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
HFs	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

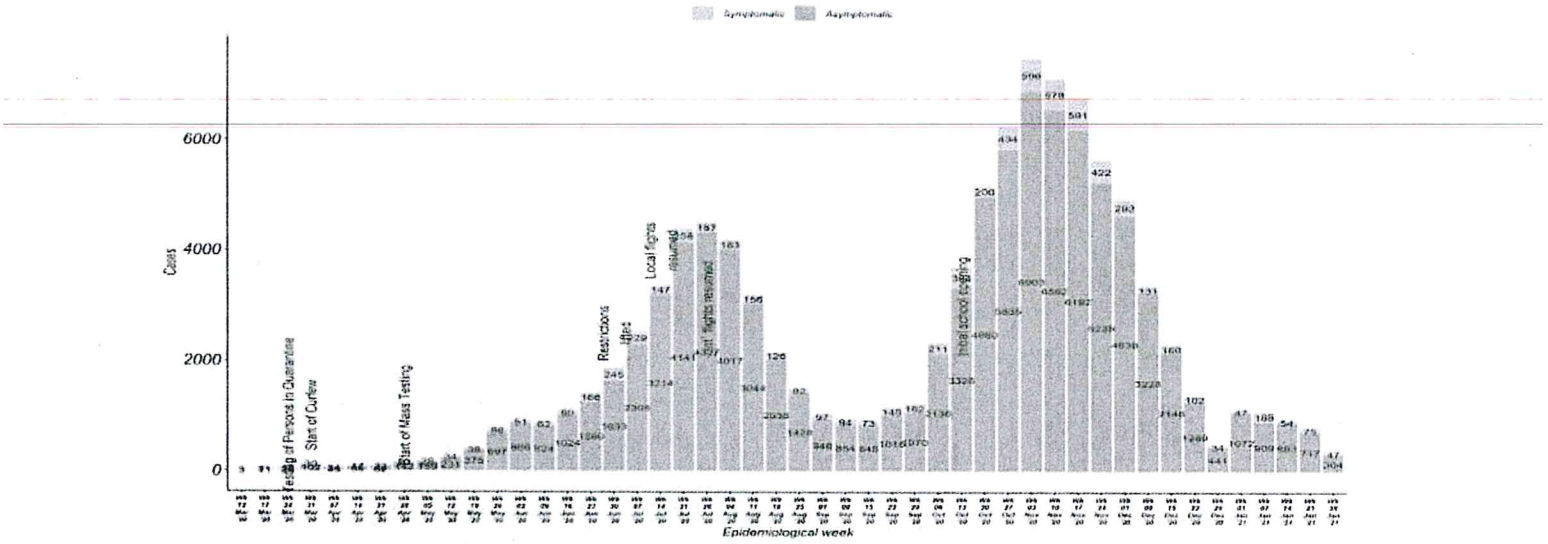
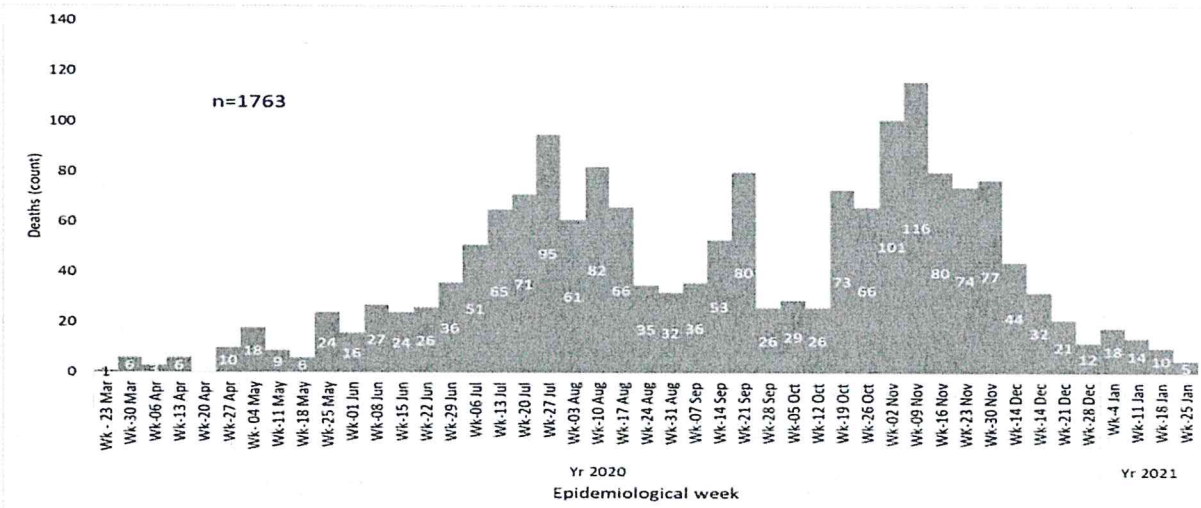
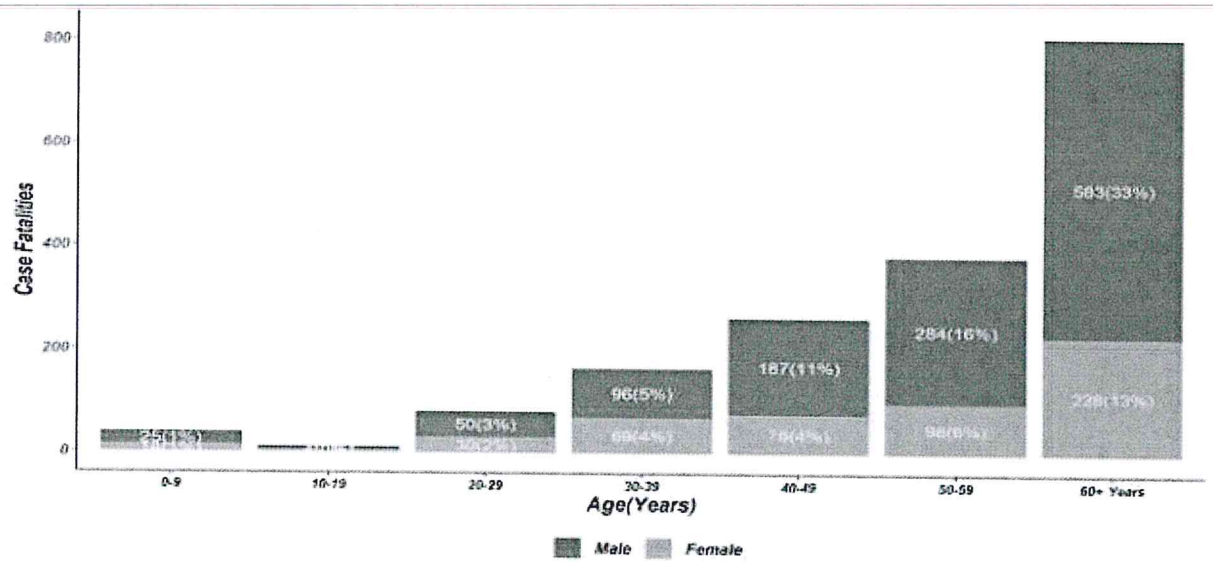


Figure 1: Trends of Fatalities by week, Kenya



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

Name of Vaccine	**WHO prequalification Or SRA's**	**Countries Using**	**Cost**	**Price under COVAX**
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	I 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 Banglades h 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
Coverage: • 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).	• Revise the primary strategy/ mode of delivery to a more sustainable approach i.e. facility-based approach • Complement the facility-based approach with accelerated immunization activities (Immunization Days) outreach approach varied depending on country context • Rump up advocacy and social mobilization efforts to ensure that the target population receives the message and seeks the vaccine at the facility
Microplanning • 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	• Ensure accurate and timely micro-planning and mapping of the target population in liaison with Counties and KNBS • Ensure timely and adequate vaccine supply, • Use appropriate advocacy and social mobilization using the disease specific platform
Staff Training • Importance of having adequate training materials developed and distributed to all service points on time	• Ensure technical guidelines and job aides are available at all levels including service points • Technical guidelines and other materials should be bundled and delivered early in advance
Cold chain / storage capacity • 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. • Need to address gaps in temperature monitoring	• Ensure adequate planning and mapping of sites with adequate CCE • Ensure continuous temperature monitoring devices (FT2) at all levels are available and working correctly • 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

Vaccine acceptability and dropout rates • Due to intensive collaboration with relevant stakeholders and packaging of messages, minimal hesitancy and refusals have been encountered. • Use of SMS and other reminders to clientele resulted in great penetration and demand generation for vaccination	• Increased engagement with stakeholders, especially religious leaders, and immunization champions, to reduce vaccine hesitancy and dropout rates. • Packaging the vaccines as a COVID Control strategy • Collaboration with other ministries e.g., Education, interior will lead to the success of the roll out. • Apply strategies that have worked in the past to increase demand for the vaccine e.g., use of SMS
Others • Concerns regarding virus mutation among Health workers. • concerns as to why only specific groups were being vaccinated and not all other populations. • Concerns about the short expiry nature of the vaccine. • Some health care workers linked the Influenza vaccination drives to a COVID-19 trial vaccine. • Most health care workers requested for influenza vaccine notification cards as proof of immunization and requested for annual vaccination.	• Ensure technical guidelines and job aides are available at all levels including service points, ahead of the introduction. • Conduct an audience segmentation and adapt messages to specific audiences targeting the concerns raised. • Engage relevant experts to continuously engage and regularly provide updates to health workers on the COVID Vaccines

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.

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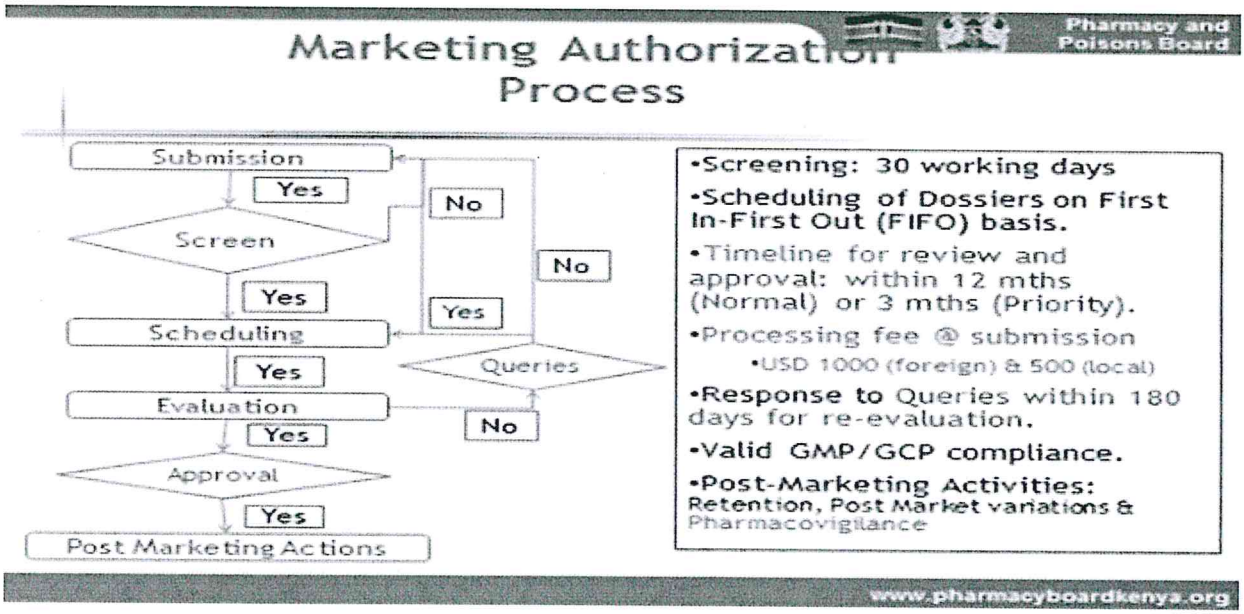
COVID-19 vaccines that have already received approval from stringent regulatory authorities (SRAs) or WHO will be expedited for approval within seven (7) days, upon application by the manufacturing company or their agent. The PPB recognizes regulatory decisions (marketing authorization or emergency approval) 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)*

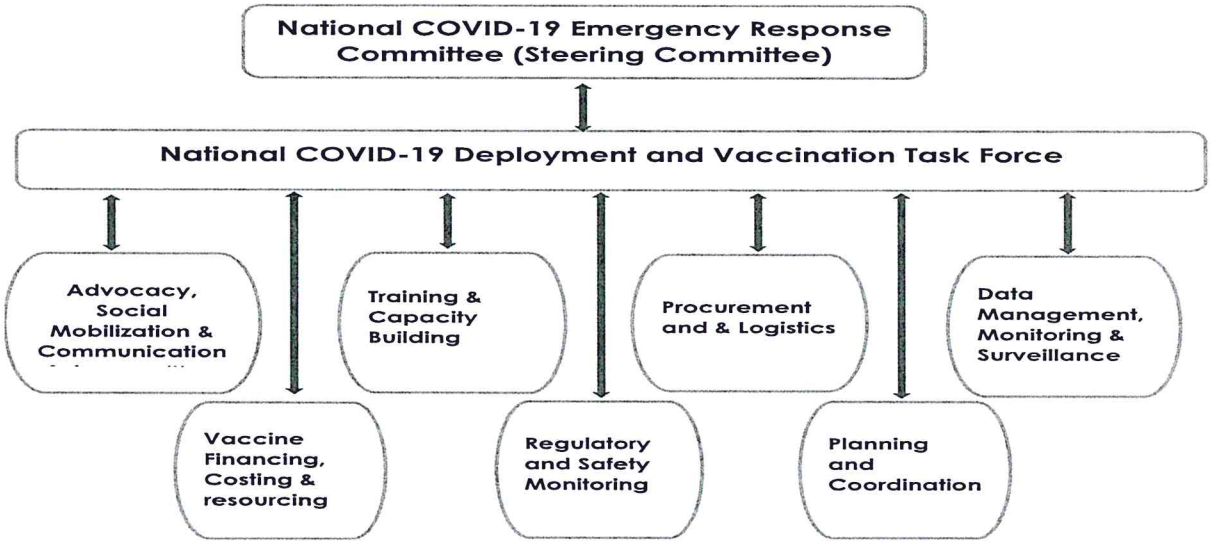
i. Primary endpoint: prevention against symptomatic COVID-19 disease of any severity
ii. Secondary endpoint: Prevention of severe disease or infection
iii. Point estimate vaccine efficacy of 50-60%, lower bound of 95% CI between 20-30% preferably above 30%, as per literature all COVID-19 vaccines have 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

National Taskforce on Covid-19 Vaccines Deployment.		
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 Manya	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

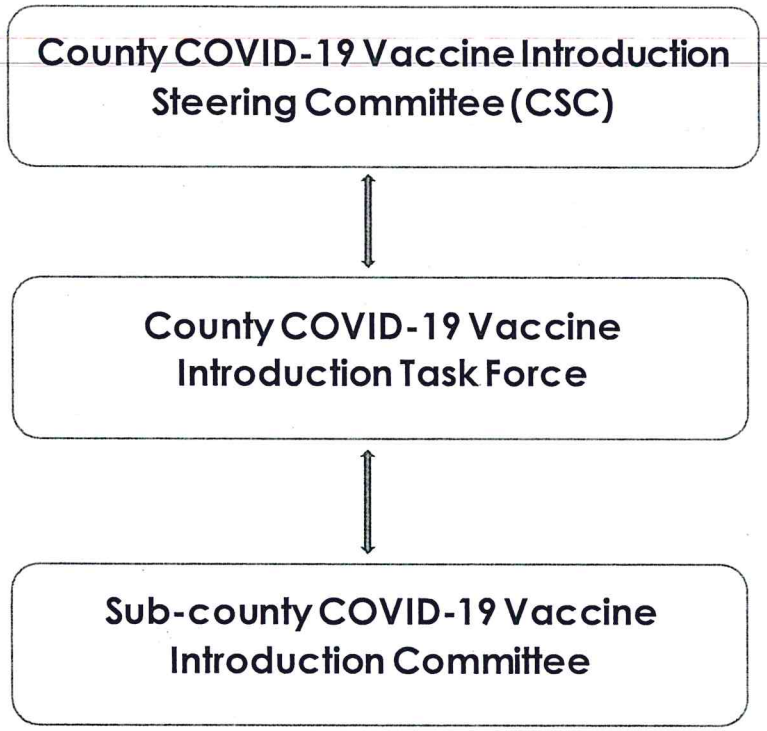
Member	Dr. Edward Abwao	USP
Member	Health Committee, CoG	Representative, Council of Governors
Member	Dr. Cosmas Mugambi	MOH
Member	Dr. Victoria Kanana	MoH, Secretariat
Member	Dr. Stephen Muleshe	MoH Kenya (Task Lead, Planning and Coordination)
Member	Mr. John Kabuchi	MoH, (Task Lead, Procurement and 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 expediated 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
Total	**14,306,567,330**	**19,711,056,609**	**34,017,623,939**

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	-
Total	**2,248,423,476**	**1,655,602,330**	**17,462,633,133**	**3,755,498,049**	**8,895,466,951**

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.)

No.	Main Activity	GoK
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
	Total	**933,167,514**

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.

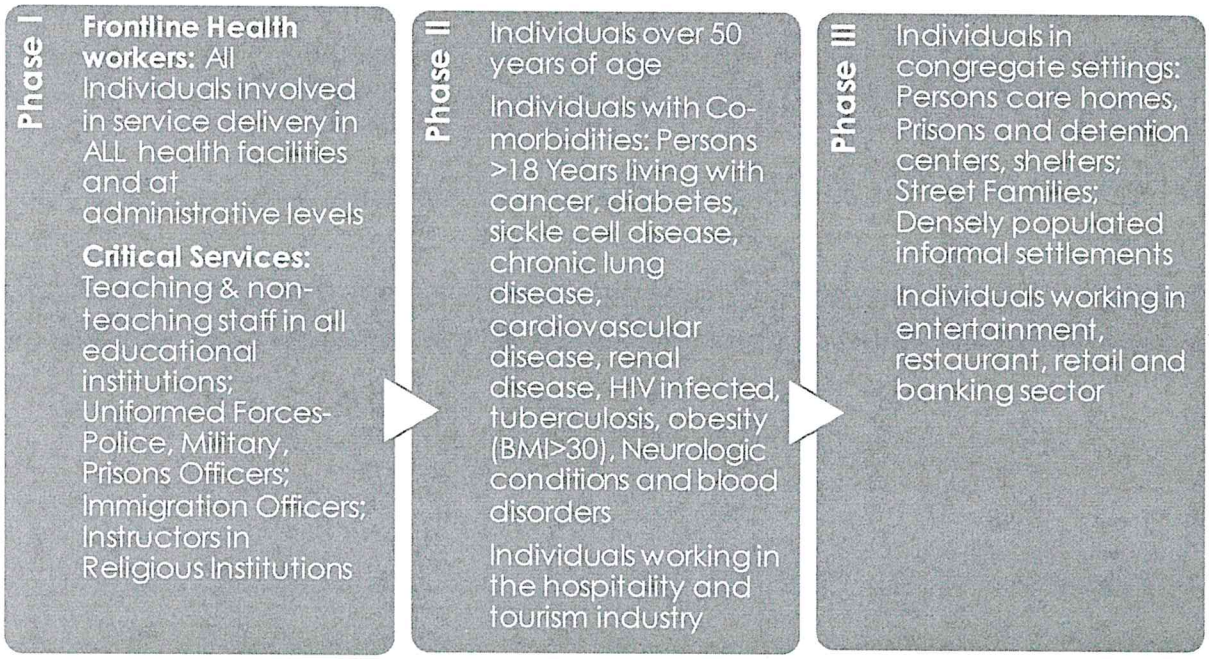
The COVID-19 vaccine rollout is envisaged in phases as below:

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

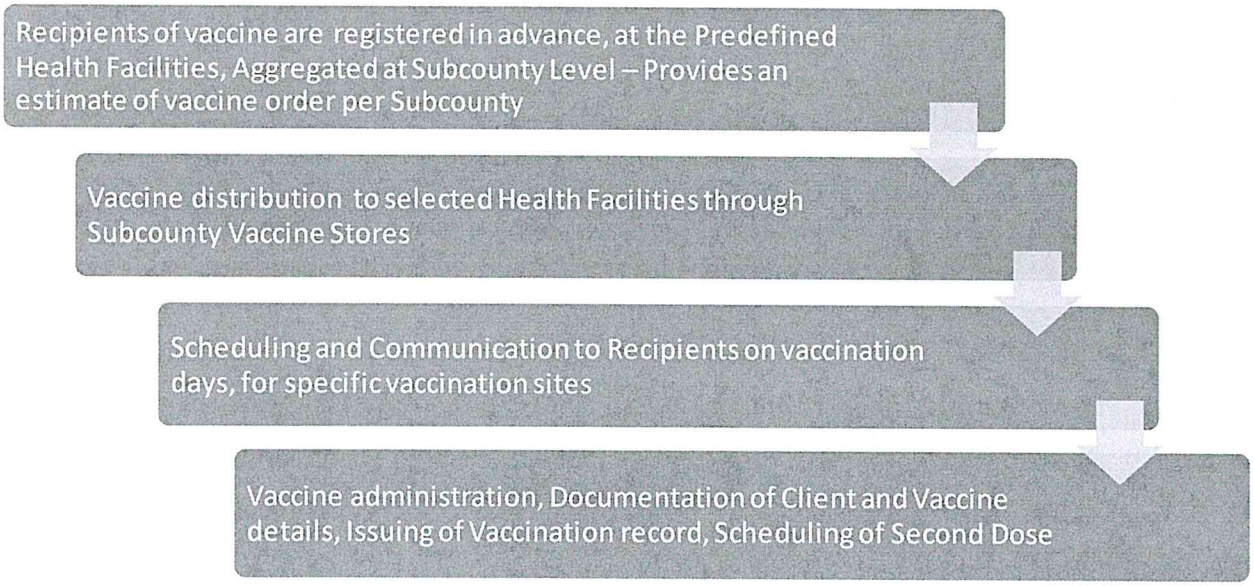
The phases are aligned to GOK financial years; Phase 1- January-June 2021, Phase II- July 2021-June 2022, Phase III- July 2022-June 2023.

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 ≥ 38°C) and no reported allergies for eggs or chicken, (Individuals who present with fever (temperature currently ≥ 38°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:

- Each vaccination site will be supplied with hand sanitizers to be used by clients and team members.
- Soap for Handwashing for fixed 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.
- 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^3 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^3.

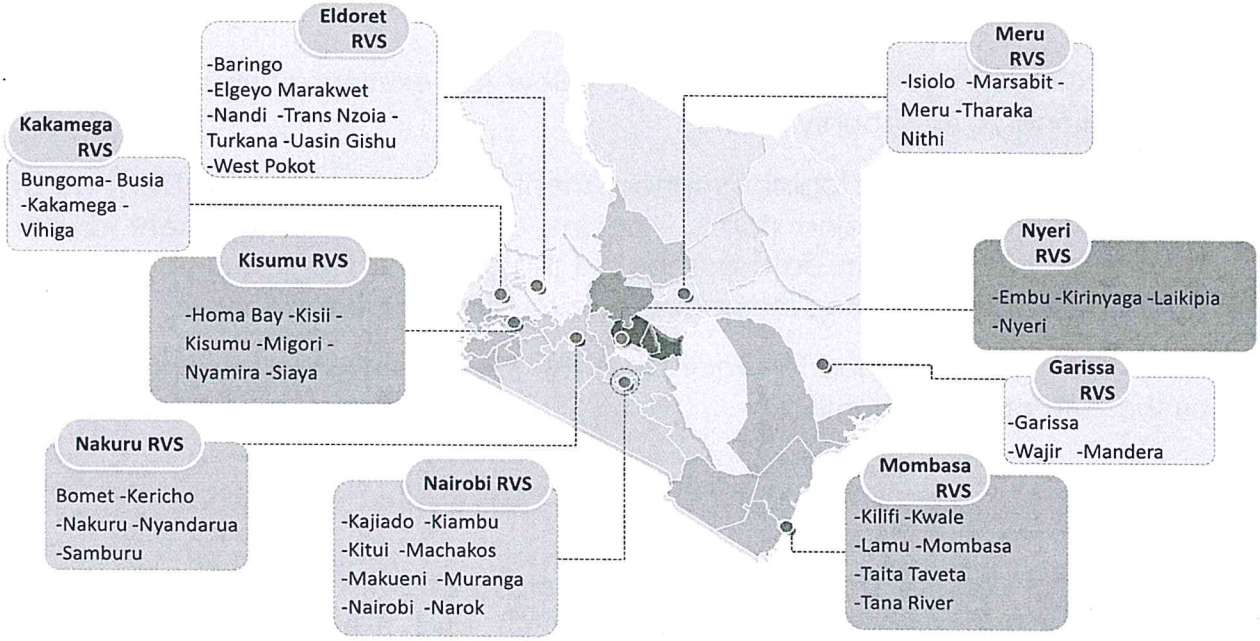
The capacity at the new National cold rooms is sufficient for deployment of vaccines requiring the +2°C to 8°C / -20°C of cold storage; with a quarterly vaccine delivery schedule to the national and regional vaccine stores. Minimal expansion will be required to provide for less frequent shipment schedules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

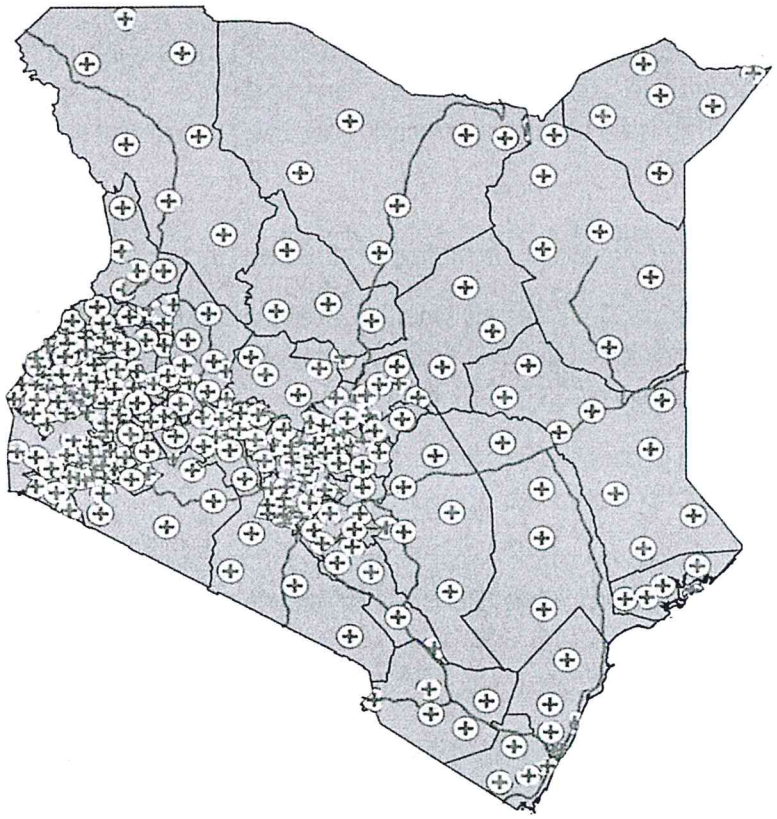


Kenya National and Regional vaccine cold store capacities estimates.

	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-FUNCTIONA
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 REGONAL 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
	NEWLY ESTABLISHED COUNTY VACCINE COLD STORAGE POINTS						
	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 **Health Facilities**, 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 **Health Facilities**, under a 10 year warranty	150
7	On-grid Cold Chain Equipment, without freezer compartment and capacity for remote temperature monitoring for **Health Facilities**, 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 **Sub-counties**, under a 10 year warranty	145
10	On-grid Cold Chain Equipment -freezers for **subcounty and regional depots**, under a 10 year warranty	154
11	Standard 5L Vaccine Carriers for **Health Facilities**	38,600
12	Standard 5-25 L Cold Boxes for **sub county stores**	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 4OOO 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	o Overview of COVID-19 pandemic o Etiology and clinical presentation of COVID-19 o Clinical management, surveillance and reporting of confirmed cases and suspected cases

Description of the vaccine Recommended schedule and target population Mode of Administration	o The vaccines will be described & 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* o The schedule for administration and how they will be integrated in the routine EPI schedules. o Case studies Managing the patient (side/adverse)
Cold Chain issues	o General cold chain aspects of EPI will be discussed, emphasizing COVID-19 vaccine cold storage requirements. o Introduction of new distinctly colored vaccines trays, and how to tackle storage challenges of high output facilities.
Documentation and record keeping	o Trainees will be introduced to the revised reporting forms, stock monitoring tools and other monitoring tools, including electronic platforms o Health facility staff will be trained on how to document and report any adverse events following immunization (AEFIs) Basics on monitoring key indicators , SOPs, wastage,
Injection Safety	o General review of injection safety measures regarding injectable vaccines and other injection waste.
IPC	o PPE use, Hand Hygiene, Hand Hygiene resources o Standard precautions for IPC o Social distancing Waste management (facility and community)

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.

They 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:

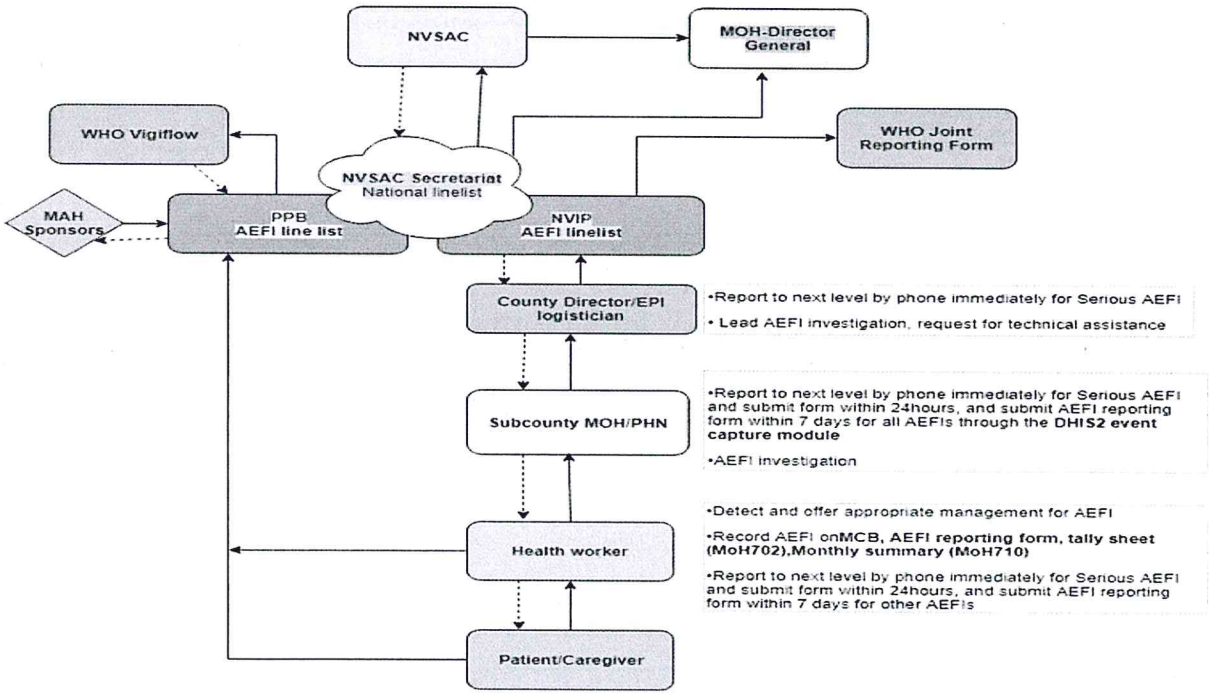
No	Stakeholder	Responsibility
1.	Ministry of Health	· Policy formulation · System and database maintenance (DHIS) · Resource mobilization
2.	National Vaccines and Immunization Program	· Provision of vaccines · Training of health workers · Feedback and information sharing · Share Information with PPB immediately for Serious AEFI · NVSAC secretariat · Participating in investigation Provision of reporting tools · Participate in Post-market surveillance · Reporting through Joint Reporting Form · Signal detection · Causality assessment Training of health workers · Maintenance of database and AEFI line list

3.	Pharmacy and Poisons Board	· Licensing of vaccines Regulatory action · Issue import permit for vaccines Feedback and information sharing · Share Information with NVIP immediately for Serious AEFI · NVSAC secretariat · Participating in AEFI investigation · Post-market surveillance · Reporting through Vigiflow® · Signal detection · Causality assessment · Provision of reporting tools · Training of health workers · Maintenance of database and AEFI line-list
4.	County Government	· Provision of vaccination services · Training of health workers · Feedback and information sharing to lower level · Lead AEFI investigation, request Technical Assistance · Participate in Post-market surveillance and pharmacovigilance activities · Reporting of AEFI · Maintenance of AEFI line-list · Resource mobilization

5.	Sub-county health management team	· Provision of vaccination services · Training of health workers · Feedback and information sharing to lower level · Initiate AEFI investigation · Participate in Post-market surveillance and pharmacovigilance activities · Reporting of AEFI · Maintenance of AEFI line list · Resource mobilization · Entering of AEFI reports into DHIS 2 by HRIO
6.	Health Care worker	· Detection, management and timely reporting of AEFI · Provision of vaccination services · Providing information on vaccines to clients · Feedback to caregivers
7.	Development partners	· Resource mobilization · Technical assistance
8.	World Health Organization	· Technical assistance · Providing information/guidance documents
9.	Media	· Responsible reporting · Support awareness creation
10.	Caregiver/client	· Report AEFI · Adhere to guidance of health worker

11.	Laboratories: NQCL, Government Chemist, NPHLS	· Timely testing of specimen · Provide advice
12.	NVSAC	· Advisory role- Refer to NVSAC Terms of Reference
13.	NVSAC secretariat	· Merge and update the joint NVIP & PPB national line list · Select cases for NVSAC to review, summarize findings from NVSAC deliberations · Share recommendations of NVSAC to NVIP and PPB · Coordinate investigations

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.

<u>Details of Data Management Procedures and Activities</u>

<u>Stock tracking of the COVID-19 vaccines</u>

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

data/ online systems	will be captured through several online systems such as KHIS, Chanjo and the national electronic database system	aggregated data will be managed by the KHIS program through password access. Access to online data repositories will be managed by the Ministry of Health in line with Kenya data laws.
National aggregate data from other Government sources	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	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.
Non-Government data	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. These data sets can include survey data on public opinion, social	These data will be aggregated by the national MoH where applicable and linkages with other data sources will be through the national MoH

	media tracking of public sentiment etc.	

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 Phase1-3

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/Welcome 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.

<u>Data analytics and Dissemination</u>

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
Pre-deployment phase	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

Group	Assumptions	Risk	High/Medium/Low	Mitigation
	counties, private sector, priority sectors)	vaccine deployment		plan implemented
The disease/virus	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
The vaccine	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
Vaccine deployment	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
Unintended Consequences	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 11th March, 2021, inviting the Cabinet Secretary to a virtual meeting on Thursday, 18th 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
Total	**14,306,567,330**	**19,711,056,609**	**34,017,623,939**

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		2314560594	-	56,762,500
Total	**1,655,602,331**	**2,248,423,476**	**3,755,498,049**	**17,462,633,133**	**8,895,466,951**

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 30th 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^3 for positive temperature cold storage (2-8°C) and 2 freezer rooms with a net capacity of 14 M^3 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 COMMITEE 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 6th 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 18th March, 2021 and 29th March, 2021 (copies attached), the oral submissions by the Cabinet Secretary of Health at the meeting held on Thursday, 1st April, 2021 (Hansard transcript attached), and the aforementioned public statement issued by the Cabinet Secretary of Health on 2nd 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 28th 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 2nd 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 16th April, 2021, and 23rd 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 28th 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 3rd March, 2021. These vaccines were distributed to all 47 counties and vaccination started on 5th 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 26th 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 27th 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 2nd 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.

30th 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 5th March 2021, Countrywide vaccinations started on the week of 8th March 2021
- Total Doses Issued **1,099,000** at 9th May 2021
- **Balance at Kitengela Central Vaccines store 21,000 doses** at 9th May 2021
- Total number of persons vaccinated to date **917,068,** 56% are male while 44% are female.

Sunday 9th May 2021

Total Vaccinated	Cumulative Persons	Vaccinations per Gender				AEFI Reported
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 9th 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%
Total		917,068	100%

- 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

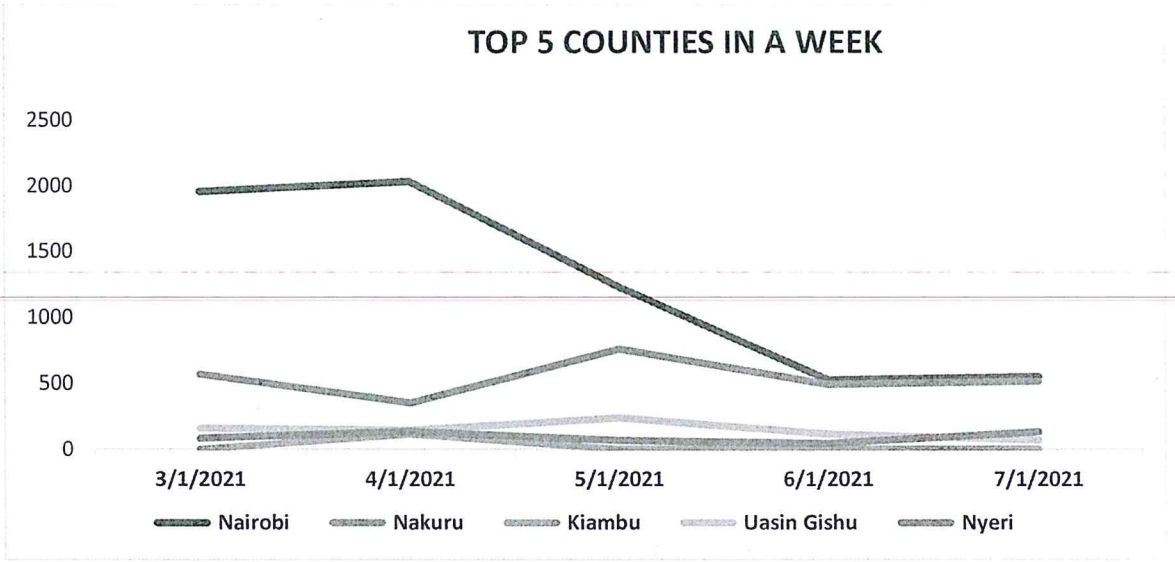


Figure 1: Number of persons vaccinated in the last 5 Days

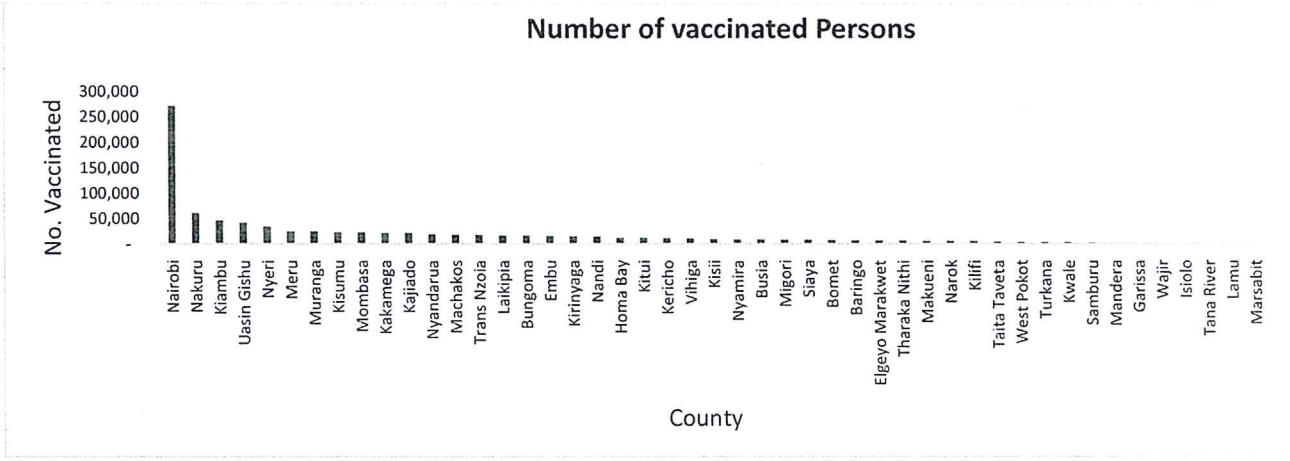


Figure 2: A graph showing number of vaccinated persons per county

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%
Total	**917,068**	100.0%

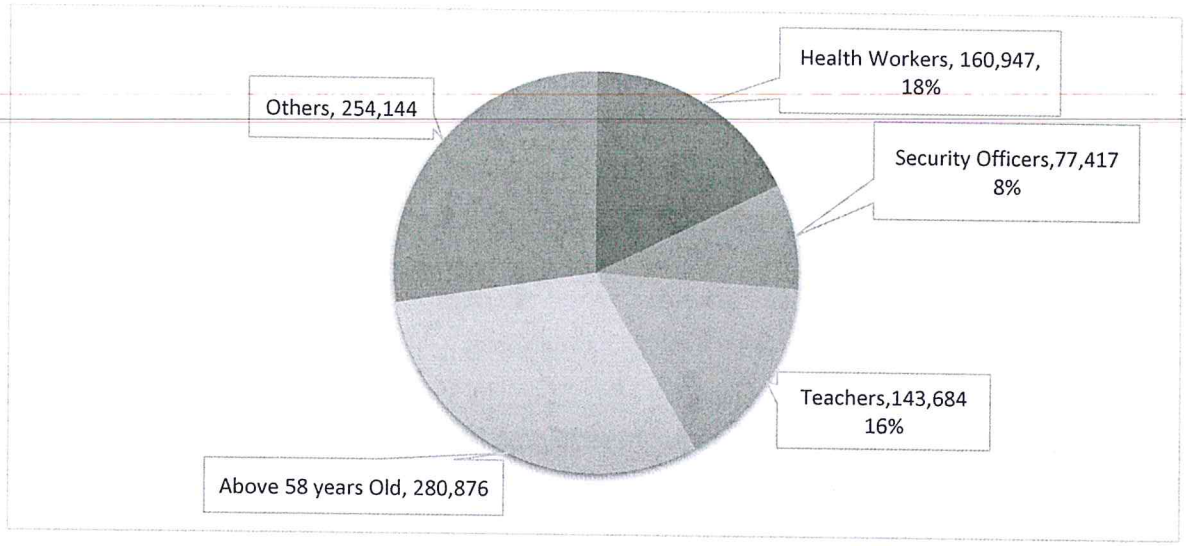


Figure :3 ***The number vaccinated by occupation***

- 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, 9th 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		
Total	**917,068**	**3,133,674**	29%

Table 4: **Vaccine Doses Dispensed as at 9th May, 2021**

Vaccine	Total doses Administered
AstraZeneca	**917,068**
Sputnik	527
Total	**917,595**

Adverse Events Followings Immunization (AEFIs)

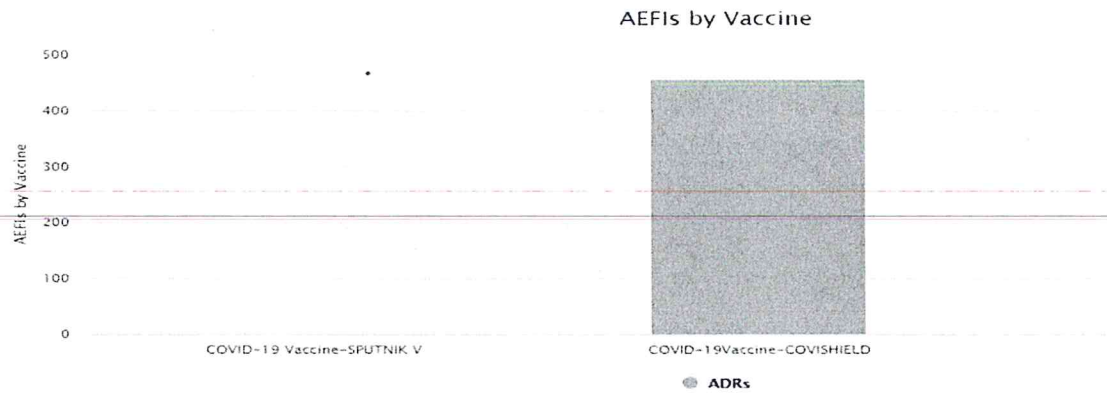


Figure3*: Adverse Events Followings Immunization (AEFIs)*

The Chart show there are 479 cases of AEFIs report on COVID shield Vaccine related through the Pharmacovigilance Electronic reporting system as at 9th 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
TOTAL RECEIVED		**1,120,000**		

- 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/ Mandera 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 9th May 2021 and a balance of **21,000** doses at Kitengela Central store.

Table 7: Distribution at Regional Depots as at 9th 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
	TOTAL ISSUED		*1,099,000*	
	TOTAL BALANCE		*4121Z010*	*21,000*

Table 8: Vaccine Logistics at County Level

Vaccine Inventory 9th May 2021			
Doses in Stock		Used Vaccines	
277,100		823,493	
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	**% Used**
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%
Total	**116,850**	**24,440**	**92,957**	79%
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	% Used
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%
Total	**105,150**	**15,310**	**90,235**	86%
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	**% used**
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%
Total	**80,170**	24,480	56,015	70%
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	**% used**
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%
Total	**77,830**	**3,050**	**75,226**	96%
Garissa County	4,600	2,390	2,207	47%
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	**% used**
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%
Total	**106,530**	**30,363**	**77,242**	72%

Level	Total Doses	Doses In Stock	Doses Used	% used
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%
Total	**38,760**	**4,900**	**33,851**	87%
Level	**Total Doses**	**Doses In Stock**	**Doses Used**	**% used**
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%
Total	**458,310**	**109,770**	**348,611**	87%
Level	**Total Doses**	**Doses in Stock**	**Doses Used**	**% used**
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%
Total	**62,000**	**22,350**	**39,641**	64%
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%
Total at county level	**1,099,000**	**277,100**	**823,493**	**75%**

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 9th May 2021

COUNCIL OF GOVERNORS

REPORT FOR THE SENATE AD HOC COMMITTEE ON THE NATIONALWIDE COVID-19 VACCINE ROLL OUT MEETING ON 18th 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 milion** 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 4th 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 (1st dose) as of 16th 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 25th 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.

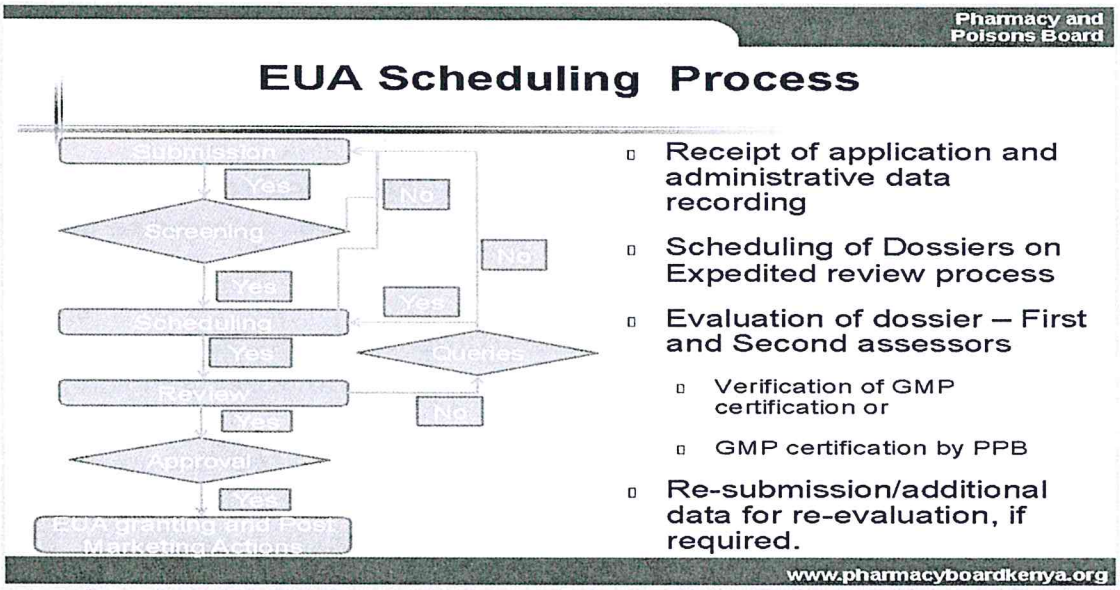
2.6 The applicant through the LTR logs into the PPB prims system and submits a Common Technical Document (CTD dossier) in the portal (all the 5 modules must be filled in). Additionally, it is mandatory for the applicant to remit fees as follows: - USD 1000 for EUA application and USD 4000 for GMP certification 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[1] 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

[1] 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 Phamarcy and Poisons Board of Kenya in line with its mandate as the regulatory authority , and as outlined in the Phamarcy 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 Phamarcy 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 Phamarcy and Poiosn 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.**

DINLAS PHARMA

Date: 10th 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

DINLAS PHARMA EPZ LTD.
LR7149/121 SYOKIMAU, MOMBASA ROAD
P.O. Box 22661 - 00505, NAIROBI - KENYA
DATE: 10/03/2021

DINLAS PHARMA EPZ LIMITED
Plot No.LR7149/121, Mombasa Road, Syokimau.
P.O. BOX 22661-00505, Nairobi-Kenya Tel: 0782 500 800 / 700
Email: info@dinlaspharma.com, Web: www.dinlaspharma.com

THE REPUBLIC OF KENYA

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 particular 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 HARIA	DIRECTOR	P.O BOX 42718 G.P.O NAIROBI	UNITED KINGDOM	
			TOTAL	1000

Yours Faithfully,
REGISTRAR OF COMPANIES

REF NO: OS-ZDFLYDQ5

REPUBLIF 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 emergence use authorization subject to the conditions indicated hereunder:	
Trade name	Gam-Covid-Vaccine (Sputnik V Vaccine)
Approved name	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
Form of preparation (Dosage form)	Solution for Intramuscular Injection
Active ingredients and quantities per unit	Solution for intramuscular injection; component I: 0.5ml/dose +component II: 0.5ml/dose
Condition(s) under which is registered	For Emergency Use Only. Please Refer to Annexure 1 for conditions.
Name and business address of manufacturer (API & FPP)	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.
Registered in the name of (EUAH)	Dinlas Pharma EPZ Limited, P.O. Box 22661-00505, Nairobi.
Local Technical Representative (LTR)	Dinlas Pharma EPZ Limited P.O Box 22661-00505, Nairobi.
Date of EUA	9th March, 2021
Date of Issue	9th March, 2021
Expiry date of EUA	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
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
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, 9th 2021

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

SR No. 016747/20

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

ID No: 11498835

Registration No: 1426

Premise: HARLEYS LTD-NAIROBI

Plot No.

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

SR No. 016749/20

FORM 33

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

Note. (i) This Registration expires on 31st December **2021**

(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 31st 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

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

Consignee Details

Name :Harleys Ltd

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

Importer Details

Name :Harleys Ltd

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

Exporter Details

Name :DINLAS PHARMA EPZ LIMITED

PIN :P000000000N

OGA Ref No :

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

Physical Country :KENYA

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

Postal Country :KENYA

Telephone :0780100035

Fax :0780100035

Email :info@dinlaspharma.com

Sector of Activity :Trade

Warehouse Code :Air Connection Ltd

Warehouse Location :JKIA

Consignor Details

Name :DINLAS PHARMA EPZ LIMITED

PIN :P000000000N

OGA Ref No :

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

Physical Country :KENYA

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

Postal Country :KENYA

Telephone :0780100035

Fax :0780100035

Email :info@dinlaspharma.com

Sector of Activity :Trade

Warehouse Code :Air Connection Ltd

Warehouse Location :JKIA

Values - Header Level

Foreign Currency Code :USD	Forex Rate :109.75	FOB FCY :3,825,000.00
Freight FCY :0.00	Insurance FCY :0.00	Other Charges FCY :0.00
CIF FCY :3,825,000.00	FOB NCY :419,789,160.00	Freight NCY :0.00
Insurance NCY :0.00	Other Charges 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	HS Description :Vaccines for human medicine		
Quantity :50000	Unit Of Quantity :Net Kilogram	Supplementary - Quantity :0	Package Type :Box
Package Quantity :50000	Foreign Currency Code :USD	Unit Price FCY :51.00	Total Price FCY :2,550,000.00
Unit Price NCY :5,597.19	Total Price NCY :279,859,440.00	Country Of Origin :RUSSIAN FEDERATION	Item Net Weight :1000 Net Kilogram
Item Gross Weight :1000 Net Kilogram	Applicant Remarks :OK		

Item Details

Item No :2

Item Description :Sputnik Vaccine Component II

Item HS Code :3002200000	HS Description :Vaccines for human medicine		
Quantity :25000	Unit Of Quantity :Net Kilogram	Supplementary - Quantity :0	Package Type :Box
Package Quantity :25000	Foreign Currency Code :USD	Unit Price FCY :51.00	Total Price FCY :1,275,000.00
Unit Price NCY :5,597.19	Total Price NCY :139,929,720.00	Country Of Origin :RUSSIAN FEDERATION	Item Net Weight :1000 Net Kilogram
Item Gross Weight :1000 Net Kilogram	Applicant Remarks :OK		

Transport Details

Mode Of Transport :R	Mode Of Transport Desc :Road
Port Of Arrival :Jomo Kenyatta International Airport	Customs Office :JKA
Freight Station :JOMO KENYATTA INTERNATIONAL AIRPORT	Cargo Type Indicator :General Cargo

Kenya Healthcare Federation

Your partner in transforming healthcare

Senate Meeting

April 19TH , 2020 @9AM

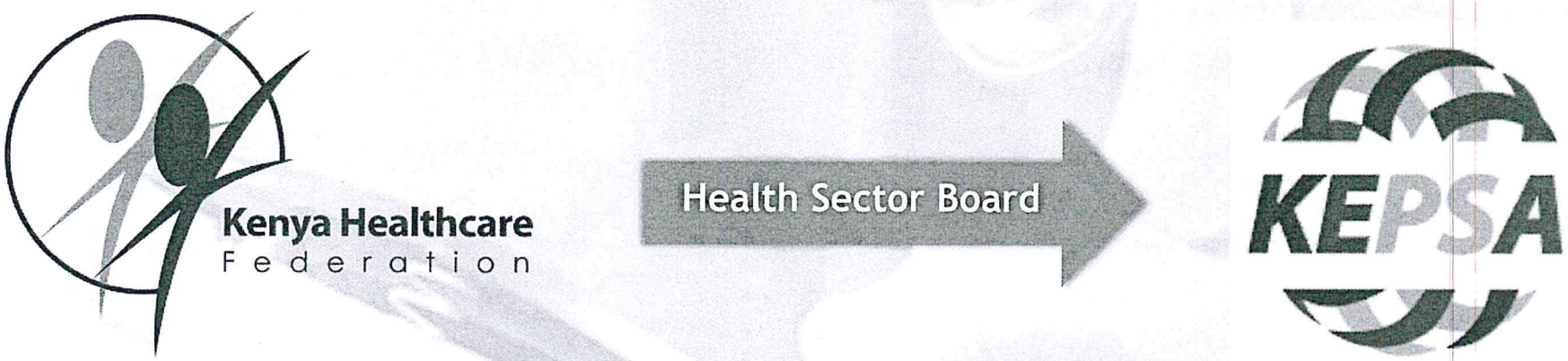
Content

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

Kenya Healthcare Federation

KEPSA

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



Kenya Healthcare Federation

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)

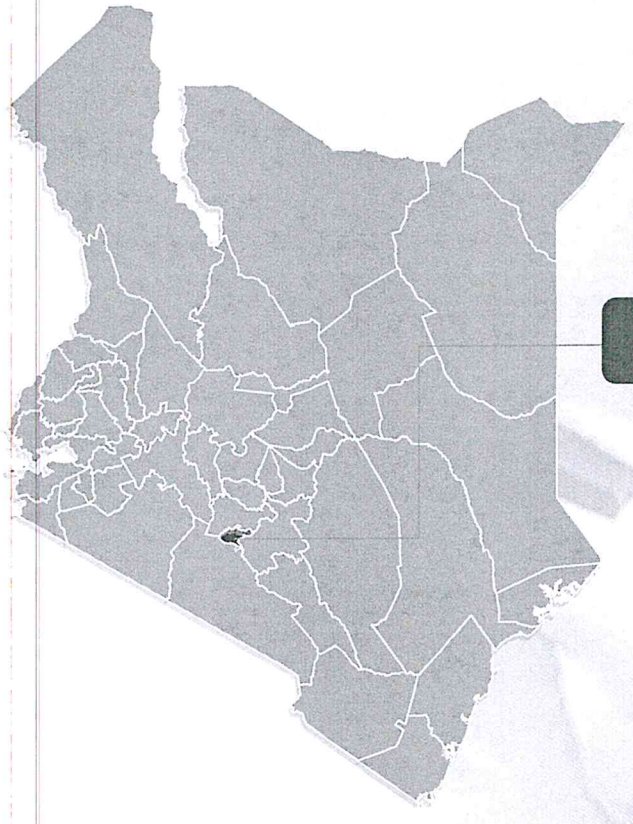
Top: Cabinet Secretary and KHF Leadership Team on August 2019 Right: CS Mutahi Kagwe accompanied by KHF chairman gives update on Covid-19 situation in Kenya

Kenya Healthcare Federation

KEPSA

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

Kenya Healthcare Federation

KEPSA

...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

Kenya Healthcare Federation

KEPSA

Content

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Kenya Healthcare Federation

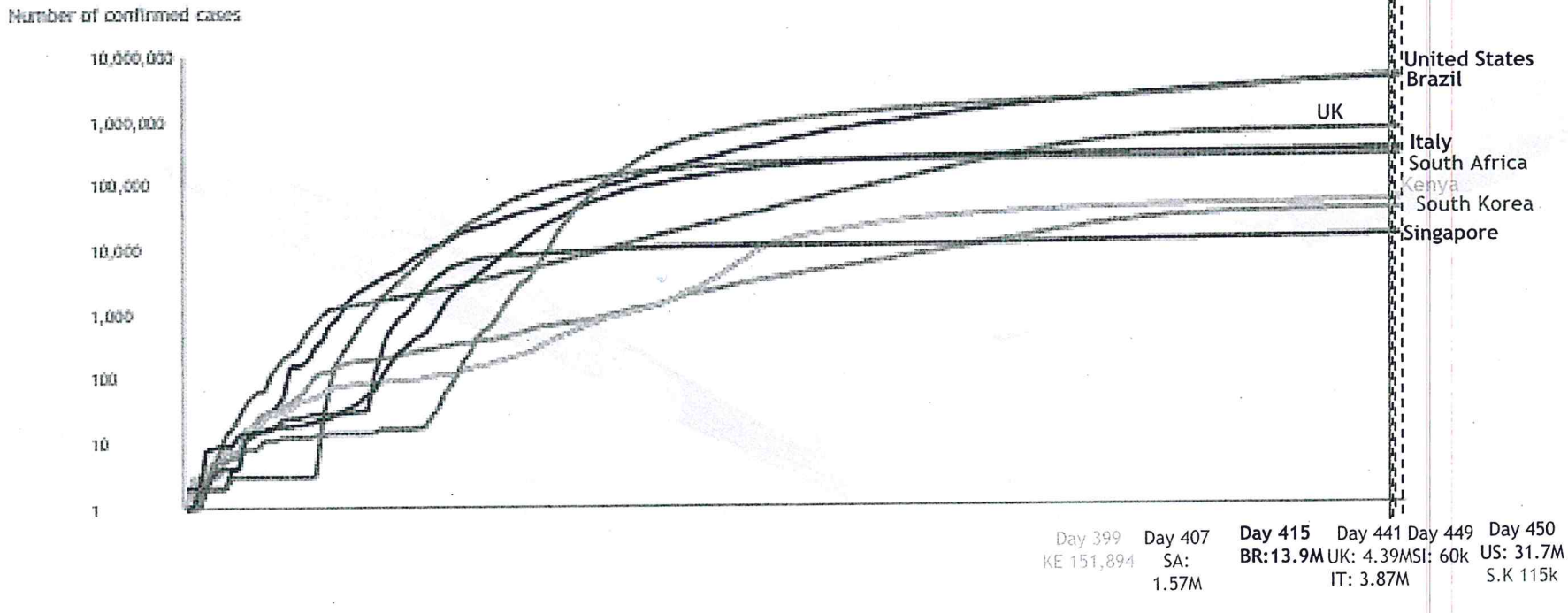
KEPSA

Owner KHF

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

Data as of 18th Apr
Kenya 19th 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	

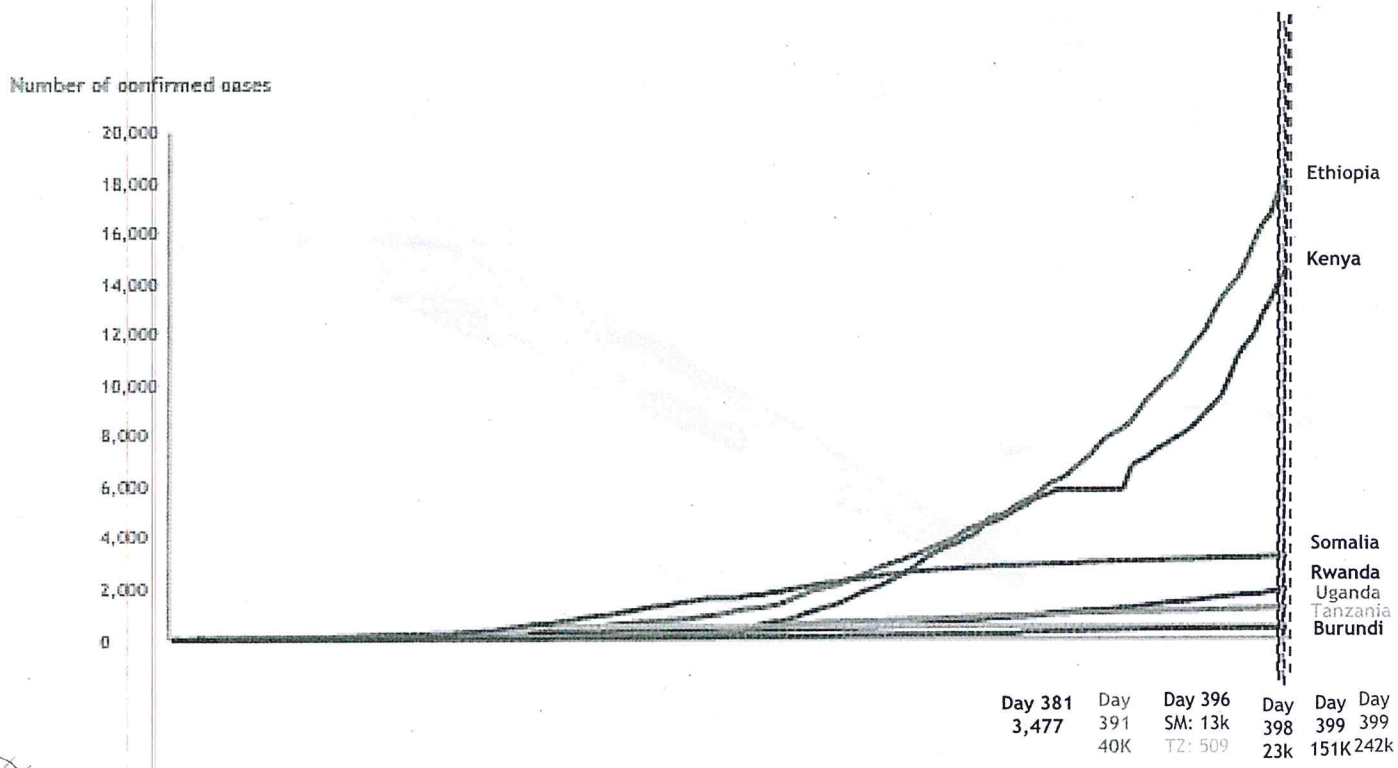


Source: Johns Hopkins, Github; Kenya more real time from GoK press release, news sources

Owner	KHF

Cases and testing in East African countries (log scale)

Data as of 18th Apr
Kenya 19th Apr



Data as of 18th Apr

	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

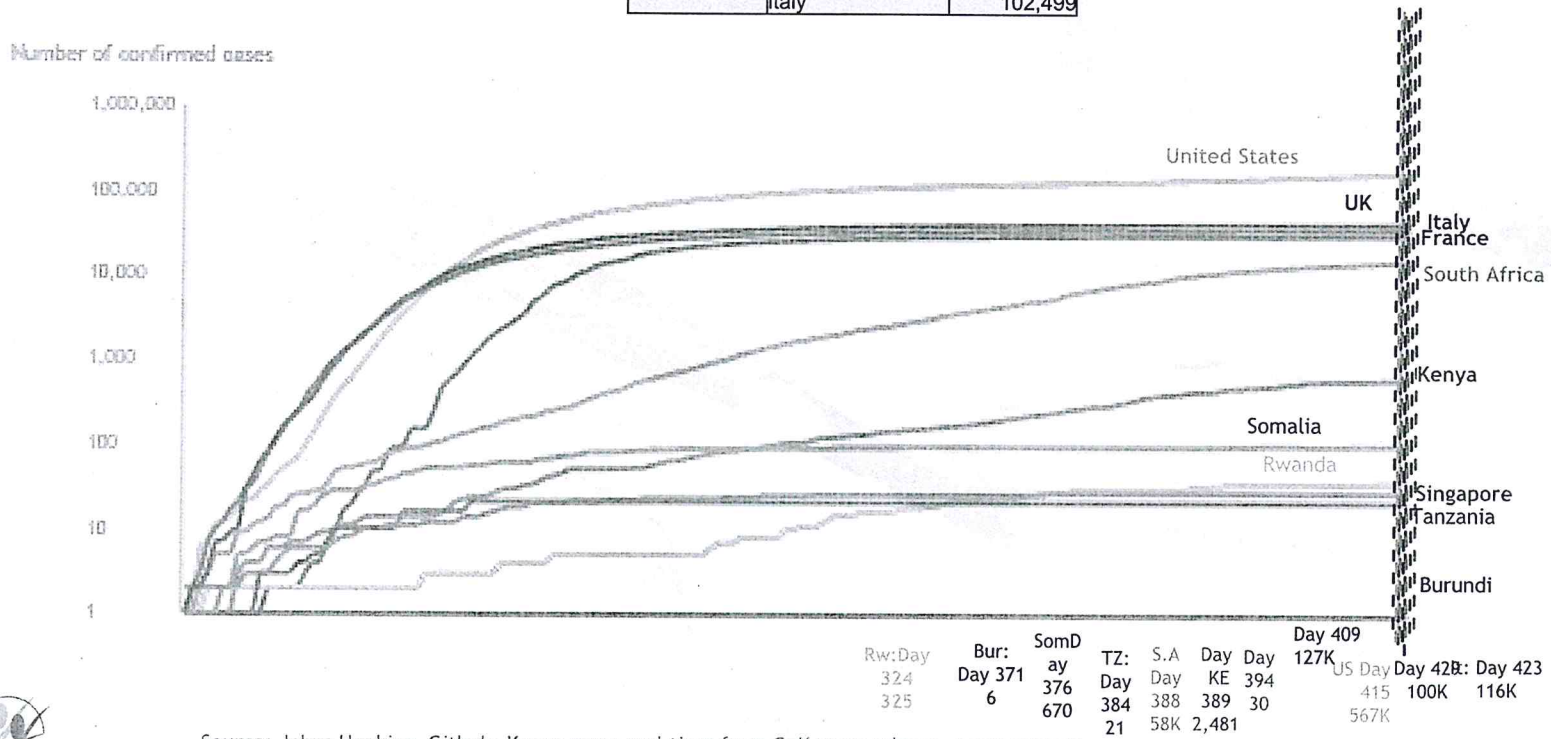
Source: Johns Hopkins, Github; Kenya more real time from GoK press release

Owner	KHF

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

Data as of 18th Apr
Kenya 19th 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



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

Data as of 18th Apr

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%

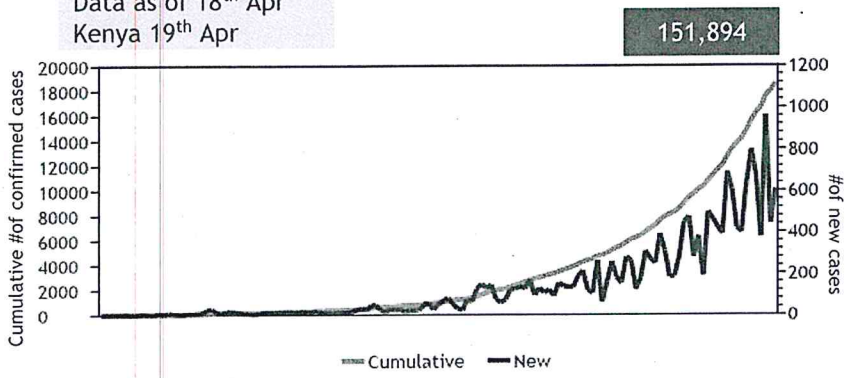
Kenya Healthcare Federation

KEPSA

Owner | KHF

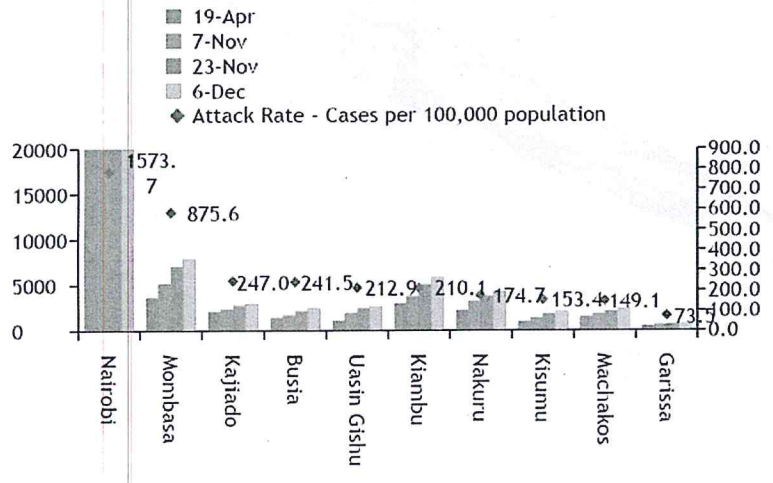
Cases by geography and testing data for Kenya

Data as of 18th Apr
Kenya 19th Apr

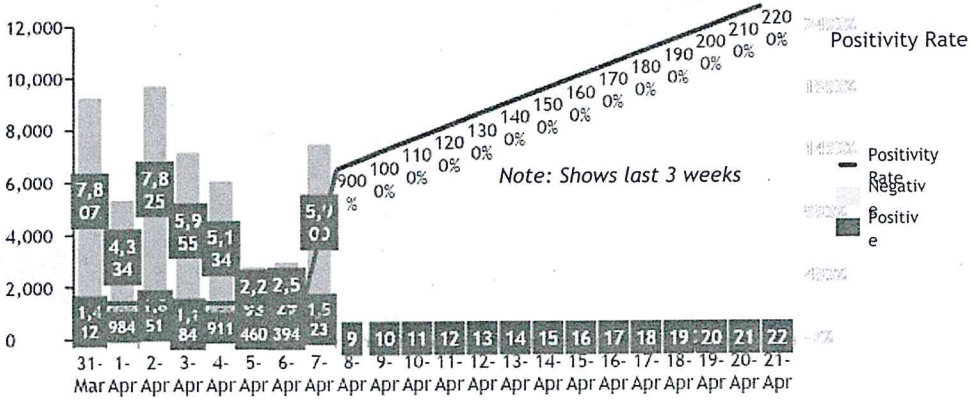


Metric	Cumulative	New	Comments
# confirmed cases	151,894	+241	As of 19 April
# confirmed deaths	2,501	+20	As of 19 April
# recovered	102,278	+636	As of 19 April
# tests completed*	1,605,847	+2515	As of 19 April

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



Total tests and positivity rate

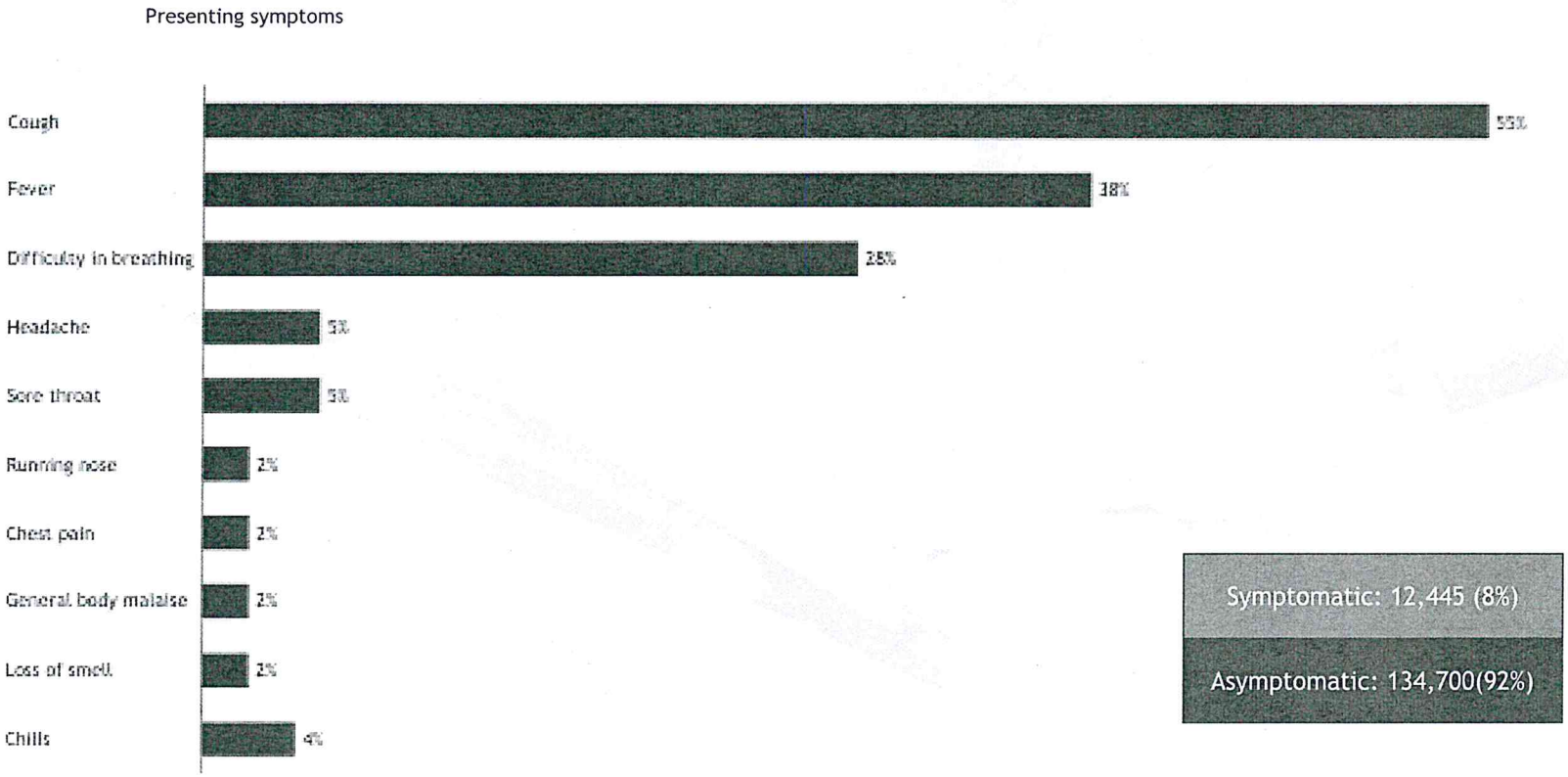


Source: Johns Hopkins, Github, GoK / NERC / MOH press releases

Owner | KHF

Distribution of presenting symptoms among symptomatic COVID-19 Cases

Data as of 18th Apr



Symptomatic: 12,445 (8%)

Asymptomatic: 134,700(92%)

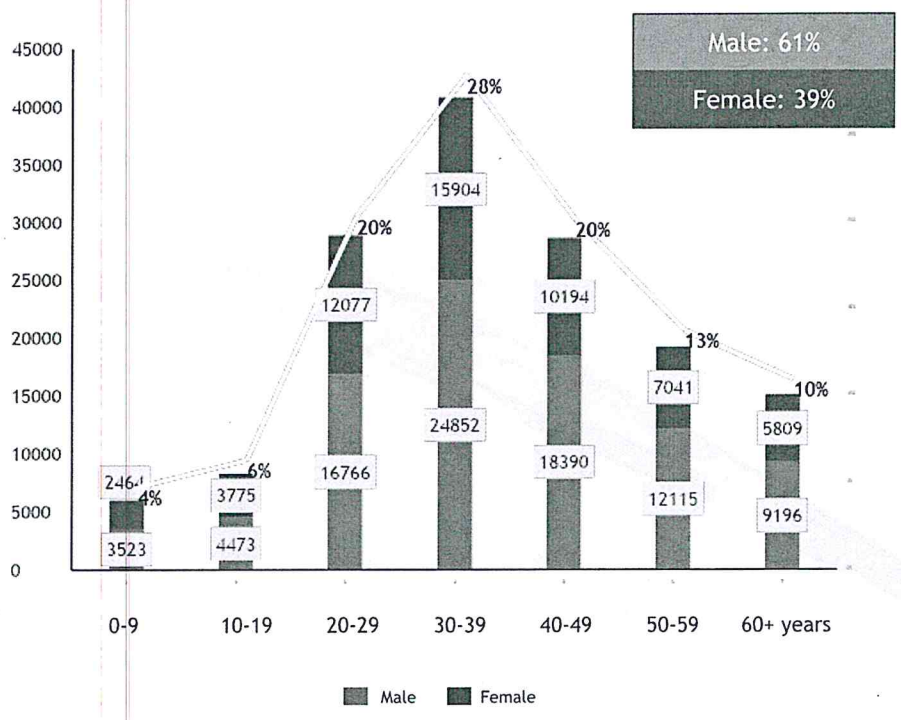
Source: GoK press release; KHF Analysis

Owner | KHF

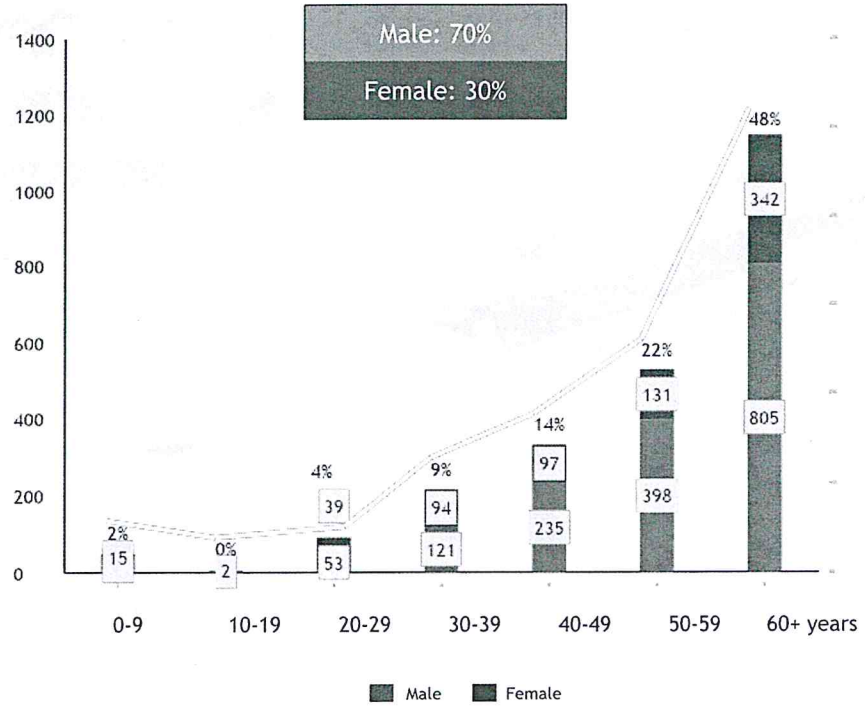
Distribution of cases and fatalities by age and sex

Data as of 18th Apr

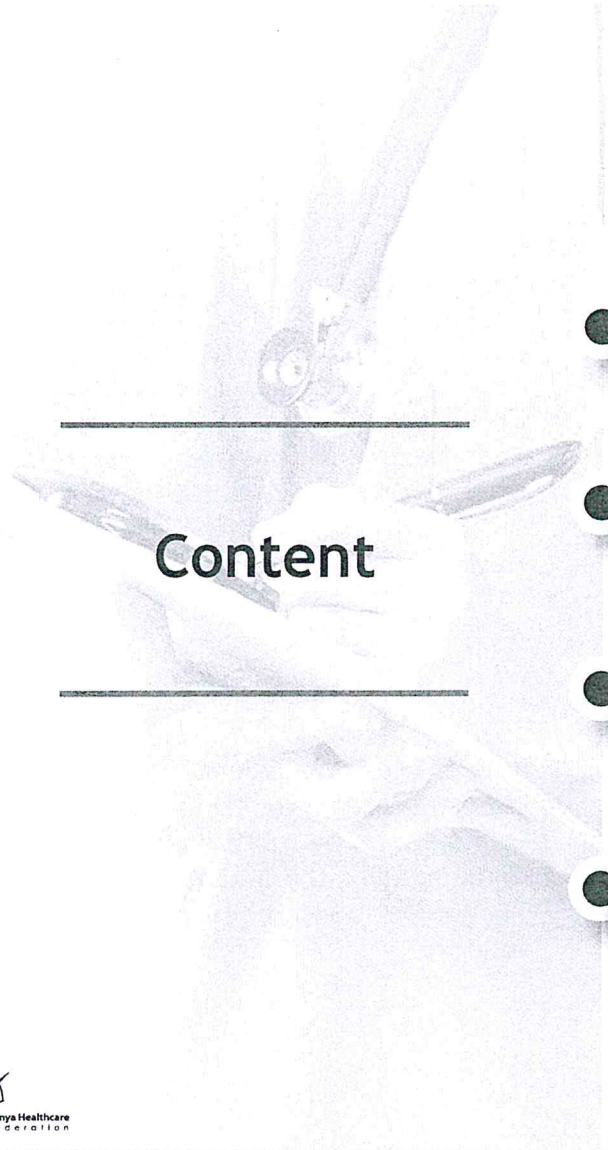
Case distribution by age and sex



Fatality distribution by age and sex



Source: GoK press release; KHF analysis



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Kenya Healthcare Federation

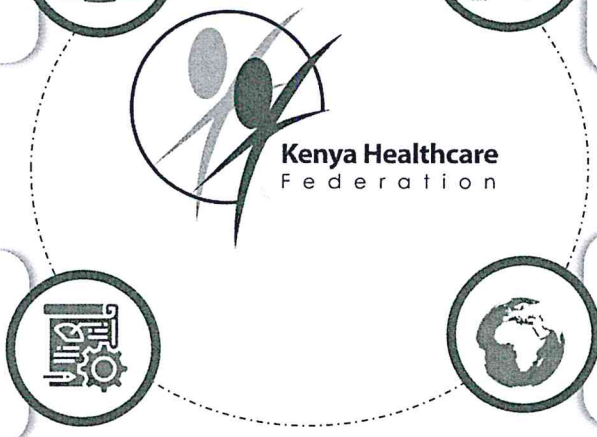
KEPSA

Owner KHF

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

Background
Global pandemic and rising levels in Kenya
3rd Wave and strain on the health system
Multi-stakeholder engagement critical

Current Landscape
Vaccine deployment plan sluggish / slow Over-reliance on COVAX
Communication strategy is weak
Hesitancy, Confusion and Angst



Visionary Roadmap approach
Increase vaccination pace and volumes
Save lives and livelihoods
Positioning Kenya for economic bounce back **Vaccines - for - all initiative** - LNOB

Role of the Private Sector
Importation and sourcing
Logistics and distribution
Administering the Inoculations*
Technology and Administrative support

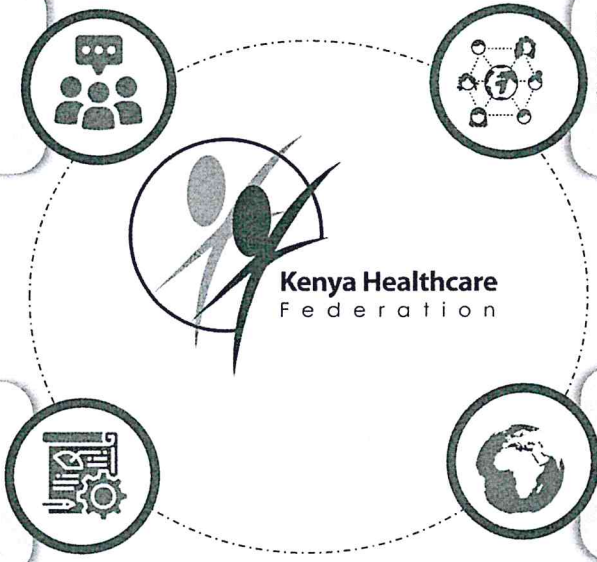
Owner KHF

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

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

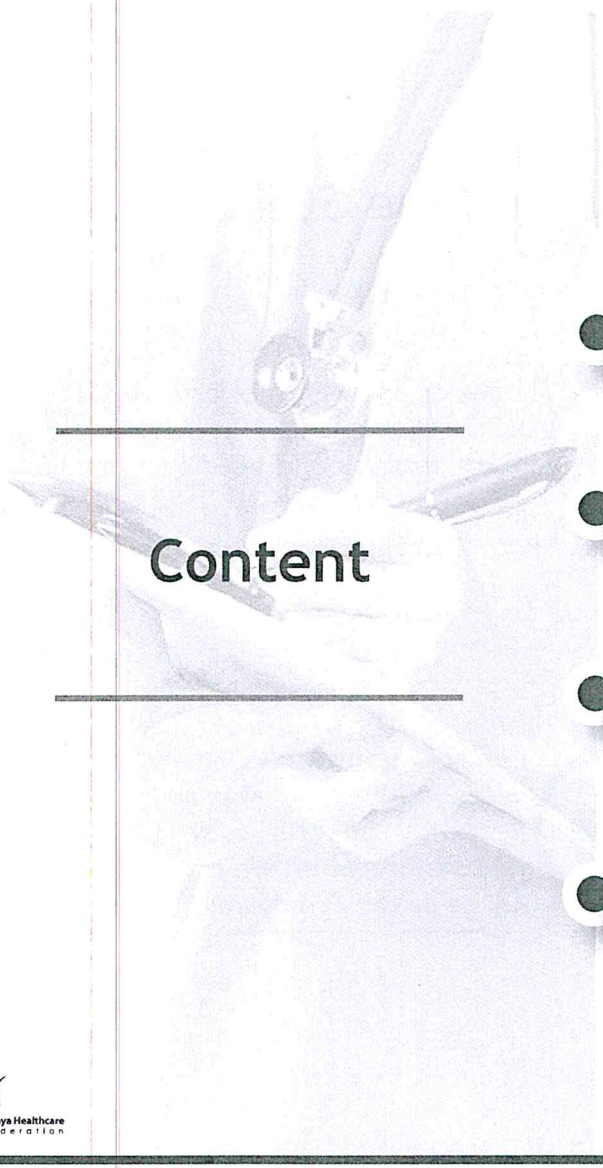
Administration of inoculations
Increase the accredited private sector facilities and consider a **dispensing fee.**
Improving the velocity

Logistics and Distribution
Utilize the expertise in private sector to **improve reach** and efficiency



ICT and Administrative support
Enhancing the Chanjo system
Communications and PR support
Supporting the global standards for ensuring travel and trade

Policy Framework - Review
In line with approval process by PPB / KMPDC
Currently imports by PS are banned (reconsider when we comply)
Agree of the **Framework of Engagement**



Content

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Kenya Healthcare Federation

KEPSA

THANK YOU!

Kenya Healthcare Federation

Visit our website:

Email us: 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,

19th April 2021

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

DINLAS PHARMA

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

MINISTRY OF HEALTH
RECEIVED
06 APR 2021
OFFICE OF THE PRINCIPAL SECRETARY
P.O. Box 30016 - 00100 NAIROBI

06th 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 8th April, 2021.

Awaiting your response.

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

DINLAS PHARMA EPZ LTD.
LR7149/121 SYOKIMAU, MOMBASA ROAD
P. O. Box 22661 - 00505 NAIROBI - KENYA
DATE: 06/04/2021

CC:

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