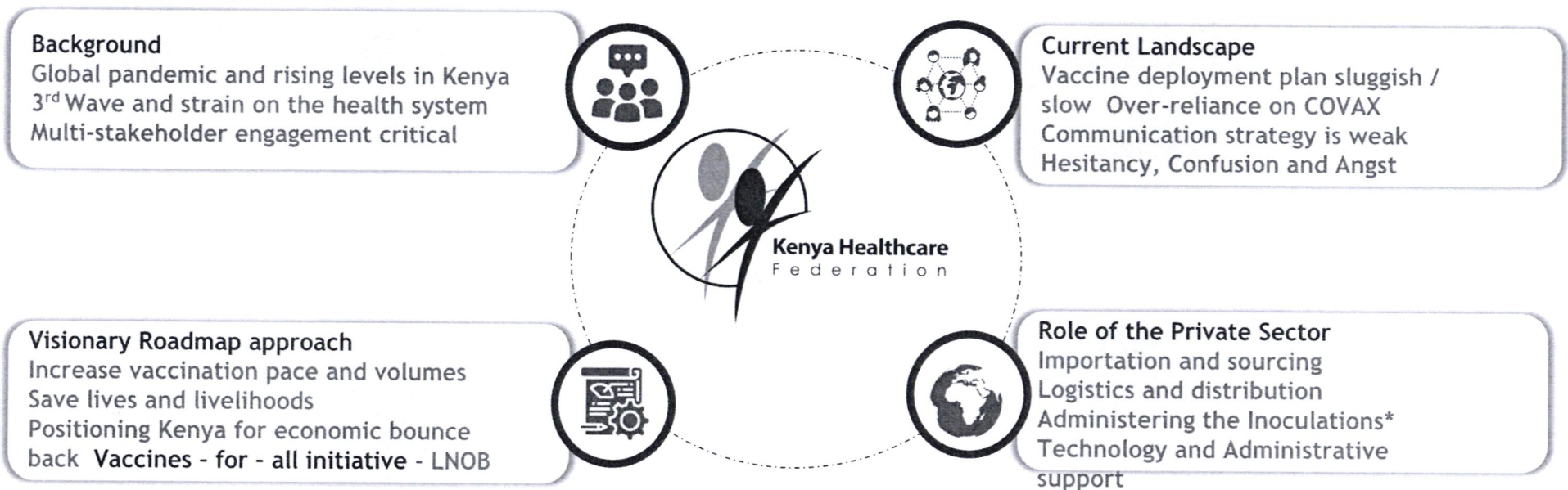




## Content

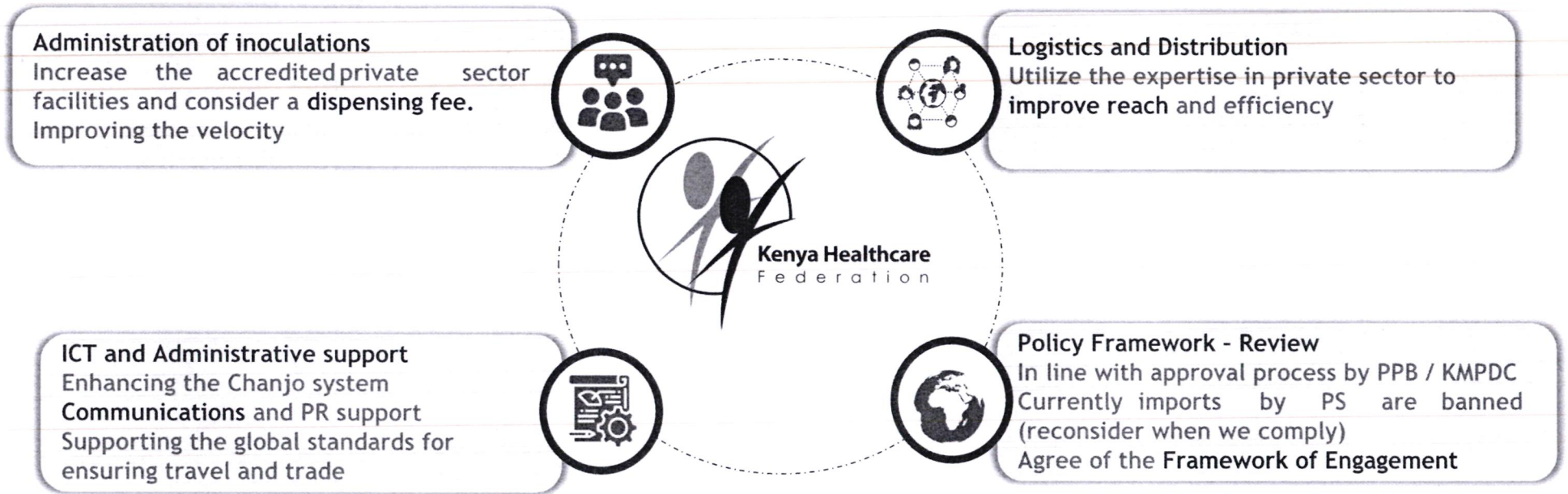
- Introduction to Kenya Healthcare Federation
- Covid19 situation update
- Vaccination Roll out
- Oxygen Supply and ICU/BED Capacity in Private sector

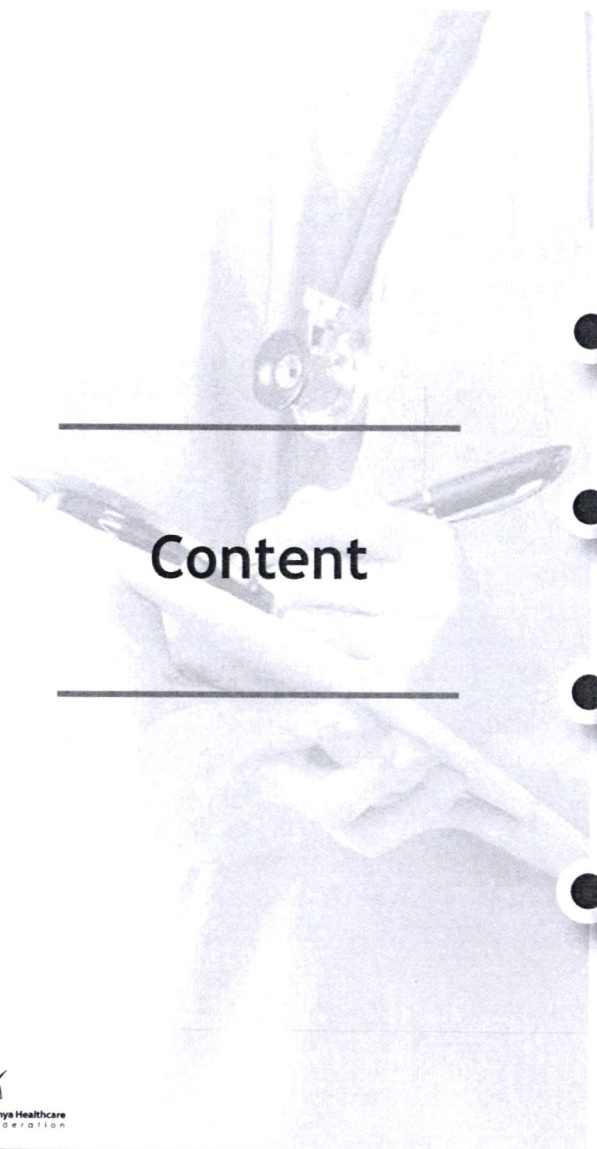
# Covid 19 Vaccine Deployment in Kenya - Private Sector Preparedness Plan - Outline for discussion



# Covid 19 Vaccine Deployment in Kenya - Private sector supporting Governments initiative

Key focus areas where the private sector can complement the GOK efforts





## Content

- Introduction to Kenya Healthcare Federation
- Covid19 situation update
- Vaccination Roll out
- Oxygen Supply and ICU/BED Capacity in Private sector

**THANK YOU!**



Visit our website: [www.khf.co.ke](http://www.khf.co.ke)



Email us: [info@khf.co.ke](mailto:info@khf.co.ke)



Call us: 0702 249 853



**Kenya Healthcare  
Federation**

The Health Sector Board for KEPSA

KHF Office Kedong House Lenana Road

+254 702 249 853

athakker@khf.co.ke

www.khf.co

Hon. Mutahi Kagwe  
Cabinet Secretary, Ministry of Health  
Dear Cabinet Secretary,



**Re: Appeal to retain the GAM-COVID Sputnik Vaccine**

We congratulate the Ministry of Health (MoH) in making sustained progress on the vaccination program. The recent increased uptake and reduction in hesitancy is very impressive in accelerating our pathway to herd immunity.

The crucial rate limiting step at the moment is obtaining adequate doses for our population in good time. We are aware of the global supply stain affecting several countries worldwide. Therefore, on behalf of the technical working group co-chaired by KMPDC and Kenya Health Federation (Health sector board of KEPSA), which also comprises of KMA (Kenya Medical Association), PSK (Pharmaceutical Society of Kenya) and Kenya Private Sector Alliance (KEPSA) we are requesting that the MoH considers allowing the effective and appropriate use of the remaining Sputnik vaccines that are in country.

There are about 70,000 Sputnik vaccine doses of good quality in the central cold store that are in the process of being re-exported and yet we will be soon be running out of the Astra Zeneca SII vaccines. The stakeholders which includes the regulatory boards, private sector and county agencies have been actively engaged with the MoH appointed technical working committee on designing the overall framework for the private sector to be able to import vaccines for local distribution and administration. We hope to this completed and approved within the next 2 weeks. The private sector will required to strictly adhere to these protocols.

We are aware of the issues surrounding the imported Sputnik vaccines. Our submission is to allow us to present an urgent regulatory outline specifically for these 70,000 doses for your approval to enable more Kenyans receive these PPB approved vaccines. The local technical representatives of the Sputnik vaccine are aware that should they be allowed to distribute the remaining doses they shall ONLY do so with observance of PPB and MoH requirements regarding safety reporting, pricing, advertising and use of the CHANJO platform.

Also identified are the first line buyers (FLBs) in the private sector who have the right capacity to import the various COVID-19 vaccines when the overall framework is ready. They have been importing similar vaccines in the past in partnership with the government. This process continues to work well to serve the population in need. We look forward to your considered response on this matter

Yours Sincerely,

*Amit Thakker*

**Dr. Amit N. Thakker  
Chairman, Kenya Healthcare Federation**

KENYA HEALTHCARE FEDERATION  
P. O. Box 3556 - 00100  
NAIROBI, KENYA  
Email: admin@khf.co.ke

Date: 20/4/2021

**Chairman:** Dr. Amit N. Thakker **Vice-Chair:** Dr. Elizabeth Wala **Treasurer:** Mr. Stephen Maina  
**Directors:** Mr. Francis Karanjah Dr. Walter Obita Dr. Jacqueline Kitulu Dr. Daniella Munene Ms. Faith Muigai Ms. Joyce Wanderi Mr Antony Jacc

From,  
Dinlas Pharma EPZ Limited  
Syokimau off Mombasa road,  
Park Rd, Nairobi  
Kenya

06<sup>th</sup> April, 2021

To,  
Principal Secretary  
Ministry of Health  
Afya House, Nairobi, Kenya



Dear Sir,


**SUBJECT: REQUEST FOR PERMISSION TO RE-EXPORT THE GAM-COVID SPUTNIK-V VACCINE TO PAKISTAN OR LEBANON**

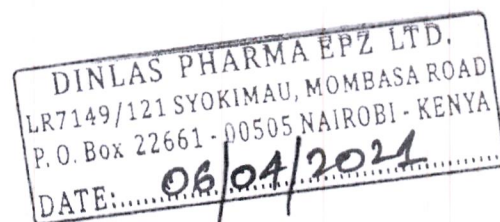
We are writing this letter with reference to the ban by Government of Kenya on import, distribution and administration of Covid-19 vaccine by private sector in Kenya. As we at Dinlas Pharma have imported the Gam COVID Sputnik-V vaccines to Kenya after receiving the import license, we are storing the vaccine under the prescribed temperature of -18 degree Celsius or below in our contracted warehouse at Jomo Kenyatta International Airport.

As we are incurring heavy cost for storage and due to the ban imposed by the Government of Kenya, we would like to immediately export all the Sputnik V Vaccine, both Component I and Component II to be sold in either Pakistan or Lebanon.

We request the Ministry of Health to give us necessary approvals and permissions at the earliest for us to export the vaccines to the above countries by 8<sup>th</sup> April, 2021.

Awaiting your response.

Regards,  
  
Nishant Mishra  
General Manager Corporate Affairs  
Dinlas Pharma EPZ Limited



CC:

1. Cabinet Secretary, Ministry of Health, Kenya
2. Chief Executive Officer, Pharmacy and Poison's Board, Kenya