MINISTRY OF HEALTH

REPUBLIC OF KENYA

AFE Kenya Health Emergency Preparedness, Response and Resilience

P180127

Draft

Stakeholder Engagement Plan (SEP)

July, 2023

Table of Contents

List of tables

List of Figures

ABBREVIATIONS AND ACRONYMS

AfDB	-	African Development Bank
BCC	-	Behaviour Change Communication
CAJ	-	Commission for the Administration of Justice
CAS	-	Cabinet Assistant Secretary
CBOs	-	Community Based Organizations
CEC	-	County Executive Committee
CERC	-	Contingent Emergency Response Component
CoC	-	Code of conduct
CoK	-	Constitution of Kenya
COVID-19	-	Corona virus disease – 2019
CS	-	Cabinet Secretary
CSOs	-	Civil Society Organizations
ECSA-HC	-	The East, Central, and Southern Africa Health Community
ESF	-	Environment and Social Framework
ESIA	-	Environmental Impact Assessment
ESMP	-	Environmental and Social Management Plan
ESS	-	Environmental and Social Standard
FAQs	-	Frequently Asked Questions
FCDO	-	Foreign, Commonwealth & Development Office
GBV	-	Gender-Based violence
GRM	-	Grievance Redress Mechanism
HUTLCs	-	Historically Underserved Traditional Local Communities
IGAD	-	Intergovernmental Authority on Development
IPC	-	Infection prevention and control
KEMSA	-	Kenya Medical Supplies Authority
KMPDC	-	Kenya Medical Practitioners and Dentists Council
KNBTS	-	Kenya National Blood Transfusion Service
LMP	-	Labour Management Procedures
MOH	-	Ministry of Health
NACSM	-	National Advocacy, Communication and Social Mobilization
NERC	-	National Emergency Response Committee
NGOs	-	Non-government Organizations
OHS	-	Occupational Health and Safety
PAI	-	Project Area of Influence
PAPs	-	Project Affected Persons
PAS	-	Public Address System
PMT	-	Project Management Team
PWDs	-	Persons with Disabilities
SEP	-	Stakeholders Engagement Plan
VMG	-	Vulnerable and marginalized groups
WHO	-	World Health Organization
IEC	-	Information Education and Communication
OIP	-	Other Interested Parties

EXECUTIVE SUMMARY

Kenya continues to experience many hurdles in reaching the fundamental capacities required to successfully prevent, identify, and respond to public health emergencies, as shown by the COVID-19 pandemic. The fragmentation of public health institutional arrangements, organizations, and activities was noted as a bottleneck in pandemic preparation and response in the 2017 Joint External Evaluation of International Health Regulations core capacities. The fragmentation affects the various organizations involved in health security activities, which leads to poor coordination between them, exacerbates administrative and technical inefficiencies, and ultimately manifests as a decreased capacity to anticipate and address threats to public health.

The COVID-19 epidemic undid years of progress in poverty reduction and human capital accumulation. Out of a total population of 54 million[1], the poverty rate grew from 28.9 percent in 2019 to 41.9 percent in 2020, meaning that 22.6 million Kenyans live below the poverty line of US$2.15 per day. The pandemic interfered with the provision of important health and educational services, both of which are necessary for the development of human capital. The pandemic had a negative effect on the provision of crucial services, like as outpatient visits, screening and diagnostic services, and childhood immunization[2]. The disruption in the provision of essential health services has jeopardized the progress made toward achieving Sustainable Development Goal 3[3] and is an important reminder of why resilient health systems must be built in every country to deal with global health emergencies that go beyond simple preparedness and response.

The country's continuous drought has also made the situation with regard to food and nutrition insecurity worse, especially in the dry and semi-arid regions. There were 4.4 million people that needed humanitarian aid and were food insecure in February 2023, up from 3.5 million in July 2022. It is estimated that the affected population will gradually increase to 5.4 million people by June 2023. Due to the drought, 970,214 children between the ages of 6 and 59 months, 142,179 pregnant women, and nursing mothers are currently malnourished and in need of nutritional supplements.

These pandemics have reinforced the case for strengthening the preparedness, response, and resilience of health systems in Eastern and Southern Africa to public health emergencies. As a result the World Bank in collaboration with Intergovernmental Authority on Development (IGAD), The East, Central, and Southern Africa Health Community (ECSA-HC), partner states and other partners are implementing the AFE Health Emergency Preparedness, Response and Resilience MPA Program Development.

The aim of the proposed project, the AFE Health Emergency Preparedness, Response and Resilience Program MPA Development Objective (PrDO) is to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa. The proposed MPA will have four components, namely:

(i)   Strengthening the preparedness and resilience of regional and national health systems to manage HEs;
(ii) Improving the detection and response to HEs at the regional and national levels;
(iii) Program management; and
(iv) Contingent Emergency Response Components (CERC).

Each component describes a menu of activities that is supported under the overall MPA; however, in line with the objectives of an MPA, countries have the flexibility to choose or introduce relevant activities under the components, based on the specific country context and priorities, as long as they are well-aligned with the PrDO and the theory of change of the MPA.

---

1 https://www.populationpyramid.net/kenya/2022/
2 Lancet Glob Health 2022; 10: e1257–67 - www.thelancet.com/lancetgh Vol 10 September 2022
3 Delany I et al (2014). Vaccines for the 21st century. EMBO Mol Med 6:708–20.

This SEP will be complemented by the following project documents that have been prepared and consulted on during the consultations conducted on May 11, 2023:

- Environmental and Social Management Framework (ESMF);
- Labour Management Procedures (LMP);
- Environmental and Social Commitment Plan (ESCP).

STAKEHOLDER ENGAGEMENT

This stakeholder engagement plan (SEP) has been prepared by the Government of Kenya for the project to serve as a framework for meaningful dialogue, informing all project components, in line with the Constitution of Kenya 2010, Environment Management and Coordination Act, 1999 (amendment 2015) among other national legislations and policies, and the World Bank's Environment and Social Framework (EFS), and specifically Environment and Social Standard (ESS) 10,

The stakeholder engagement processes at Project preparation included the identification of the key stakeholders for the project. The identified project affected parties included local communities, community members and other parties that may be subject to direct impacts from the Project. Key stakeholders during project implementation include: (i) Beneficiaries and local communities hosting the projects where rehabilitation of facilities will be undertaken; (ii) Civil Society Organizations (CSOs) including Non-government Organizations (NGOs), Community Based Organizations (CBOs), Faith Based Organizations (FBO) and other non-state actors; (iii) Project Affected Persons (PAPs); (iv) users of healthcare facilities; (v) women and other vulnerable groups; (vi) implementing agencies including Ministries of Health, NQCL, KBI, PPB; (vi) Development partners such as African Development Bank (AfDB) and Foreign, Commonwealth & Development Office (FCDO) among others.

Stakeholder engagements have been conducted, mainly with staff of NQL, NQCL, KBI, PPB, MOH during the development of safeguards documents including ESMF and GBV action plan and ICWMP, LMP and SEP. The ESMF, SEP and the Environmental and Social Commitment Plan (ESCP), have been disclosed in draft for stakeholder consultations.

Further stakeholder engagements on the SEP are expected during.

- Discloser of finalized ESMF, SEP, LMP and ESCP
- Information dissemination to Communities, workers, National and County governments, CSOs on safeguards implementation
- Contact with the SCT Environmental and Social Project Management Experts

GRIEVANCE REDRESS MECHANISM

The SEP also includes a Grievance Redress Mechanism (GRM) available to all stakeholders and impacted parties. A GRM will be established by the Programme to provide a formal process for managing complaints from stakeholders (members of the public, employees, and partners) as provided under ESS10 of the WB ESF and the participating states national requirements. There are variety of international and domestic stakeholders who are involved in the project therefore there is need to create a systematic method of engaging stakeholders that is based on meaningful consultation and disclosure of pertinent information while taking into account the unique difficulties posed by COVID-19. The GRM will have open and inclusive channels for anyone impacted by Project operations to voice their complaints.

The Grievance Management Process will involve the following steps:

i). Grievance Reporting: through formal and informal channels, partners and national judicial system ;.

ii). Grievance Receipt and Logging: for centralized logging and tracking;

iii). Acknowledgement/ Recognition: the Grievance Manager to let the complainant know of the next steps.

iv). Screening and Validation of Complaint: to help determine eligibility, categorization, classification, and next steps including escalation;

v). Documentation of initial Grievance Response by Grievance Committee ;

vi). Communication and Agreement with Complainant of proposed solution an in a suitable manner and language (in person, by phone, or by email).

vii). Appeal Mechanism: for complainants who may not be satisfied with the resolutions.

viii). Implementation of Agreed Actions: through a procedure overseen by GRC.

ix). Review of Unsuccessful Approach: by the grievance committee to address any concerns.

x). Closeout: of satisfactory resolution, documenting and reporting to relevant stakeholders.
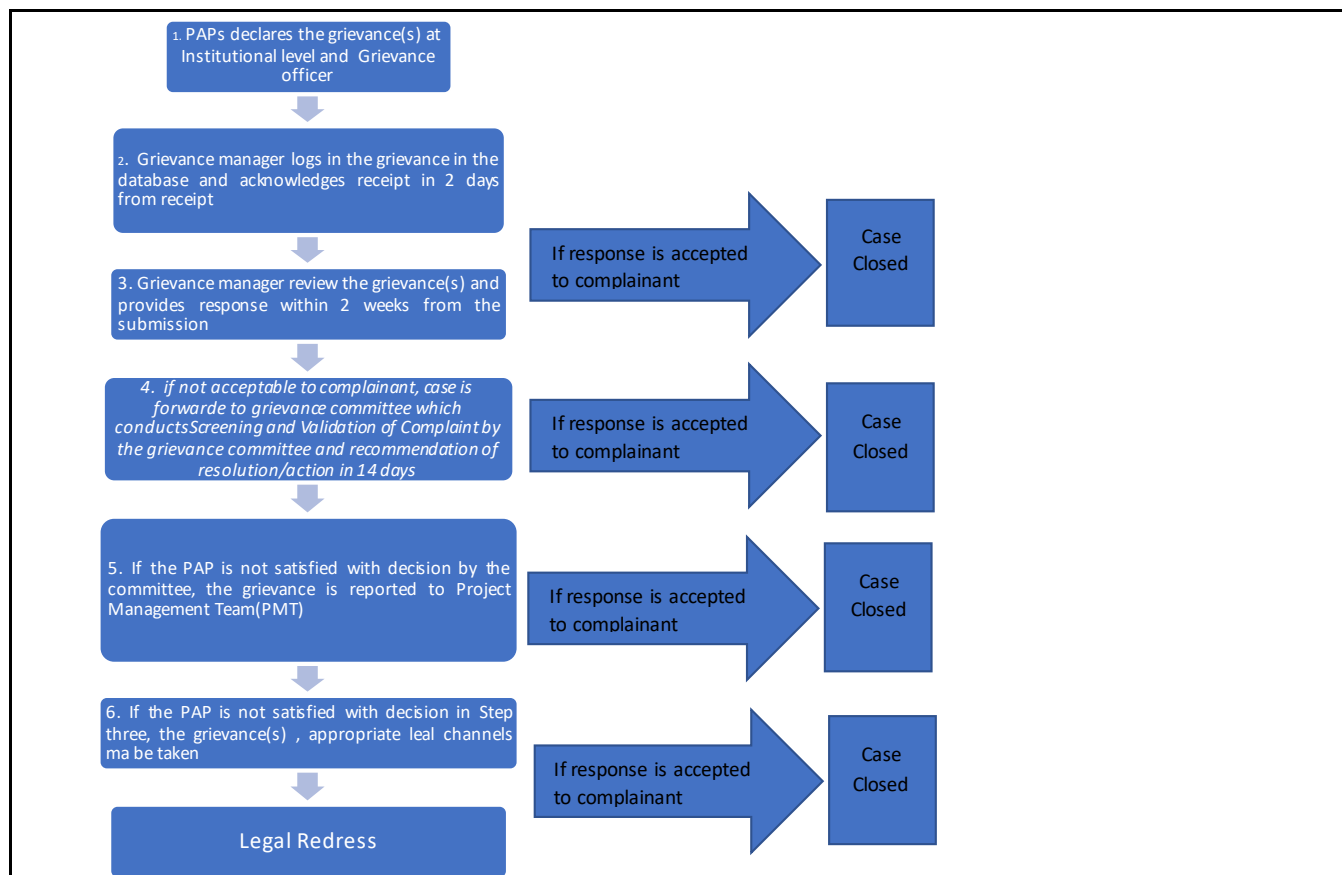
Figure 1: Summary of the GRM Process

MONITORING AND EVALUATION

The SEP will be periodically reviewed and modified as required to make sure that the information and interaction strategies are still pertinent and efficient in light of the Project's context and the pandemic's spread. Any significant alterations to the Project's operations or schedule will be properly represented in the revised SEP.

The programme will establish and maintain a database and activity file detailing public consultation, disclosure information and grievances collected throughout the program, which will be available for public review on request. Stakeholder engagement shall be periodically evaluated by the PIU. The following indicators will be used for evaluation:

xi). Bi-annual grievances received, speed of resolution and how they have been addressed; and

xii). Level of involvement and participation of stakeholders including project affected people (disaggregated by gender and vulnerable groups).

The project will prepare and regularly avail important information on to stakeholders (based on information need) including project implementation progress, actions on commitments made to various stakeholders and any new or corrected information since the previous report

1.0. INTRODUCTION

Kenya continues to experience many hurdles in reaching the fundamental capacities required to successfully prevent, identify, and respond to public health emergencies, as shown by the COVID-19 pandemic. The fragmentation of public health institutional arrangements, organizations, and activities was noted as a bottleneck in pandemic preparation and response in the 2017 Joint External Evaluation of International Health Regulations core capacities. The fragmentation affects the various organizations involved in health security activities, which leads to poor coordination between them, exacerbates administrative and technical inefficiencies, and ultimately manifests as a decreased capacity to anticipate and address threats to public health.

Despite geographic and economic disparities, the overall health status of Kenyans was on an improving trajectory before the pandemic. The population was estimated to be 47.6 million people as of the most recent census in 2019, with 65 percent of people living in rural areas and 36 percent living below the poverty level [4]. Kenyans' average lifespan had increased from an average of 63 years in 2013 to 67 years in 2020[5]. The mortality rate for children under five and infants decreased from 52 and 39 deaths per 1,000 live births in 2014 to 41 and 32 in 2022, respectively, in part because of enhanced primary care inputs and considerable advancements in the HIV/AIDS response. In addition to this, the country had also recorded improvements in childhood nutrition. The number of children aged below 5 years that are stunted was recorded at 18.0 percent, a decline from 26 percent in 2014. Overall, the disease burden had decreased, with mortality falling from 1,052 to 585 deaths per 100,000 people between 2000 and 2019, owing mostly to a reduction in the spread of communicable diseases[6]. HIV/AIDS, lower respiratory tract infections, diarrheal diseases, and malaria were the top 10 causes of death in 2019, despite a decrease in the incidence of communicable diseases. Neonatal abnormalities and non-communicable diseases (NCDs) had also made gradual but steady progress.

The COVID-19 epidemic undid years of progress in poverty reduction and human capital accumulation. Out of a total population of 54 million[7], the poverty rate grew from 28.9 percent in 2019 to 41.9 percent in 2020, meaning that 22.6 million Kenyans lived below the poverty line of US$2.15 per day. The pandemic interfered with the provision of important health and educational services, both of which are necessary for the development of human capital. The pandemic had a negative effect on the provision of crucial services, like as outpatient visits, screening and diagnostic services, and childhood immunization[8]. The disruption in the provision of essential health services has jeopardized the progress made toward achieving Sustainable Development Goal 3[9] and is an important reminder of why resilient health systems must be built in every country to deal with global health emergencies that go beyond simple preparedness and response.

Kenya's economy is also currently recovering from the COVID-19 outbreak after the decline in 2020. Real Gross Domestic Product (GPD) grew by 7.5% in 2021, and for the foreseeable future, it is anticipated to remain higher than the pre-pandemic average of 4.8%. Kenya is having trouble maintaining its economic recovery as a result of persistent shocks including the protracted drought and rising prices, even though growth prospects are still good.

The country's continuous drought has also made the situation with regard to food and nutrition insecurity worse, especially in the dry and semi-arid regions. There were 4.4 million people that needed humanitarian aid and were food insecure in February 2023, up from 3.5 million in July 2022. It is estimated that the affected population will gradually increase to 5.4 million people by June 2023. Due to the drought, 970,214 children between the ages of 6

---

4 Kenya Demographic and Health Survey 2022
5 World Bank Estimates: https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=KE
6 IHME. Global Burden of Disease 2019
7 https://www.populationpyramid.net/kenya/2022/
8 Lancet Glob Health 2022; 10: e1257–67 - www.thelancet.com/lancetgh Vol 10 September 2022
9 Delany I et al (2014). Vaccines for the 21st century. EMBO Mol Med 6:708–20.

and 59 months, 142,179 pregnant women, and nursing mothers are currently malnourished and in need of nutritional supplements.

These pandemics have reinforced the case for strengthening the preparedness, response, and resilience of health systems in Eastern and Southern Africa to public health emergencies. As a result the World Bank in collaboration with Intergovernmental Authority on Development (IGAD), The East, Central, and Southern Africa Health Community (ECSA-HC), partner states and other partners are implementing the AFE Health Emergency Preparedness, Response and Resilience MPA Program Development.

The aim of the proposed project the AFE Health Emergency Preparedness, Response and Resilience MPA Program Development Objective (PrDO) is to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa. The proposed MPA will have four components, namely:

i.   Strengthening the preparedness and resilience of regional and national health systems to manage HEs;
ii. Improving the detection and response to HEs at the regional and national levels;
iii. Program management; and
iv. Contingent Emergency Response Components (CERC).

Each component describes a menu of activities that is supported under the overall MPA; however, in line with the objectives of an MPA, countries have the flexibility to choose or introduce relevant activities under the components, based on the specific country context and priorities, provided they are well-aligned with the MPA PrDO and theory of change.

This SEP will be complemented by the following project documents that have been prepared and consulted on during the consultations conducted on May 11, 2023:

- Environmental and Social Management Framework (ESMF);

- Labour Management Procedures (LMP);

- Environmental and Social Commitment Plan (ESCP).

Project Components

The proposed AFE-HEPRR project aims to assist Kenya establish a robust emergency preparedness and response ecosystem through local human vaccine manufacturing and strengthening national public health institutions. The project has the following three components and sub-components:

Component 1: Strengthening Capacity for Local Manufacturing (US$ 70M). This component focuses on a phased implementation of four (4) key activities**.** In the first two years, the project will support the GoK to meet the prerequisites for vaccine manufacturing (sub-components 1.1-1.3). Most of these requirements are at an advanced stage and may be achieved earlier, however, the project will aim to fill any remaining gaps and ensure that Kenya Biovax Initiative (KBI) meets all the World Health Organization (WHO) requirements before proceeding to implement sub-component 1.4.

- Sub-Component 1.1: Human resources capacity, learning, development, and technology transfer
- Sub-Component 1.2: Strengthen the regulatory capacity of the pharmacy and poisons board (PPB)
- Sub-component 1.3: Strengthening quality control (QC)/Assurance

- Sub-component 1.4: Establishing capacity for Fill & Finish (F&F[10]) of human vaccines.

Component 2: Strengthening Capacity of the National Public Health Institute (NPHI). This component will build on support provided through the Kenya COVID-19 Health Emergency Response Project (CHERP) and KHEPRR will fund: (i) development of statutory instruments including organization structure, staff establishment report, and human resources and procedures manual; (ii) strengthening human resources capacity through training, learning exchange programs with a well-functioning equivalent institution; and (iii) development and application of a dedicated Information and Communication Technology system (ICT) which is linked to existing routine health information system among others.

- Strengthening of laboratory testing and genomic surveillance capacity
- Development and deployment of the Electronic Integrated Diseases Surveillance and Response Information System (eIDSR)
- Strategic stockpiles for preparedness and response
- Strengthening cross-border surveillance at Points of Entry (PoE)
- Establishment of system for health workforce surge capacity

Component 3: Project Management. This component concerns project implementation, i.e., planning, organizing, executing, controlling resources (e.g., people, budget, time, etc.) and monitoring to achieve specific goals and objectives of the project.

1.1. Project management

A project management team (PMT) formed especially for this Project will be in charge of project management. The PMT will make use of the mechanisms already in place to oversee the execution of ongoing initiatives, such as the Kenya COVID-19 Emergency Response Project (P173820) and the Transforming Health Systems for Universal Care Project (P152394). The MoH will need to do the following: (a) establish a special PMT; (b) designate staff with the necessary skill sets and hire on a case-by-case basis to cover skills gaps; (c) increase staff capacity; and (d) make resources available to carry out daily tasks.

The PMT will coordinate and oversee the prompt and efficient execution of the Project under the direction of a dedicated project manager. An Environment specialist and a social Specialist will be engaged in the PMT to coordinate the implementation of the safeguards. The MoH will relieve the personnel assigned to this PMT of all other obligations. The PMT will create quarterly financial and technical reports and deliver them on time to the World Bank.

An oversight committee will be formed by the MoH, with the Principal Secretary serving as its chair. A multisectoral oversight group will also be established to direct the implementation procedure. In order to guarantee that the project's goals are achieved, the PMT will collaborate closely with the oversight committee. M&E tasks will fall within MoH's purview. The MoH will: (i) gather and consolidate all relevant data for the outcomes framework; (ii) assess results; and (iii) give the PMT the pertinent performance statistics. Prior to each semi-annual oversight expedition, the PMT will be in charge of reporting outcomes to the World Bank.

2.0. PURPOSE OF THE SEP

Engaging with stakeholders is imperative to the success of any project. Key stakeholder opinions and insights are incredibly valuable in all stages of project planning and development. Stakeholder engagement facilitates hybrid

---

[10] F&F refers to the process of filling a container/unit (vial or syringe) with vaccine drug as quickly as possible. It entails the following: (i) receiving of bulk drug substance; intermediate bulk day storage; dilution of bulk /compounding /formulation; sterile filtration; filling and sealing; capping; inspection; labeling and manual packaging; intermediate cold storage.

views, promotes ownership and enhances the operating environment for the attainment of project goals. It is important to ensure that participation of stakeholders and the access to benefits is inclusive. The project objectives need to be understood, which necessitates the basis for clear and consistent communication especially to and from those who will affect or be affected by the outcomes of the project.

A stakeholder engagement plan is necessary for the AFE project to ensure compliance with the World Bank's Environmental and Social Framework (ESF) particularly Environmental and Social Standard 10 (ESS10). The overall objective of this SEP is to define a program for stakeholder engagement, including public information disclosure and consultation, throughout the project cycle. The SEP outlines the ways in which the project team will communicate with stakeholders and includes a mechanism by which people can raise concerns, provide feedback, or make complaints about the project and any activities related to the project. The involvement of all the stakeholders concerned is essential for the success of the project to ensure smooth collaboration between project staff, to minimize and mitigate environmental and social (E&S) risks related to the proposed project activities.

3.0. LEGISLATIVE AND REGULATORY FRAMEWORK
This section provides the legal basis for stakeholder engagement and public consultations as stipulated by country legislation and pertinent World Bank regulations.

All State organs, State officers, public officers, and all persons are bound by the Constitution of Kenya (CoK), 2010, and in particular Article 10 on national values and principles of governance whenever any of them apply or interpret the Constitution, enact, apply, or interpret any law, or make or implement public policy decisions to ensure human dignity, equity, social justice, inclusiveness, equality, human rights, non-discrimination, and protection of the marginalized. The rights of vulnerable groups, such as children, people with disabilities, young people, members of marginalized groups, and senior citizens, are covered by Articles 53–57. Additionally, Art. 69, 1(d), promotes public involvement in environmental management, preservation, and protection. The proposed MPA project will strengthen these efforts even more.

Section 6 (b) of the Environmental Management and Coordination (Amendment) Act (EMCA 1999, Amendment 2015) mandates the submission of documentation regarding public involvement in the development of policies and environmental action plans. Public engagement and project information sharing are mandated by the Environmental and Social Impact Assessment (ESIA) Guidelines and Administrative Procedures during ESIA processes. This will apply to the installation of waste management facilities, the construction of oxygen plants, and the conversion of healthcare institutions into isolation centers during the compilation of ESIAs for civil works under the project.

The ESS10 provides guidance on stakeholder engagement including on how to identify stakeholders and foster positive relationships with them, according to the World Bank's ESF. It highlights the necessity of evaluating stakeholders' support for the project and their interests in doing so, allowing for the inclusion of stakeholders' opinions in project design, promoting effective and inclusive engagement with project-affected parties throughout the project life cycle, and ensuring that the right project information is disclosed to stakeholders in a timely, clear, accessible, and appropriate manner.

4.0. STAKEHOLDER IDENTIFICATION AND ANALYSIS
Project stakeholders are defined as people, organizations, or other entities that: (i) are affected by the Project or are likely to be affected by it directly or indirectly, favorably or unfavorably (also known as "affected parties"); (ii) may have an interest in the Project (also known as "Other interested parties") - this category includes people or organizations whose interests may be affected by the Project and who may be able to influence the Project outcomes in some way; and (iii) disadvantaged and vulnerable groups that include persons who may be disproportionately impacted or further disadvantaged by the project as compared with any other groups due to their vulnerability and

that may require special efforts to ensure their equal representation in the project consultation and decision-making processes.

Identification of individuals within the groups who act as legitimate representatives of their respective stakeholder group—i.e., the people who have been entrusted by their fellow group members with advocating for the group's interests in the process of engagement with the Project—is necessary for cooperation and negotiation with the stakeholders throughout the Project period. Representatives from the community might offer valuable insights into the local context, serve as the major channels for the conveyance of project-related information, and serve as the key liaison between the Project and the targeted communities and their established networks. Verifying stakeholder representatives—that is, making sure they are authentic and sincere supporters of the community they represent—remains a crucial step in building relationships with the stakeholders in the community.

Legitimacy of the identified representatives can be corroborated casually engaging a sample of community members through FGDs and getting their views on who is best suited to represent their interests in the most effective way.

4.1. Methods

The project will implement the following stakeholder engagement practices to identify the best approaches and techniques for effective results:

a. ***Openness and lifecycle approach***: Public consultations for the project will be scheduled throughout its whole life, conducted in an open manner, and free from outside intervention, coercion, or intimidation;

b. ***Informed participation and feedback***: information would be made available to and extensively disseminated among all stakeholders in an acceptable format to enable stakeholders to take project advantages from a perspective of informed knowledge. There will be possibilities for disseminating stakeholder feedback, for assessing and resolving comments and concerns, and this is especially true for the vaccine intervention where community stakeholder engagements have shown[11] that there are misconceptions about the program among some community members.

c. ***Sensitivity and inclusiveness***: Stakeholder identification will be done to facilitate improved communication and establish effective relationships. The project's and its subprojects' participation procedures will be open to everybody. Participation from all parties will be encouraged during the consultation process. All interested parties will have equal access to information. The fundamental tenets that guide the selection of interaction strategies are sensitivity to stakeholders' demands and the requirement to guarantee that techniques employed don't expose people to COVID-19.

During stakeholder engagement special consideration will be given to women, youth, the elderly, residents of informal settlements, the urban poor, refugees, individuals living on the streets and people with disabilities (PWDs).

In order to ensure that historically underserved traditional local communities (HUTLCs) as defined in ESS7[12] , also known as traditional minorities or vulnerable and marginalized groups (VMGs), such as hunter-gatherers, forest dwellers, and nomadic pastoralists, are also included in the process, pertinent information and services will be provided in local languages and in culturally appropriate ways. In Kenya, the term "VMGs" is used to describe those organizations that meet the criteria for HUTLCs as defined by the World Bank. It is essential to note that the VMGs have not been impacted and may not directly benefit from the project at this point.

---

[11]CHERP, Report of Consultative Meeting Held with VMGs Community Representatives February, 2021.

[12]A distinct social and cultural group possessing the following characteristics in varying degrees: (a) Self-identification as members of a distinct indigenous social and cultural group and recognition of this identity by others; and (b) Collective attachment to geographically distinct habitats, ancestral territories, or areas of seasonal use or occupation, as well as to the natural resources in these areas; and (c) Customary cultural, economic, social, or political institutions that are distinct or separate from those of the mainstream society or culture; and (d) A distinct language or dialect, often different from the official language or languages of the country or region in which they reside.

The stakeholders of the proposed project(s) have been divided into the following three main categories in order to facilitate effective and targeted involvement:

a. **Affected Parties**: people, organizations, and other entities within the Project Area of Influence (PAI) who are directly impacted by the project (actually or potentially) and/or who have been identified as being most vulnerable to change associated with the project. These parties need to be closely involved in identifying impacts and their importance, as well as in decision-making regarding mitigation and management measures.

b. **Other Interested Parties:** Individuals, groups, or entities that might not directly be impacted by the Project but who believe or perceive that the Project will have an impact on their interests and/or who may have the ability to influence the Project and the process of its implementation.

c. **Disadvantaged and vulnerable Groups**: persons who may be disproportionately impacted or further disadvantaged by the project as compared with any other groups due to their vulnerable status and that may require special engagement efforts to ensure their equal representation in the consultation and decision-making process associated with the project.

4.2. Affected parties

These include local communities, community members and other parties that may be subject to direct impacts from the Project. Specifically, the following individuals and groups fall within this category:

- Beneficiaries and local communities hosting the projects where rehabilitation of hospitals will be undertaken;
- Civil Society Organizations (CSOs) including Non-government Organizations (NGOs)
- Community Based Organizations (CBOs)
- Faith Based Organizations (FBO) and other non-state actors;
- Project Affected Persons (PAPs);
- Users of healthcare facilities;
- Women, children, elderly and other vulnerable groups meeting the criteria specified in paragraph 8 and 9 of the ESS7;
- Ministries and Departments responsible for Health in national government and counties;
- Intergovernmental Authority on Development (IGAD);
- The East, Central, and Southern Africa Health Community (ECSA-HC);
- Development partners financing transport related projects such as African Development Bank (AfDB) and Foreign, Commonwealth & Development Office (FCDO)
- Ministry of Health (MOH) - Republic of Kenya
- Neighboring communities to laboratories and screening posts;
- Workers at construction sites of laboratories and screening posts;
- Healthcare workers;
- Waste collection and disposal workers;
- Security personnel;
- County governments, especially the Council of Governors (CoG) and County Executives (CECs) for Health;
- Other public authorities;

4.3. Other interested parties

The project stakeholders include parties other than those directly affected, including:
- Mainstream media;
- Participants on social media;
- Politicians;
- Religious groups/organizations

- Other national and international health organizations;
- Other national and international NGOs;
- Businesses with international links;
- The public at large;
- Other organizations involved in protection of human rights;
- Health workers' unions and associations, regulatory bodies; and
- Government oversighting Agencies e.g. NEMA, IPOA, DOSH, National Council for Persons with Disabilities (NCPWDs), National Gender and Equality Commission (NGEC), Kenya National Commission for Human Rights (KNCHR), among others.

4.4. Vulnerable and Marginalised groups

The vulnerable and marginalized groups in the project include women, illiterate people, people belonging to ethnic and religious minorities, elderly, children, people living in remote areas (marginalized areas, informal settlements), people with specific language/communication requirements (e.g. people with hearing impairment)

The communication techniques must be modified to account for these groups and individuals, ensuring a thorough grasp of the project's actions and advantages, and safeguard them from effects of diseases.

The findings from the national KAP Survey conducted by the communication and community health teams in 2021 will be useful in identifying any additional communication gaps for possible interventions by the Project. These include the overall effect of risk communication-channels (Radio, CHV, TV, religious meetings), language (especially for vulnerable and marginalized groups), understanding of MoH guidelines, community awareness and trust, and age of community members on vaccine acceptance/hesitancy, Other planned activities include: Focus group Discussions (FGDs) and Training of Trainers (ToT) on BCC with representatives from VMG communities and community outreach sessions across the country.

5.0. STAKEHOLDER ENGAGEMENT PROCESS

Stakeholder engagement is the process of working with stakeholders to develop new ideas, identify challenges and gaps, and determine how to handle possible constraints that may arise during or due to project implementation. All of this aids in meeting the needs and expectations of stakeholders.

This stakeholder engagement plan (SEP) has been developed in accordance with ESS10 requirements and will serve as a framework for meaningful dialogue, informing all project components. To ensure that strategies, mechanisms, platforms, plans, and systems for community engagement, community development, empowerment, and protection are developed based on full participation and engagement of stakeholders consistent with ESS10.

Stakeholder participation for the MPA will be critical to ensure consensus and timely implementation of activities, as well as monitoring and evaluation and access to project benefits. It will also be necessary to manage social tension and improve inclusiveness in project design, particularly for women and other underprivileged/vulnerable groups. This plan will be reviewed, discussed, and approved before being made public both in the country and on the World Bank website.

Planning for stakeholder involvement ensures that information is relevant, timely, and available to all relevant parties, considering the use of various languages, addressing cultural sensitivities, as well as issues resulting from illiteracy or impairments. The disparities of regions and socioeconomic classes would be similarly taken into consideration during the rollout of the activities under the subcomponents due to the anticipated countrywide implementation of activities. It is expected that meaningful engagement would result from appropriate timing and manner of engagement and an effective feedback mechanism that informs design and operations in the project. Additionally, effective stakeholder engagement, through the SEP, will result in fairness and equity among different groups.

5.1. Stakeholder engagements Techniques

These are the various ways that stakeholders will be involved throughout the course of the project. These measures will include information sharing initiatives to widen the scope for access to information about the project. The performance of the project will be motivated and improved by making information public. The creation of specific sub-projects and plans will be informed by engagement during implementation, when new activities are produced. There will be more interaction with stakeholders during implementation of the SEP. Different engagement strategies are suggested, each of which addresses a different stakeholder need.

1) Workshops - This workshops is prepared based on the project component/ subproject under consultation. Using a focused agenda will ensure that key strategic and risk items can be discussed with decision-makers and influencers to mitigate risk proactively. This tool will be used with both PAPs and OIPs.

2) Focus Group Meetings/ Discussions - The aim of a focus group is to bring together stakeholders with the same interests or common characteristics into a meeting to discuss specific topics or project components in a focused manner. For example, focus group methods may be used to explore issues that are relevant to specific stakeholders in the health sector.

3) Consultations in public/ community meetings- These will be mainly aimed at identifying and discussing stakeholder concerns and to disclose project information to both PAPs and to a lesser extent OIP. Such consultations will, wherever feasible, make use of local languages and be accessible (location, time, open invitation etc) to reach a broad range of groups and individuals within the region. Participation of both genders will be encouraged.

4) Formal meetings - Are meetings held with institutions and or organized interest groups to identify and discuss specific stakeholder concerns and to disclose project information. Participation in these meetings will be influenced by the issues under consideration and will include adequate representation of women as well as other marginalized and vulnerable people where possible.

5) One-on-one interviews – The interviews will aim to give chance to individuals (mainly leaders, representatives of various groups) to air concerns on project and will involve PAPs and OIPs depending on the issues to be addressed. Such meetings will be available to all the stakeholders concerned.

5.2. Stakeholder engagement during the preparation of the risk management instruments

The Project has been engaging stakeholders since September, 2022. This SEP incorporates progress achieved in the engagement of stakeholders including stakeholders input during the ESIA. Some stakeholders reached include relevant MoH Departments, NQCL, BioVax, PPB, and Community members.

Stakeholders consultations have been conducted with both implementing agencies and members of the public during project preparations. A total of 17 members (10 males, 7 females) participated in a consultation meeting on September 14 2022 during ESIA preparation for human Vaccine Manufacturing Facility at KEMSA warehouse in Embakasi with participants being local leadership, CITAM church representatives, KQ, and community residents. Further consultations were made with the staff of implementing institutions during the site visits on May 5, 2023 and with NASCOP on May 15, 2023. The objective was to gather comments, suggestions and concerns of the interested and affected parties within the neighborhood and create awareness among the public on the need for the ESIA for the proposed project

A stakeholder workshop was held on May 11,2023, to disclose the draft environmental, social risk management documents, and was attended by 33 participants from different agencies including NQCL, PPB, World Bank, MOH, United States Pharmacopeia, Kabarak University, Association of Medical Laboratory Scientific Officers, Kenya Association of Pharmaceutical Industries / GlaxoSmithKline, Institute of Primate Research, Federation of Kenya Pharmaceutical Manufacturers and KEMRI. Presentations and discussions were made about the risk management

documents including the ESMF, ICWMP, GBVAP Action plan, SEP and the LMP. Further presentations were made by the implementing agencies NQCL, BioVax, PPB, NPHI, which covered objectives of the project, roles of respective agencies in the project, the expected activities and challenges faced in healthcare service delivery. Overall, it was noted that there were important strides towards improvement of services with NQCL attaining prequalification by WHO (the only one in Africa). Key challenges include shortage of essential medical supplies, quality medicine to ensure safety of the users, Inadequate Staff affecting turn-around-times, lack of experts and infrastructure for analysis of vaccines and other biologics, old equipment and inadequate Information Communication Technology Infrastructure. Summary of the issues and responses are as tabulated.

A summary of the stakeholder engagements conducted during the project preparation ESMF / ESIA process, and key issues raised/ comments made is presented in Table and 2 respectively. The results of the stakeholder consultations have been incorporated into the design and the risk management documents.

Table 1: Summary of the Stakeholder Engagements Conducted during project preparation

Safeguard Instrument	Stakeholder	Mode of Engagement	Engagement Date	Venue
ESIA for Biovax Manufacturing Facility	Area chief, area OCS, the representatives of CITAM Church Embakasi, KEMSA, Kenya Airways and community members (the elderly, women, youth, people with special needs)	Public Baraza	September 14 2022	KEMSA, Embakasi Warehouse
ESMF, LMP, GBVAP, SEP, ESCP	Kenya Biovax Initiative (KBI)	Courtesy call and site inspection	May 5 2023	KEMSA, Embakasi Warehouse
ESMF, LMP, GBVAP, SEP, ESCP	Pharmacy and Poisons Board (PPB)	Courtesy call and site inspection	May 5 2023	PPB headquarters along Lenana Road, Nairobi.
ESMF, LMP, GBVAP, SEP, ESCP	National Quality Control Laboratory (NQCL)	Courtesy call and site inspection	May 5 2023	NQCL laboratory within UoN Pharmacy Department, KNH
ESMF, LMP, GBVAP, SEP, ESCP	Project beneficiaries, health sector practitioners, local healthcare products and products (HPTs) manufacturers	Meeting	May 11 2023	Mercure Hotel, Upperhill, Nairobi.
GBVAP	NASCOP Operations -Insights on progress of activities on GBV/SEA	Meeting-	May 15 2023	Virtual meeting

Table 2: Risk Management Instruments Public Consultation Outcome

Participant	Key Issue / Concern / Comment	Response
Human Vaccine Manufacturing Facility ESIA		
Participants-community members	• Liquid and solid waste treatment	• Biovax team will deploy a wastewater treatment plant, to treat all wastewater from the facility before discharging into the public sewer line. further autoclaving shall be done for vaccines to keep the environment safe. • For solid waste and any waste that requires incineration, Biovax will work with partners who are licensed to collect and dispose of the same safely. • Biovax shall renew effluent discharge license annually and this will ensure standards of wastewater from the system are checked before discharge
	• Integration of the proposed human vaccine manufacturing facility with other activities in the area	• The facility would be set up is an industrial zone, in conformance with the zonation laws of the area. futher, there would be synergy and partnership with institutions including KQ during importation of vaccines and other raw materials, contracting Bollore to offer transport and logistics and move vaccines from the airport to the manufacturing facility and manufactured vaccines from the facility to KEMSA go-down for storage. KEMSA to offer storage space prior to distribution and also give the distribution network for the manufactured vaccines
	• Continuous Stakeholder engagement	• Community residents recommended a need for continuous engagement especially through the annual environmental audits in order to monitor and evaluate the effects of project
	• Waste management and pollution prevention	• The community residents recommended that proponents should manage all sorts of waste from the facility responsibly to avoid polluting the environment.
	• Employment opportunities for Community members	• The community members requested to be considered for employment opportunities during the construction and operation of the manufacturing facility.
Billy, CITAM rep	• What sensitization channels will Biovax put in place to educate members of public about the vaccines and possible impacts to human health?	• Biovax team explained that Biovax Institute Ltd has a communications department that will disseminate information to members of public through various channels such as social media (Facebook and twitter) as well the print media and TV stations. Biovax will also have a website where they will post updates and information and live chats will be encouraged for members

Participant	Key Issue / Concern / Comment	Response
		of public to seek clarification on any matters to do with the vaccines.
Gatobu, KQ	• With growing population and demand of the vaccines locally and internationally, what plans does Biovax have as far as future expansion is concerned?	• It was explained that highly efficient machines make production faster. For start, the current space is sufficient since the machines will produce up to ten million vials per month. For future expansion, Biovax Kenya Limited will consider leasing the adjacent go-downs and negotiate with KQ for a possible purchase of part of their land. Biovax plans to venture into manufacturing of anti-venoms and vaccines against cancer in future.
Safeguards Instruments Disclosure (ESMF, ESCP, SEP, LMP, GBVAP)		
Dr. James Kimotho, KEMRI	• What is the project?	• The project is about strengthening Kenya's health emergency preparedness, response and resilience. It is implemented by KBI, PPB, NPHI and NQCL.
	• Limited capacity in waste management and there is need for capacity building	• Waste management is a critical component and capacity building on waste management will be key to avoid potential risks
Kari Mwanga, PPB	• There was limited consideration of Patient Safety, • Health Worker Safety and Quality of Care is not included in the presentations.	• This is noted and will be included in the ESMF.
Pauline, KNH	• What is the role of KNH in the project? • Appreciated the significant impact of microwave donated to KNH in management of clinical waste.	• KNH is one of the buyers of health products. • KNH can also help build capacity of the beneficiary institutions in healthcare waste management.
Dr. Peter Mburu, WHO	• Does the project budget include co-financing? • What is being done to avoid duplication of the project by other ongoing initiatives	• KBI is exploring co-financing options • There is no duplication of roles between PPB, NCQL, NPHI and KBI. KBI contributes to health systems strengthening by ensuring commodity security for vaccines and specialized health products and technologies. • MOH is the umbrella organization for the project and is charged with overall coordination, which would reduce chances of duplication and ensure connectivity between the different interventions and many players in the health sector. • Also Development Partners in Healthcare in Kenya (DPHK) are aware of the project.

Participant	Key Issue / Concern / Comment	Response
Dr. Mwai (USP)	• Is KEPI aware of the initiative to manufacture vaccines locally? During Covid-19 emergency, Kenya wanted to buy vaccines from Biovax but that was changed to Serum institute. • What is the sustainability mechanism in vaccine production? Any measures on transition of uptake of vaccines? Potential changes in procurement processes	• KEPI is aware and this explains why PPB wants to achieve Maturity Level 3 with human vaccine production. • Based on current progress, Kenya would have attained ML3 by December 2024, which is way ahead of GAVIs exit in 2027. • Further engagement with vaccine users' community is ongoing and the process will be quickened.
Abwao (PPB)	• Level of involvement of the association of local manufacturers and other sector players and initiatives	• prospective human vaccine manufacturers, including Moderna Inc., serve complementary roles. • Also KBI is indeed part of the association of pharmaceutical manufacturers.

5.3. Plan for Engagement

Table 3 outlines the plan for continuous stakeholder engagement during the implementation of the Project (i.e., in relation to the development of instruments and activities) and will be reviewed and updated throughout the lifecycle of the Project. During this process the focus and scope of the SEP may change to reflect the varying stages of project implementation and to encompass any changes in project design and lessons learnt from previous phases of the Project.

Table 3: Stakeholders engagement plan

Objectives	Target Stakeholders	Messages/Agenda	Means of Communication	Schedule/ Frequency	Responsibility
Project preparation					
Environmental and social risk assessment	Communities, MOH NQCL, PPB, BioVax, NEMA, CSOs	Inform of project, identify potential risks and impacts	FGDs, media	Once during ESIA	MOH-PMT/Consultant/NEMA
To present drafts and get stakeholders inputs on the following instruments: • Environmental and Social Management Framework (ESMF); • Stakeholder Engagement Plan (SEP) • Environmental and Social Commitment Plan (ESCP)	Communities, MOH NQCL, PPB, BioVax, NEMA, CSOs	a.) Present the Project – objectives, rationale, components, benefits and beneficiaries, implementation arrangements. b.) Indicative implementation schedule and period, project contacts. c.) Potential environmental and social impacts; measures for mitigation and	Presentation Reports-soft copies	once	MOH-PMT

Objectives	Target Stakeholders	Messages/Agenda	Means of Communication	Schedule/ Frequency	Responsibility
• Labour Management Procedures		management as per the ESMF. d.) Potential land requirements; process of land acquisition and resettlement; compensation and other resettlement assistance as detailed in the RPF. e.) Describe Grievance Redress Mechanism (GRM). f.) Present stakeholders identified and describe approach to stakeholder engagement. g.) Sets out measures, actions, plans, and			

Objectives	Target Stakeholders	Messages/Agenda	Means of Communication	Schedule/ Frequency	Responsibility
To disclose finalized ESMF, SEP, LMP and ESCP	Communities, MOH staff NQCL, PPB, BioVax, NEMA	• Email message to advise Stakeholders of disclosure and where to access the disclosed documents. Advertisement in the Newspaper • Disclosure of Project documentation in a culturally appropriate and accessible manner	Presentation Reports-soft copies	once	MOH-PMT
THROUGHOUT THE PROJECT (ALL COMPONENTS)					
Environmental and social audits	Communities, MOH staff NQCL, PPB, BioVax, NEMA	Establish project risks and impacts, challenges and lessons	FGDs, print media,website	Annual	MOH, PMT/consultant
Information dissemination	Communities, workers, National and County governments, CSOs	General information on project, activities	Website, print media, social media, local radio and Tv stations, public barazas	Continuous	MOH, PMT

Objectives	Target Stakeholders	Messages/Agenda	Means of Communication	Schedule/ Frequency	Responsibility
Contact with the ICT Environmental and Social Project Management Experts	MOH staff NQC, PPB, BioVax, NEMA	Maintain website with contact box for people to submit questions.	Website	continuous	PMT

The Project will continue to consult, plan, and execute in order to improve project outcomes. Project components will aim to engage stakeholders within the scope of their operations and populate stakeholder engagement data in the following format. Depending on the information demands of the stakeholders, the format may be modified. Throughout the project's duration, the social safeguards officers will keep a current repository of stakeholder engagement activities using the reporting matrix in Table 4. This table will be filled according to the format provided in Table 6.

Table 4: Stakeholder Engagement Reporting Format

Stakeholder Category	Stakeholder Target	Stakeholder attributes and responsibilities	Object of Engagement	Stakeholder contribution to the Project	Engagement Method	Date of engagement

5.3. Proposed Strategy for information disclosure

The project will employ safe information disclosure approaches to reduce exposure to potential risks. Focus group discussions (FGDs), internet platforms, the creation and distribution of Information Education and Communication (IEC) materials, home outreach utilizing regional focal points, and community consultations are all examples of this. Other channels will include local radio and TV stations. The COVID-19 protocols will be followed when community meetings or dialogues are held.

In order to guarantee that the various stakeholder groups have an opportunity to engage in the Project activities and gain from the interventions, it will be crucial to ensure the inclusivity and cultural sensitivity of the various activities. This will necessitate the use of many languages, verbal communication, or visuals rather than text, among other things. It is important to note that face-to-face meetings may not always be acceptable in all cases, and other means of communication will be used to reach key stakeholders including social media.

5.4. Stakeholder engagement process

The project consists of substantial resources to undertake stakeholder engagement activities. The Kenya Draft Health Sector RCCE Strategy, which embraces the WHO principles and National Risk Communication principles for Emergencies and Disaster Management, also covers the specifics of the methodologies to be used. The project will ensure that VMGs are included and that appropriate feedback mechanisms are set up and - functional including communication through their representatives, public barazas or community meetings.

As the project progresses and evolves, stakeholders will continue to be updated, including by reporting on project E&S performance and the adoption of the SEP and GRM which the public will find significant. The project's major milestones that must be met as part of this SEP are listed in Table 5.

Table 5: Milestones for the SEP

Project stage	Topic of consultation / message	Method used	Target stakeholders	Responsibilities
After appraisal - implementation	• Awareness of project scope • RCCE strategy	Virtual sessions, workshops, Key informant discussions, FGDs, community outreach sessions, media communications	Information users including affected parties (implementers, communities), other interested parties and VMGs,(PWDs, Women,	PMT Communications, safeguards officers

Project stage	Topic of consultation / message	Method used	Target stakeholders	Responsibilities
			Disadvantaged Persons, Communication and media experts,	
	Complaints management on service provision	Focal Persons logs and reports and national hotline, verbal reporting, complaint boxes, community outreach sessions, local leaders, partner grievance redress mechanisms	Receivers and users of information and services. Information or data managers.	MoH/PMT
	Emergency preparedness and response plan preparation- ERP Plan- importance, emergencies, responses and responsibilities	FGDs, Key informant interviews with technical staff and professionals, literature review	Communities including vulnerable groups, local leaders, staff of implementing institutions, CSOs	MOH/PMT, Consultant
Construction and operations phase-	Sensitization on the project, benefits and potential effects	FGDs, Key informant interviews with technical staff and professionals,	Communities including vulnerable groups, OIP (local leaders, CSOs), affected parties (staff, communities),	MOH/PMT, Consultant
Operations Phase	Environmental and social audits (Annual) to establish implementation of the ESMP, potential impacts	FGDs, Key informant interviews with technical staff and professionals, literature review	Communities including vulnerable groups, local leaders, staff of implementing institutions, CSOs	MOH/PMT, Consultant
	Occupation health and safety Audits (Annual) -on Implementation OHS plans and status of OHS risks, overall compliance	FGDs, Key informant interviews with technical staff and professionals, literature review	Affected (persons mainly Staff)	MOH/PMT, Consultant
	Fire safety audits-on Implementation fire safety plan, fire risks, overall compliance	FGDs, Key informant interviews with technical staff and professionals, literature review	Staff of implementing institutions, communities	MOH/PMT, Consultant
	Project evaluation Quarterly/annual, Mid- End-term evaluation and feedback survey Feedback on effectiveness and impact of project activities, challenges, lessons learnt	FGDs, Key informant interviews with technical staff and professionals, literature review, beneficiary survey and Direct observation of project subjects	Different stakeholders Affected parties, other interested parties, and VMG groups	MoH/PMT/ consultant

6.0. COMMUNICATION

Strategic communication to stakeholders including members of the public is critical in ensuring creating awareness on services, combating misinformation and myths and building public confidence in services and vaccines for optimal uptake and acceptance. The implementing agencies, other agencies of national and county governments will need to work with local partners and use trusted messengers and local champions/influencers to manage spread of misinformation.

Maintaining an accurate record of who is speaking for the Project, who is speaking on behalf of third parties, and what is being said by third parties are all aspects of managing and improving stakeholder relationships to each another. The following critical factors will direct the creation of communication messages and decisions regarding the channels to be employed;

a. The involvement of the affected parties in the Project Area of Influence (PAI) and community members in the design and dissemination of information;
b. Use of multiple channels of communication including radio, newsletters, social media, fact sheets, frequently asked questions (FAQs), etc. based on the needs and access requirements of the target audience. All documents will be presented in English, Kiswahili and other local languages as appropriate and will include visual depictions for non-literates;
c. Ability to communicate to a broad range of people, which will be ensured through the use of media that is easily understood, such as radio stations that use local languages and other forms of communication (sign language, braille and pictorials) that reach the particular groups of interest;
d. Sensitivity to GoK policies and regulations, the financiers (WB and others) and other communication requirements to safeguard the integrity of the process and the authenticity of the messages;
e. Evidence-based media engagement: the communication team will be required to monitor and evaluate the effectiveness of the information shared and the channels used, and adjust as necessary; and
f. Demand side and multiple stakeholder approach: at the community level and social mobilization activities will rally communities through: (i) engagement of key community influencers (religious leaders, clan leaders, local administrators). The plan will use a mix of multi-media approaches (e.g., health talks, chiefs' barazas, and community dialogue).

6.1. Targets, messages and communication channels

Table 6 lists the important parties who will be informed about the Project and its services, as well as their frequency of involvement and degree of interaction. It is noteworthy that the communication described here goes beyond the media usage during press conferences that are broadcast to all citizens. This list will be periodically evaluated and modified considering existing situations and developing communication needs.

Table 6: Communication Matrix

Stakeholder category	Specific stakeholder group	Message	Communicator	Delivery method	Schedule
Vulnerable groups	-residents of Informal settlements -VMGs/HUTLCs -Organizations for VMGs/HUTLCs -Women -PWDs	- Sensitization on safety measures and available health services Project performance -Sensitization on stigma associated with vaccines-grievance redress mechanism (GRM)	-Health officers -Promotion team -CEC for health -Implementing partners (with local networks)	-community meetings -Fact sheets -Radio -TV -Posters/flyers* -PAS	Annually, On-need basis

Stakeholder category	Specific stakeholder group	Message	Communicator	Delivery method	Schedule
Healthcare workers	All cadres including CHWs	-Vaccination drives and plans - safety protocols (Personal, institutional) -IPC -GRM for workplace - -Update on protocols -Status of infection in the country	-Acting Director of Health -Chair KMPDC -Chair of the relevant councils, unions and associations -County teams	-Update reports on WhatsApp -Webex/zoom meetings -In-person briefings -Workshops/ trainings sessions	Regularly and on-need basis
MoH	The entire health system	-Update on protocols -Vaccination drives and plans -Information on KHEPRR progress and risk management requirements	CS, CAS, PS and Director of Health, PMT	-Update reports on WhatsApp -virtual meetings -In-person briefings -Workshops	Monthly and on-need basis
National coordination teams	National Emergency Taskforce National Emergency Response Committee (NERC)	-Country needs/ emerging challenges -Citizens' perceptions and complaints mechanisms -Country progress on vaccination and vaccines production -Updates on protocols	CS, CAS, PS and Acting Director of Health	-Update reports on WhatsApp -Online meetings -In-person briefings	Daily and on-need basis (e.g. during a crisis)
County Governments	County Governors, CECs for Health, Project Focal Persons, Healthcare facilities	-County status on vaccine supplies -County preparedness -Challenges -Complaints and grievances - Community concerns -KHEPRR scope and safeguards requirements	- NERC -CoG -MOH including PMT	-Update reports on WhatsApp -Online meetings -Virtual monitoring tools e.g. GEMS -Workshops	Daily and on-need basis
Public Authorities	Ministry of Interior and Coordination of National Government (Department of Interior, Police Service Commission, NYS)	-Update on protocols -Safety measures -Referral pathways -Security safeguards measures	-NERC -MoH	-Update reports -Protocols -Online meetings -Workshops	Weekly and on-need basis
Health community – local and global	Africa CDC, WHO, World Bank and other key partners	-Country progress - emerging Country needs/ challenges -Global trends	-National Taskforce on Emergency Response	Update reports	On need basis
Organizations responsible for Environmental	NEMA	-Sub-Projects compliance with ESMP, NEMA conditions and processes	MOH	-ESIA/Audit reports -Site supervision visits	sub-Project screening and

Stakeholder category	Specific stakeholder group	Message	Communicator	Delivery method	Schedule
and social risk management					supervision visits
	Department of Labour	- compliance to the National Employments Act	MOH	-Virtual meetings -Site supervision visits	During sub-project supervision visits
	NCPWDs	- compliance with accessibility rights for PWDs	MOH	-Virtual meetings -Update reports -Consultative sessions -Supervision visits	During sub-project supervision visits
	Organizations for VMGs/HUTLCs (State Dept. for Social Protection, Youth, Gender, NCPWDs and related NGOs)	-health services, Inclusion for VMGs/HUTLCs -GRM	MOH	-Update reports -Virtual meetings -Consultative sessions	Annually, On need basis
	Primary project suppliers, Contractors and contractor workers	-Sub-project designs requirements -Environmental and social risk management -GRM	MOH	-Bid documents -presentations -Supervisory visits -	At the start and throughout Contract period
	NGEC, DCS, NPS, CID, Judiciary, Ministry of Gender, other relevant Government Agencies and NGOs	- GBV/SEA activities and integrated GBV approaches, Access to services	MOH	-Consultative sessions -Training sessions	On need basis
Resource institutions	The National Treasury, World Bank,	-Project performance -Resource utilization -Resource gaps	MOH/PMT	-Progress updates and reports	Quarterly
Parliament	Parliamentary Departmental Committees for Health (National Assembly and the Senate)	Project performance -Resource utilization -Resource gaps	MOH	-Committee meeting sessions -Parliamentary briefs -Letters	Annually, On need basis
Media Organizations	Print, TV, radio	-Project scope and services -Success stories	MOH	-Media Briefs, Newspaper Pull outs	On need basis
KNBTS	National Office and Regional Blood Centers	-Risk management requirements	PMT	-Virtual/meeting session	On regular basis

6.2. Communication escalation process

Depending on the size, scope, and quantity of the project, communication can be a very complicated procedure. The key stakeholders can better comprehend the stages involved in exchanging Project information thanks to the

flowchart shown in Figure 1. It should be noted that there might be times or circumstances that do not fit into the communication flowchart when more explanation is required. In these circumstances, it will be the Principal Secretary's (PS) responsibility to discuss the issues with the PMT and make a decision on how to proceed.
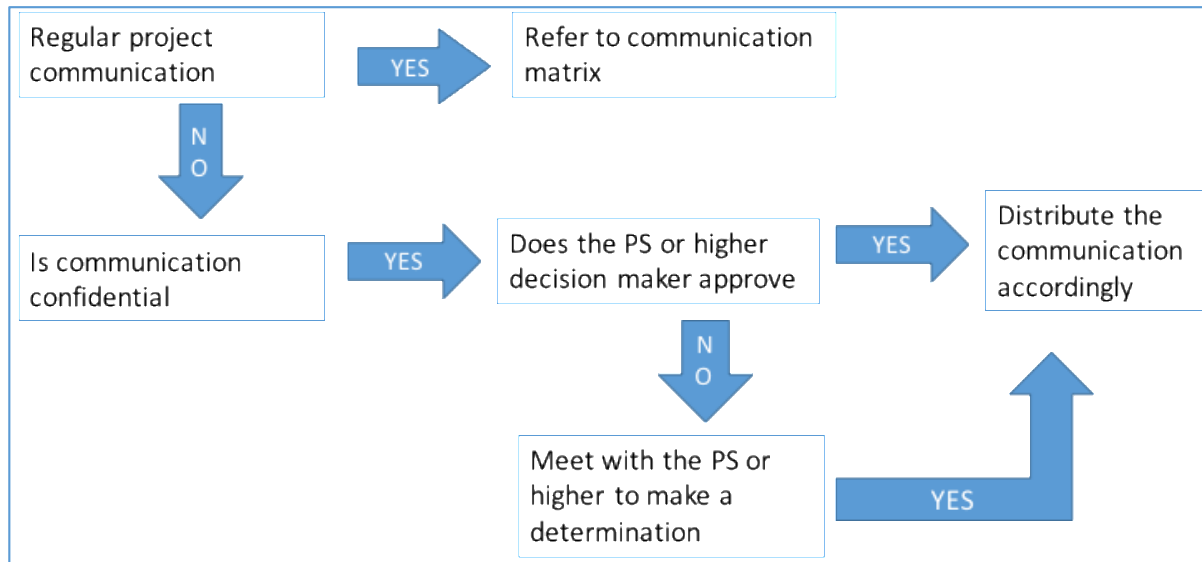

Figure 2: Project communication flow chart

The communication team will routinely evaluate and improve the communication plans. The preferred information sources, best communication methods, and public impressions of the SEP will all be indicators included in the SEP monitoring tools.

6.3. Methods of public disclosure of project information

Disclosure of project information allows stakeholders to have informed knowledge of project scope and benefits and enable them to raise any concerns they may have regarding the project. The process may comprise submitting any relevant information that might be considered for project enhancement. Tables 6 provide that Project Appraisal Document, ESMF, LMP, and SEP will all be disclosed on the MoH and WB websites.

Table 2.2: Schedule of disclosure of project documents

Project stage/timelines	Target stakeholders	List of information to be disclosed	Methods and timing proposed
Before appraisal	Health stakeholders and the general public	SEP ESCP ESMF LMP	*WB and MOH website*
Within six months of effectiveness	All Stakeholders identified above	Updated SEP, LMP and ESMF	*WB and MOH website*
Quarterly	Implementing partners	Project scope, Progress report including summaries of complaints and resolution	*WB and MOH website*
Before key activities	Key stakeholders for specific activities	ESIA or ESMP	*WB and MOH website*

Project stage/timelines	Target stakeholders	List of information to be disclosed	Methods and timing proposed
Annual	General public	Annual report on progress and lessons learnt	*WB and MOH website*

7.0. Resources and Responsibilities for implementing stakeholder engagement activities

a. Resources

The MoH will be the main implementing agency for the project and will lead the execution of project activities, including this SEP. The SEP and GRM should be referenced when developing the detailed workplan. Adequate resources will be provided for the implementation of the SEP. information or questions about the project and overall consultation process can be sought from the Head PMT

b. Management functions and responsibilities

The project will be managed by the PMT. The MoH will be required to: (a) sustainably strengthen the PMT with staff with appropriate skills and social specialist will be assigned to the PMT); (b) build staff capacity; and (c) make resources available to conduct day-to-day functions. The Ministry may also get staff from other Ministries on secondment to augment the capacity of the PMT. The project has a dedicated PM with overall responsibility for effective implementation of the activities. The PMT will prepare quarterly financial and technical reports and submit them to the World Bank within the stipulated timelines. All stakeholder engagements will be documented, tracked, and managed (for example by stakeholder database, commitment register among others). Communication officer will be hired to implement communication campaigns.

c. Budget for implementation of the SEP

Table 7.1 presents a list of proposed costed activities for the implementation of the SEP and an estimated budget.

Table 7.1: Estimated Stakeholder Engagement Budget

No.	Activity	Timeline	(Approx KShs)	Responsible
1.	Project awareness and consultation sessions	Once and on need basis	15,000,000	PMT
2.	Sensitization/training on GRM and other safeguards requirements (Contractors, contractor worker, county Government and health facilities)	Contractors during contracting and on quarterly basis	10,000,000	Social specialist
3.	Printing and Distribution of GRM logs/ registers	annually	3,000,000	Social specialist
4.	Information, Education and Communication materials (IEC materials, translations, media costs)	Annually, on need basis	30,000,000	MOH and PMT Communications Team
5.	Updating of SEP	Annually, On need basis	3,000,000	PMT
6.	Monitoring of SEP activities	Biannual	7,000,000	PMT
			68,000,000	

8.0. GRIEVANCE REDRESS MECHANISM

A grievance is an issue, concern, or claim (either perceived or actual) that an individual or community group wants addressed or resolved by the programme. These may include complaints of impacts, damages or harm caused by the project or related activities during construction, operation, or decommissioning phase.

In accordance with ESS10 of the WB ESF and the national regulations of the participating nations, a GRM will be formed by the project to provide a formal process for handling grievances from stakeholders (the general public, employees, and partners). For the mechanisms to be effective, they must be clear, gender-responsive, culturally acceptable, easily available, cost-free, without retribution, and with an appeals process. All complaints will be promptly recorded, examined, addressed, and closed.

A carefully planned out and implemented complaints handling mechanism greatly improves operational efficiency in a number of ways, such as increasing public awareness of the project and its goals, preventing fraud and corruption, reducing risks, giving project staff useful suggestions/feedback that enables them to be more accountable, transparent, and responsive to beneficiaries, evaluating the efficiency of internal organizational processes, and increasing stakeholder involvement in the project. In order to protect the project's finances and reputation, a successful GRM can assist in identifying issues before they get more serious[13]. The GRM specifically:

a. Provides affected people with avenues for making a complaint or resolving any dispute that may arise during the course of the implementation of a project;
b. Ensures that appropriate and mutually acceptable redress actions are identified and implemented to the satisfaction of complainants;
c. Ensures compliance with laws and regulations and reduces exposure to litigation and the need to resort to judicial proceedings.
d. Ensures prompt, consistent, and respectful receipt, investigation, and response to complaints.
e. Ensures proper documentation of complaints and implementation of actions.
f. Contributes to continuous improvement in performance through lessons learned.
g. Enhances trust and positive relationships with stakeholders; and

The project will incorporate a GRM as a crucial component for successful delivery of the components. The PMT will prepare a simple booklet, with easily understood illustrations, explaining the GRM as applicable all the stakeholders of project. The booklet will include details of how, when and where to report/ handle grievances. This booklet will be disseminated to all key project stakeholders including direct workers.

8.1. Grievance Management Process

a. The Social specialists will receive and document complaints on behalf of the PMT. Complaints received will be channeled to the Project Component Leads who will liaise with the User Departments to ensure that the respective complaints are resolved and feedback channeled to the complainant. The Social Specialists will table summary complaints during biweekly PMT meeting to discuss and deliberate on any outstanding complaints (including any general PMT staff concerns). Membership of the bi-weekly PMT meeting will comprise of: the Project Manager, Deputy Project Manager, Component Leads, Procurement Officer, Internal Auditor, Accountant, M&E Officer, Environmental and Social specialists, Project Finance Officer, Communication Officer and Project Administration Officers. Minutes of the meetings will be kept and action points summarized for ease of follow-ups. Any preliminary investigation should take place within one

---

[13] Adapted from:
http://documents.worldbank.org/curated/en/342911468337294460/pdf/639100v10BRI0F00Box0361531B0PUBLIC0.pdf

month of the committee meeting. All formally raised complaints require feedback to the complainants within 4 weeks (28 days) of a decision being made.

b. For informal complaints, i.e. those raised through social media, print media or not formally lodged, the committee should deliberate upon them to decide whether to investigate them based on the substance and potential impact/reputational risk to the MoH and the World Bank.

c. If the complaint should be referred to the government's legal complaints structures (e.g. EACC, CAJ, etc.),

d. Complaints regarding GBV/SEAH should be kept confidential, the name of the complainant should not be recorded, only the age and gender of the complainant, and whether a project worker was involved. The complaint should be sent directly to the PM who should immediately inform the World Bank.

e. No disciplinary or legal action will be taken against anyone raising a complaint in good faith.

f. A quarterly report of complaints resolution should be provided to the World Bank (as per the reporting format in Annex 2).

Grievance management process steps:

1. *Grievance Reporting*: The project will offer a number of formal and informal channels in addition to those of partners and the national judicial system for reporting occurrences, complaints, or grievances. Some of the channels are GRM focal point persons and programme officials, in person visits to the MoH offices, health facilities, and county offices, letters to the Ministry's postal office box (county level, facility and national levels), Email addresses for grievance receipt and the whistleblowing portal and email. Each implementing agency should provide for the channels. For greater accessibility, the channels will be published and publicized, including on the websites and social media platforms for the program.

2. *Grievance Receipt and Logging*: For accountability purposes as well as to make it possible for continuous monitoring and learning, centralized logging and tracking is essential. Any complaints that are received through one of the methods must be shared with the grievance manager within 48 hours so that they can be included in the database. The database will be kept, and updated regularly with information on the decisions made, the status of the complaints, and timeline compliance.

3. *Acknowledgement/ Recognition*: The Grievance Manager will acknowledge receipt of a complaint and let the complainant know that it will be logged and checked for eligibility. When a complaint is received verbally, it will be acknowledged verbally. When a complaint is received by email or through a whistle-blower channels, it will be acknowledged in writing, either via a standard letter or email. In any case the acknowledgement shall be within two (2) days of grievance receipt.

4. *Screening and Validation of Complaint*: The received grievances will go through a screening procedure that will help determine eligibility, categorization, classification, and further steps to be taken, including escalation to the appropriate/relevant office within two (2) weeks.

   Eligibility of the grievance will be determined by:

   i. The nature of the claim, including its potential to have an adverse economic, social, or environmental impact.

   ii. Whether the complaint details the specific damage or harm that has happened or could happen, as well as how the Project has contributed to or could contribute to that impact.

   iii. If the person making the complaint has been impacted, is at risk of being impacted, or is a representative of the stakeholders who have been impacted or who could be impacted,

   If there is sufficient data to make decisions regarding the preceding three issues The Grievance Manager will then provide feedback to the complainant, which may include;

   - Request for more information if information provided is insufficient.
   - Referral to relevant partners if ineligible under the project.
   - Action taken and next steps, if eligible.

5. Initial Grievance Response: The Grievance Committee will provide recommendations on how to resolve the grievance, which will be recorded and stored in a database. The appropriate response is to either: i) resolve the issue locally - relevant stakeholders (from the escalation matrix) may take direct action to resolve the complaint; or ii) request an investigation to gather more data - additional assessment to ascertain what occurred, the causes, responsible parties, and actions to mitigate and prevent future recurrence. This process and communication will be in two (2) weeks of receipt of the grievance by the committee.

6. *Communication and Agreement with Complainant*: The Grievance Manager will inform the complainant of the proposed solution in a suitable manner and language (in person, by phone, or by email). Every correspondence must be documented, dated, and include space for the complainant to respond and sign off.

7. *Appeal Mechanism:* The project GRM provides an appeal mechanism for complainants who may not be satisfied with the resolutions by implementing Agencies', facilities, PoEs and county focal persons. Where the complainant challenges the suitability of a finding, rejects a proposed action, or is not keen on participating in the process. The grievance manager will inform the complainant of available alternatives, whether through the judicial system or other administrative channels, and clearly document the decision taken by the complainant and the reasons. The decision on appeal will be communicated within one (1) week of receipt by the PMT.

8. *Implementation of Agreed Actions:* When a complainant and the grievance manager agree to move forward with the agreed action, the grievance manager will oversee the inquiry while the response will be carried out through a procedure overseen by GRC. Agreed actions will be implemented within timelines identified in the grievance resolution.

9. *Review of Unsuccessful Approach*: If the proposed response by the facility, county is unacceptable to the complainant, the grievance committee will discuss and review the issue and consider whether a change to the proposed response could address the concerns of the complainant. The Grievance Manager will let the complainant know about other channels, such as using legal or other administrative channels for resolving disputes.

10. *Closeout*: The final step is to close out the grievance. If the response accepted by the complainant, the Grievance Manager will document the satisfactory resolution and report the results to relevant stakeholders. This feedback shall be captured in the database.
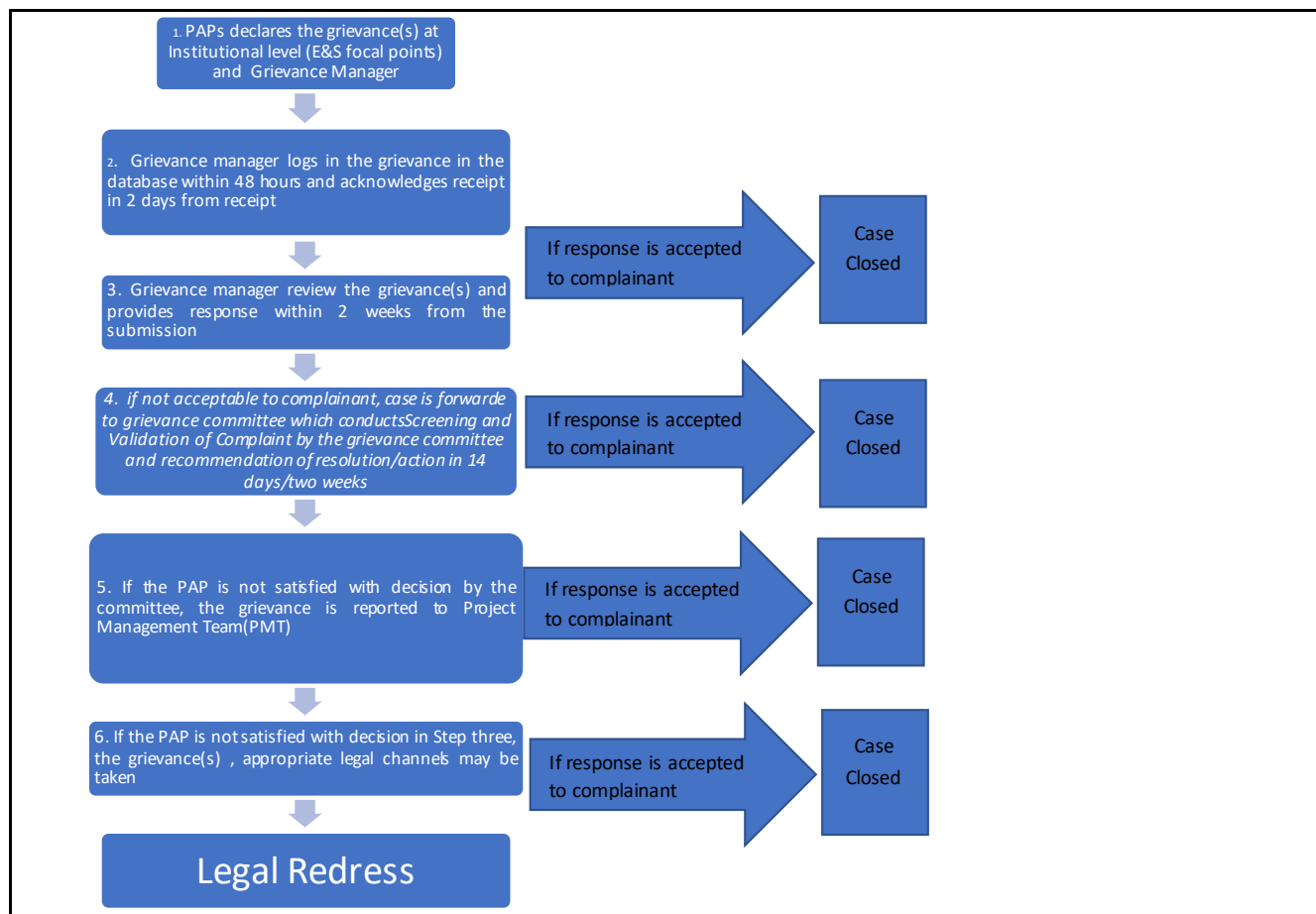
Figure 3: the GRM process

8.2. Linkage with GRMs of Implementing Entities'

For effective implementation, wide coverage, and access by all key stakeholders each of the implementing agencies (KBI, NQCL, NPHI and Counties, PPB, MOH) will establish a GRM with a dedicated E&S focal person (s), with linkages to the grievance manager at PMT. Reported grievances will be referenced to respective agencies for follow-up and resolution through the E&S focal points. The E&S focal point will also coordinate the preparation of regular updates on the status of the grievances including resolved, escalated, or those referred to courts, for submission to the PMT. The E&S focal points will be capacity built and resourced to effectively deliver their responsibilities.

Roles and responsibilities

Grievance Manager (PMT Social Specialist):

To establish and oversee the functioning of the Grievance Mechanism, including in the whole project:
1. Design the system and tools; receive reports and monitor it's functionality including at national level, oversee implementation at sub-project level and with contractors;
2. Train all staff and contractors on the GM process and their roles and responsibilities; including how to respond if a complaint is raised to them and where to refer it;
3. Receive and resolve complaints at overall project level, and reporting to the PMT and grievance committee, working in close collaboration with the implementing entities E & S focal point persons;

4. Receive reports and grievance logs from implementing entities and contractors and summarise progress and recommendations to the Project Coordinator on the progress, challenges and future actions, including reports and presentations for inclusion in the project quarterly reports.

E & S focal point persons:

1. Oversee the functioning of the grievance mechanism at sub-project level including activities implemented by the agency;
2. Receive reports from project members and grievant and monitor the GRMs functionality;
3. Train all staff and contractors at within the implementing entity on the GM process and their roles and responsibilities; including how to respond if a complaint is raised to them and where to refer it;
4. Receive complaints at sub-project level/related to activities directly overseen by the implementing entity, and forward to the grievance committee, working in close collaboration with the Grievance Manager;
5. Act as the secretary to the grievance committee, calling meetings, taking minutes and follow up and document actions and resolution;
6. Receive reports and grievance logs and summarise progress and recommendations to the Grievance Manager on the progress, challenges and future actions, including reports and presentations for inclusion in the project quarterly reports.

8.3 World Bank's Grievance Service

World Bank Kenya Office: If no satisfactory resolution of complaints has been received from the NPIU, complaints can be raised with the World Bank Kenya office on kenyaaalert@worldbank.org.

World Bank's Grievance Redress Service: Communities and individuals who believe that they are adversely affected by a World Bank supported project may submit complaints to existing project-level GMs or the WB's Grievance Redress Service (GRS). For more information: http://www.worldbank.org/grs, email: grievances@worldbank.org or address letters to:

> **The World Bank**
> Grievance Redress Service (GRS)
> MSN MC 10-1018
> 1818 H St NW
> Washington, DC 20433, USA
> Email: grievances@worldbank.org
> Fax: +1 – 202 – 614 – 7313

Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and World Bank's country office has been given an opportunity to respond. Project affected communities and individuals may submit their complaint to the WB's independent Inspection Panel which determines whether harm occurred, or could occur, as a result of WB non-compliance with its policies and procedures. For information on how to submit complaints to the World Bank Inspection Panel, visit g www.inspectionpanel.org

8.4. GRM Monitoring and Reporting

The GRM's effectiveness will need assessment on a regular basis. This is crucial because it enables quick response to problems and the ability to find solutions as they appear. To guarantee the project moves forward smoothly, some of the procedures implemented for this include a quarterly report on the number of grievances received, those resolved, and the ones outstanding. This will be done and communicated to PMTs. PMT Monitoring shall include the

opinions of the stakeholders for whom the Grievance Mechanism is designed as part of stakeholder engagement and consultation.

9.0. MONITORING AND REPORTING

The SEP will be periodically reviewed and modified as required to make sure that the information and interaction strategies are still pertinent and efficient in light of the Project's context. Any significant alterations to the Project's operations or schedule will be properly captured in the revised SEP.

The project will establish and maintain a database and activity file detailing public consultation, disclosure information and grievances collected throughout the program, which will be available for public review on request. Stakeholder engagement shall be periodically evaluated by the PMT. The following indicators will be used for evaluation:

i). Bi-annual grievances received, speed of resolution and how they have been addressed; and

ii). Level of involvement and participation of stakeholders including project affected people (disaggregated by gender and vulnerable groups).

The project will prepare and regularly avail important information on to stakeholders (based on information need) including project implementation progress, actions on commitments made to various stakeholders and any new or corrected information since the previous report.

Table 8.1: Methods and frequency of reporting to stakeholders

Reporting Party	Reporting Method	Stakeholder	Reporting Information	Frequency
Project Management Team (PMT)	Official Correspondence	Relevant Ministries & Agencies	Project progress ✓ Plans for next step ✓ Issues and changes	Quarterly
Environment and Social specialists	Official Correspondence ✓ Correspondence by email or postal mail ✓ Website and social media	Local Community	Project progress ✓ Plans for next step ✓ Issues and changes	• Quarterly • when changes occur

9.0. ANNEXES

Annex 1: Complaints form

1.   Complainant's Details: (Optional)
Name (Dr / Mr / Mrs / Ms) _____
ID Number _____
Postal address _____
Mobile _____
Email _____
County _____
Age (in years): _____

2.   Are you requesting for confidentiality for the information
☐ Yes   ☐ No

3.   Is there any fear/risk of retaliation or attack or victimization?

☐ Yes   ☐ No

4.   Which institution or officer/person are you complaining about?
Ministry/department/agency/company/group/person
_____
_____
_____

5.   Have you reported this matter to any other public institution/ public official?
☐ Yes   ☐ No

6.   If yes, which one?
_____
_____

7.   Has this matter been the subject of court proceedings?
☐ Yes   ☐ No

8.   Please give a brief summary of your complaint and attach all supporting documents [Note to indicate all the particulars of *what* happened, *where* it happened, *when* it happened and by *whom*]
_____
_____
_____
_____
_____
_____
_____

7.. What action would you want to be taken?
_____
_____
_____
_____

Signature _____

Date_____

*Based on the Kenya Public sector complaints handling guide, CAJ.

Annex 2: Complaints Register Format

	County Department for Health_____
	Complaints Register for_____

N o.	Date Received	Name and Address of the complainant	Contact of the Complainant	Complaina nt Issue	Complain Channel	Date acknowledge	Action Taken	Complain status

Annex 3: Minutes from Stakeholder Engagement

TITLE	MINUTES OF STAKEHOLDER CONSULTATIVE MEETING FOR THE REGIONAL PROJECT ON STRENGTHENING HEALTH EMERGENCY PREVENTION, PREPAREDNESS, RESPONSE AND RESILIENCE (SHEPPRR): KENYA PROJECT.
OBJECTIVE	PUBLIC CONSULTATION ON DRAFT SAFEGUARDS FOR ENVIRONMENTAL AND SOCIAL MANAGEMENT FRAMEWORK (ESMF), INFECTION CONTROL AND WASTE MANAGEMENT PLAN (ICWMP), STAKEHOLDERS ENGAGEMENT PLAN AND LABOUR MANAGEMENT PLAN
DATE	11th May 2023
TIME	0835 – 1100 hours
VENUE	Crowne Hotel Plaza, Nairobi

Members present

S/No	Members	Organization	Designation
1.	Dr. Michael Lusiola	Kenya BioVax Institute (KBI)	Chief Executive Officer
2.	Poline Njue	Kenyatta National Hospital (KNH)	Disaster Coordinator
3.	Peter Mutua	Kenya BioVax Institute	Consultant
4.	Ireen Mueni	Kenya BioVax Institute	Consultant
5.	Lolem Lokolile Bosco	MoH	Safeguards Specialist
6.	Ethnzy Kibet	Dawa Limited	Business Development
7.	Sonali Saula	BIODEAL	Regulatory
8.	Mwai Ngibuini	United States Pharmacopeia (USP)	Technical Advisor
9.	Col. Robert Gatata	Kenya BioVax Institute	Facility Readiness / Safety / ICT
10.	Lucas Nyangweso	Kenya BioVax Institute	Supply Chain Management
11.	Loise Wanja	Federation of Kenya Pharmaceutical Manufacturers	Executive Officer
12.	Okach Kephas	Ministry of Health	Safeguards Consultant
13.	Jacquline Ressa-Mbala	Ministry of Health	Safeguards Specialist
14.	John Ambuya	Ministry of Health	Safeguards Consultant
15.	Cecilia Wanjala	Kenya BioVax Institute	Regulatory
16.	James Kimotho	KEMRI	Head of Innovation, KEMRI
17.	Michelle Omondi	Federation of Kenya Pharmaceutical Manufacturers	Pharmacist
18.	Dominic Kariuki	Pharmacy & Poisons Board	Head of GMP
19.	Karim Wanga	Pharmacy & Poisons Board	Director, Regulatory
20.	Rebecca Manani	National Quality Control Laboratories	Deputy Director Pharmaceutical services
21.	Dr. Serah Muteru	National Quality Control Laboratories	Ag. Director-General

22.	Dr. Sultani Matendechero	Ministry of Health	Deputy Director-General
23.	Dr. Joseph Kamau	Institute of Primate Research	Director

24.	Javan Wachenje	Kenya BioVax Institute	Projects Officer, Facility Readiness
25.	Dr. Felistas Chepwogen	Pharmacy & Poisons Board	Head of Bioequivalence
26.	Dr. Winnie Ng'ang'a	Kenya Assn. of Pharma. Industries / GlaxoSmithKline	Chairperson
27.	Safari Kithi	Association of Medical Laboratory Scientific Officers	Chairman
28.	Ibrahim Basweti	Public Health Officers & Technicians Council (PHOTC)	DPHO
29.	Peter Borus	WHO	Scientist
30.	Edward Abwao	United States Pharmacopeia	STA-RSS
31.	Dr. Rabera Kenyanya	Kenya BioVax Institute	Head, Technical Operations
32.	Suge Titus	Kabarak University	Dean
33.	Ian Oduor	Kenya BioVax Institute	ICT Officer

Agenda:

1. Preliminaries, welcoming and opening remarks
2. Presentation by the Implementing Agencies:
   a. Kenya BioVax Institute
   b. National Public Health Institute
   c. National Quality Control Laboratory
   d. Pharmacy and Poisons Board
   e. Presentation from NCQL
3. Overview of safeguards instruments:
   a. Environmental safeguards;
      i. ESMF,
      ii. ICWMP,
   b. Social safeguards;
      i. SEP,
      ii. LMP.
4. Plenary session with Q&A
5. A.O.B and Close.

Minute 1/11/05/2023: Preliminaries & remarks by the CEO, Kenya BioVax Institute

The meeting was opened by the Chief Executive Officer (CEO), Kenya BioVax Institute (KBI) at 8.35am followed by a welcoming address to stakeholders. In his remarks, the CEO appreciated stakeholders for their attendance and spelt out the purpose of the meeting as being for consultations and engagement on strengthening health systems emergency prevention, preparedness, response and resilience as would be presented by representatives from the BioVax, National Quality Control Laboratories (NCQL), Pharmacy and Poisons Board (PPB), National Public Health Institute (NPHI) and safeguards experts from the Ministry of Health and WorldBank.

He noted that the BioVax project under the oversight of the Ministry of health, is a project with cross-border

collaborations and will contribute to this cause by strengthening of local national institutional capacity which includes pharma-manufacturing to avert shortage of essential medical supplies as witnessed during the Covid-19 pandemic. The ultimate expectations, he noted, will be better capacity to respond to public health emergencies, improved health security, strengthened health systems and enhanced universal health coverage.

Dr. Lusiola finished by mentioning that the regional project has four (4) components with the beneficiary institutions being the Pharmacy & Poisons Board (PPB), the National Quality Control Laboratory (NQCL), the National Public Health Institute (NPHI) and the Kenya BioVax Institute (KBI). The components will also have sub components which touch on human resources development and technology transfer, regulatory strengthening for PPB, Strengthening of Quality Control/assurance and establishing capacity for local vaccines manufacturing of 'fill-and-finish'.

Minute 2/11/05/2023: Presentation from National Public Health Institute (NPHI)

Dr. Sultan Matendechero – Deputy Director General, NPHI presented a high-level summary on the establishment and operationalization of NPHI. He highlighted that the role of NPHI is to promote public health issues by consolidating the management and coordination of response strategies and activities in prevention and early detection of public health issues of concern.

He gave an explanation of NPHIs operational strategy and administrative strategy. The operational strategy involves; establishment of NPHI complex, organizational establishment, equipping & networking labs, Human resource and training, establishing strategic national stockpile for public health response commodities, establishment of data systems and coordinate emergency response. The administrative strategy involves; Leveraging existing brick and mortar facilities, Laboratory network, Coordination of public health emergencies response and strategic national stockpiles of essential commodities, Human resource management and development, Public health data management, Public health education and management of public health surveillance and disease surveillance.

Dr. Matendechero then gave the regional project scope whose objective is to support the establishment and operationalization of NPHI by; strengthening genomic surveillance, strengthening cross border surveillance at Port of entries, strengthening lab networks, enhancing disease surveillance, and having strategic national stockpiles for medical commodities.

Minute 3/11/05/2023: Presentation from National Quality Control Laboratory (NQCL)

Dr. Serah Muteru - Acting director, NCQL gave a presentation on NQCL regarding to its establishment, history and legal mandate, its administration and organization, Pre-qualification (PQ) status by World Health Organization (WHO) and Global Benchmarking Tool (GBT), support by development partners, range of clientele, gaps and future outlook. She stated NQCLs legal mandate as; Testing Health Products and Technologies (HPTs) on behalf of the Government and Administering the data bank for quality of HPTs in Kenya.

She further informed participants that NQCL is one of the only nine (9) WHO pre-qualified quality control Laboratories in Africa and among the forty-five (45) in the world, which is a significant achievement in the field of quality control. She highlighted major challenges and gaps as; Inadequate Staff which affect Turn-around-Times, lack of experts and infrastructure for analysis of vaccines and other biologics, old equipment and inadequate Information Communication Technology Infrastructure.

Minute 4/11/05/2023: Presentation from Pharmacy and Poisons Board (PPB)

Dr. Dominic Kariuki gave an overview of the regulatory role of PPB in as regards to Health Products and Health Technologies (HPTs); to ensure that all HPTs comply with the requisite safety, quality and efficacy standards.

He reported that Kenya is making remarkable progress towards attainment of WHO maturity level three (ML3) as it underwent WHO GBT Assessment in 2022. He explained that the attainment of WHO ML3 means a functional level

of maturity: a stable, well-functioning and integrated regulatory system to ensure the quality, safety, and effectiveness of HTPs that are manufactured, imported or distributed in the country. Its attainment, he added, is a pre-condition for the penetration of Kenya into the international market for locally manufactured HPTs and will join five (5) other African countries that have already attained the status. He also informed members that already two assessments have been made by the WHO GBT team in November 2022 and April 2023 where recommendations reduced from 119 to 84, and from 84 to 53 respectively.

The presentation also highlighted priority areas and requests to World Bank; development of key Regulatory information management system (RIMS) including batch tracing systems and GCP inspections, development of a robust Post Marketing Control system, implementation of Bioequivalence Framework, establishment of Lot release function, establishment of a Monitoring and Evaluation framework and support of local manufacturers

Minute 5/11/05/2023: Presentation on Safeguards instruments (ESMF, ICWMP, SEP, LMP): Jacky Mbala gave an overview of the social safeguards Instruments and stated that the aim is to ensure that the project does not hurt people and the environment and, promotes right working conditions and ensures that the community is not affected negatively. She noted that it's a conditional requirement for stakeholder engagement to be done before any project is implemented. She then invited Consultants John Ambuya, Okach Kephas and Bosco Lolem to make presentations as she wrapped up with the last presentation.

Presentation on Environmental Safeguards Management Framework (ESMF) by John Ambuya

Consultant John Ambuya gave an overview that the project is Kenya Health Emergency Preparedness, Response & Resilience (HEPRR) with a Project development objective of strengthening national systems for public health emergency preparedness through strengthening capacity for local manufacturing and public health institutional arrangements.

He listed the policy, regulatory, legal and institutional frameworks relevant to the project and the four concerned institutions citing various pieces of policies and legislations such as Environmental Management and Coordination Act, 1999 (Revised 2015), Health Act 2017, National Environment Policy, 2014, Kenya Health Policy, 2012 – 2030, among others.

The presentation also listed some of the anticipated environmental and social impacts and risks at the design & planning phase, construction phase and the operations phase. It further enlisted procedures to address environmental and social impacts and risks and detailed the steps involved in the environmental and social screening process. Areas for capacity building and training were also highlighted such as; training on biosafety and biosecurity, training on environmental and social framework, infection control and waste management, among other areas.

Presentation on Infection Control and Healthcare Waste Management (ICHWM) by Lolem Bosco

Expert Lolem Bosco elaborated on healthcare waste management (HCWM), Emergency preparedness & response, Institutional arrangement, Infection control & waste management plan, and Capacity building and training.

He highlighted on two components where component 1 targeted: KBI, PPB and NQCL while component 2 targeted laboratories at county and national level, KEMSA national or regional warehouses and the Points of Entry (POE). He stressed on the design requirements of laboratory facilities, quarantine / Isolation Rooms at Healthcare Facilities, KBI vaccine manufacturing facility, waste treatment equipment installation & shed as well as provision for Biosafety Levels 3 Laboratories (BSL III). The presentation also factored in various areas of health care waste management such as Waste Management Hierarchy, Waste Segregation, Waste Treatment & Disposal Methods and Emergency Preparedness and Response (EPR).

Members were informed that beneficiary institutions will be required to prepare, receive approve and implement a specific ICWMP for their facility/operation based on MOH environmental health guidance. The specific plan

should be based on their specific characteristics and conditions and meet the prescribed requirements; identify indicators to be tracked, specific tasks to be executed, and responsibility assigned for waste collection.

Presentation on Stakeholder Engagement Plan (SEP) by Kephas Okach

Consultant Kephas Okach gave an overview of the Stakeholder Engagement Plan, categories of stakeholders and the requirements of Environmental and Social Standard 10 (ESS10) of the ESF on Stakeholder Engagement and Information Disclosure.

He went on and explained the methods and communication models used in stakeholder engagement, the communication Escalation Process and the Grievance redress mechanism which is a mandatory requirement in World Bank projects.

Presentation on the Labour Management Plan (LMP) by Jacky Mbala

In her overview of LMP, Expert Jackie Mbala explained its purpose; it identifies the key labor requirements, related risks, processes and resources required to manage the labor-related challenges for the project. The LMP defines different types of project workers; - direct workers, contracted workers and supply chain workers, and key requirements to manage labor issues.

She listed the following as the potential Occupational Safety and Health (OSH) risks that could be associated with the project: Sexual harassment, exploitation and abuse, Child labor, Labor disputes over terms and conditions of employment, Non-compliance of employers to terms and conditions of employment, Discrimination and exclusion of vulnerable groups, Labor influx related risks (including spread of diseases among workers and the nearby communities, including HIV/AIDS and COVID-19 through project activities.

The presentation also shed light on the need to formulate and implement Grievance redress mechanism, Capacity building matters and Gender-Based Violence Action Plan (GBVAP), all being requirements for the project.

Minute 6/11/05/2023: Plenary session

The following questions were asked and responses given during the plenary session:
  i. Dr. Kimotho (Head of Innovation, KEMRI) asked about the aim of the project to which Dr. Lusiola replied that it is for strengthening health systems, resilience and health commodity security where the implementing agencies would participate in building resilience and enhancing preparedness for the next pandemic.
  ii. Dr Wanga (PPB) pointed out that safety of workers was not captured in the presentation, a point noted by Mr. Lolem).
  iii. Ms. Poline (Rep. of CEO, KNH) placed a question about the role of KNH in the project and at what point is it expected to execute its role. Dr. Rabera replied that KNH is an important stakeholder whose role will be vital during clinical trials of KBI products and consumption/use.
  iv. Dr. Peter Borus (Scientist, WHO Country Office) enquired about the budget scope and if there was co-financing, the connection of the project to the bigger health strengthening component while avoiding duplication or efforts and if there is the overarching of the project regarding health strengthening. Dr. Rabera responded that KBI is exploring co-financing options and that there is no duplication of roles between PPB, NCQL, NPHI and KBI. Dr. Rabera added that KBI contributes to health systems strengthening by ensuring commodity security for vaccines and specialized health products and technologies.
  v. Dr. Mwai Ngibuini (Technical Advisor, the USP) sought to know about the sustainability plan, measures to ensure vaccine uptake during transition from GAVI and plans for procurement processes even as Kenya is yet to attain ML3. Dr. Karuiki (PPB) replied that based on current progress, Kenya would have attained ML3

by December 2024, which is way ahead of GAVIs exit in 2027. Dr. Rabera and Dr. Lusiola also replied that engagement with vaccine users' community is ongoing and the process will be quickened.

vi. Dr. Edward Abwao (Director of Regulatory PPB) enquired about the place of other prospective human vaccine manufacturers in the region and whether the KBI is a member of the association of pharmaceutical manufacturers. Dr. Lusiola responded that other prospective human vaccine manufacturers, including Moderna Inc., serve complementary roles. He also mentioned that the KBI is indeed part of the association of pharmaceutical manufacturers.

There being no other business the meeting was adjourned at 1100 hours.

Minutes prepared by: Mr. Javan, Wachenje, Projects Officer, Kenya BioVax Institute. **Minutes approved by:** Dr.

Michael Lusiola – Project Lead / CEO Kenya BioVax Institute. Signed:

Date: 11ᵗʰ May 2023.