REPUBLIC OF KENYA

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Enhancing Accountability

REPORT

2 1 MAR 2024

Hort NAOMI WAGO, MP Deputy Majority Whip

OF

THE AUDITOR-GENERAL

ON

KENYA BIOVAX INSTITUTE LIMITED

FOR THE YEAR ENDED 30 JUNE, 2023





KENYA BIOVAX INSTITUTE LIMITED

ANNUAL REPORT AND FINANCIAL STATEMENTS

FOR THE FINANCIAL YEAR ENDED 30^{TH} JUNE 2023

Prepared in accordance with the Accrual Basis of Accounting Method under the International Public Sector Accounting Standards (IPSAS)

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1. Key Entity Information and Management

(a) Background information

The Kenya Vision 2030 commissioned, in 2008, envisioned transforming Kenya to a newly industrialising middle-income economy by 2030 and it was to be implemented in 5-year plans. One strategy through which this was to be achieved was through the manufacture of basic commodities for East and Central Africa. The COVID-19 pandemic brought to light the urgent need for the country to strengthen local manufacturing of pharmaceuticals to reduce the dependency on imported health products and technologies (HPTs), including human vaccines. In response, the GoK established the Kenya BioVax Institute (KBI) in 2021, under the Companies Act (2015), with the mandate of manufacturing and commercialising health products and technologies that include human vaccines, therapeutics, and other biomedical products. The establishment and operationalization of the KBI was informed by a feasibility study commissioned by the Ministry of Health through the Kenya Medical Research Institute This initiative would enable the country to assure availability of biopharmaceuticals including vaccines which are critical to universal health coverage and preventive healthcare as guided by the Vision 2030 blueprint.

At Cabinet level, KBI is represented by the Cabinet Secretary for Health, who is responsible for providing the general policy and strategic direction of the KBI. The KBI is domiciled in Kenya.

(b) Principal Activities

The principal activity of the KBI is to manufacture and commercialise specialised health products and technologies (HPTs), including human vaccines, biological therapeutics and diagnostics.

Vision:

Innovate, Empower, Impact through production of quality human vaccines and therapeutics

Mission:

Innovate, develop, manufacture and commercialise vaccines and other specialised health technologies to improve access to quality health care.

Core values:

The core values of KBI are innovation, collaboration, quality, customer-centric, integrity, professionalism, resilience, courage, trust and respect.

(c) Key Management

The Institute's day-to-day management is under the following key organs:

- Kenya Biovax Institute Board of Directors
- Chief Executive Officer/Director General
- The Management

(d) Fiduciary Management

The key personnel of the KBI who held office during the financial year ended 30th June 2023 and who had fiduciary responsibilities were as follows:

No.	Designation:	Name:
1	Chief Executive Officer / Director-General,	Dr. Michael Lusiola
2	Head of Technical Operations	Dr. Rabera Kenyanya
3	Head of Regulatory, Quality and Planning	Dr. Cecilia Wanjala
4	Head of ICT, Facility readiness, Biosafety and Security	Col. Robert Gatata
5	Supply Chain Manager	Mr. Lucas Nyangweso

(e) Fiduciary Oversight Arrangements

The oversight responsibilities by the Board of Directors of the Institute were under the following Board Committees, with the memberships as listed:

No	Committee:	Membership of the Committees:
1	Risk, Compliance and Audit Committee	Dr. Dennis Rangi
		(Chair)
		 Dr. John Kiiru
2	Strategy and Planning Committee	Ms. Shamim Chanzu
		(Chair)
		• Mr. Sachen
		Chandaria
		 Dr. Dennis Rangi
		• Dr. John Kiiru
3	Human Resources, Finance and	Mr Sanchen
	Administrative Committee	Chandaria (Chair)
		• Ms. Shamim Chanzu
		Mr. Alphaxard Kyallo
4	Technical, Research & Development	Dr. John Kiiru
	Committee (including on Drug	(Chair)
	Substance, Production, Innovation	• Mr. Sanchen
	Research & Development, Engineering).	Chandaria
		Dr. Dennis Rangi

(f) Entity Headquarters

Kenya BioVax Institute Off Utawala Road, Embakasi P.O. Box 40779-00100 Nairobi, KENYA

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(g) Entity Contacts

Telephone: 254 727237836

E-mail: info@biovax.go.ke

Website www.biovax go ke

(h) Entity Bankers

1. Central Bank of Kenya

Haile Selassie Avenue

P.O Box 60000

City Square 00200

NAIROBI, KENYA

2. Kenya Commercial Bank

Milimani Branch

P. O. BOX 2117 - 00202 KNH - NAIROBI

Nairobi, KENYA

(i) Independent Auditor

Auditor-General

Office of the Auditor General

Anniversary Towers, University Way

P.O Box 30084

GPO 00100

Nairobi, Kenya

(j) Principal Legal Adviser

The Attorney General

State Law Office and Department of Justice

Harambee Avenue

P.O. Box 40112

City Square 00200

Nairobi, Kenya

2. The Board of Directors/Council

Ref	Directors	Details
1.	Mr. Mugo Kibati, MBS Chairman, Board of Directors.	Mr. Mugo Kibati holds a Master's Degree in Technology and Policy, an MBA/MA degree in International Economics, and a B. Tech degree in Electrical Engineering. He has been a Chairman and a Board Member of various organisations including MKOPA Solar Ltd Lake Turkana Wind Power Limited and Sanlam Kenya Ltd. He is currently the Chief Executive Officer of Telkom Kenya Ltd
	Mr. Sachen Chandaria Director (Independent).	Mr. Sachen Chandaria holds a BSc degree in, Chemistry and in Management. He is a Director in various organisations including Endeavor Kenya Ltd and Icolo.io Ltd. He is currently the Chief Executive Officer of Stellar Investment Holdings and Orbit Products Africa Ltd. Mr. Chandaria is the Chair of the Human Resource, Finance and Administration Committee of the Board.
2.	Ms. Shamim Chanzu Director (Independent)	Ms. Shamim Chanzu holds an MBA degree, a Bachelor of Education degree in Business Studies, a Higher National Diploma (IHRM), and a Diploma in Management. She has worked as the Head of Human Resources & Public Affairs at Ola Energy, Head of HR Operations, and as Programs & Policies Manager at Exxon Mobil. She is currently the Regional Human Resource Business Partner at Plan International. Ms. Chanzu is the Chair of the Strategy & Planning Committee of the Board.

3.	Dr. Dennis Rangi Director (Independent)	Dr. Dennis Rangi holds a PhD in Partnerships, an MBA in Strategic Management, a Bachelor of Science degree in Biological Sciences and a Post-Graduate Diploma in Microbial Technology. He is currently the Director-General at the Centre for Agriculture and Bioscience International. Dr. Rangi is the Chair of the Risk, Compliance & Audit Committee of the Board.
4.	Dr. John Kiiru Director (Alternate to PS, Ministry of Health)	Dr. john Kiiru holds a PhD in BioSciences Engineering, an MSc in Molecular Biology, an MSc in Microbiology, and a BSc degree in Biological Science. He has over 10 years of experience as a Research Scientist at the Kenya Medical Research Institute (KEMRI), and is a Post-Doctoral Researcher at the University of Liverpool, UK, the KEMRI, the University of Nairobi and the International Livestock Research Institute (ILRI). Dr. Kiiru is the Chair of the Technical Committee of the Board.
5.	Mr. Alphaxard Kyalo Director (Alternate to Cabinet Secretary, the National Treasury and Economic Planning)	
6.	Prof. Elijah Songok Director	
8.		Dr. Michael Lusiola holds a Doctorate and Masters degrees in Evidence-based Medicine, Pharmacotherapeutics and Business Admnistration. He has post-graduate diplomas in Management, in Global Health and in Clinical Pharmacology. He has over 23 years experience working in global pharmaceutical

Dr. Michael Lusiola – Chief Executive Officer / Director- General.	research and development, and in clinical practice in the UK and USA. Dr. Lusiola is an ex-officio member of the Board.
Mr. Bernard Kuria Corporation Secretary.	Mr. Bernard Kuria holds a Bachelor's degree in Law. Mr. Kuria is the Corporation Secretary of the Board of Directors.

3. Key Management Team

	Management	Details
1.	Dr. Michael Lusiola – CEO / DG.	Main areas of responsibility include development of the corporate strategy, aligning the organisation, managing and leading the project teams, engaging internal and external stakeholders and being the liason with the Board of Directors.
2.	Col. Robert Gatata – Head of ICT, Facility Readiness and Security	Main areas of responsibility include preparedness of the manufacturing facility in readiness for installation of machinery and equipment, oversight of the information, communication and technology infrastructure (ICT) and biosafety / biosecurity. Colonel Gatata has been seconded from Ministry of Defence.
3.	Dr. Rabera Kenyaya – Head of Technical Operations	Main areas of responsibility include managing the operations and interactions within related government agencies, and supporting the planning activities to enable the establishment of the Institute. Dr. Rabera has been seconded from the Ministry of Health.



Dr. Cecilia Wanjala

Head of Regulatory, Quality

and Planning

Main areas of responsibility include developing the Regulatory strategy for the facility and for the HPTs that are to be manufactured at the Institute, and embedding a quality management system across the organisation. In addition, Dr. Wanjala's responsibilities include supporting the CEO / DG in developing the corporate strategy for the organisation. Dr. Wanjala has been seconded from Kenya Medical Research Institute.

4.

5.



Mr. Bernard Kuria

Head of Legal Services / Corporation Secretary
(seconded from the Ministry of Health).

Main areas of responsibility include providing the legal and corporate service support for the organisation.

Mr. Kuria has been seconded from the Ministry of Health.

Note: The CEO and the Entity Secretary will feature both under the 'Board' and 'Management'.

4. Chairman's Statement

The establishment of the KBI is intended to position Kenya as a biotechnology manufacturing hub for the Region and Africa, promoting investment in research and development, including technology and knowledge transfer to support existing and novel research areas that are relevant to national and regional issues. As a hub, KBI in particular, and Kenya as whole will create opportunities for investment in research and development, commercialisation of research outputs from research institutions and universities and also create job opportunities for Kenyans.

In terms of sustainability and self-reliance, the KBI will play a major role in controlling the Government's healthcare expenditure on human vaccines and other HPTs, making these more affordable. Currently, Kenya imports over 70% of finished health products and technologies and 100% of raw materials for human health products manufacturing – an unsustainable situation that impacts on self-sufficiency efforts.

During the FY2023 2024 the board has finalized the development of the institutes' governance structures ensuring compliance to all statutory requirements, initiated rigorous resource mobilization and human resource establishment strategies, and advanced engagements with potential partners and stakeholders globally and within the country. A major achievement was the pronouncement of Kenya Biovax as the regional spoke for the WHO mRNA Technology Transfer Programme.

The Institute has encountered challenges that delayed fulfilment of its mandate including but not limited to: inadequate allocation and delays in accessing funding for development and operations and delays in requisite approvals for recruitment of critical staff to support operations and a suitable regulatory framework for human vaccine manufacturing. KBI is required to procure highly-advanced technology, machinery and equipment for fill-and-finish. However, funding for this procurement has not been sufficiently availed through exchequer. In addition, challenges have been experienced in the identification of highly-skilled technical personnel vaccine manufacturing activities for the Institute To this end, the Institute is exploring options on upskilling of personnel and identification of consultants to support initial operations. On matters health products and technologies regulation, KBI has also set out to support efforts by the National Regulatory Authority to attain Maturity Level 3.

On behalf of the Institute Board and staff, I would like to take this opportunity to thank the Government of Kenya for its unequivocal support during the year under review. I also appreciate the financial, material and moral support of our strategic partners, collaborators and friends during the year.

I am optimistic that Kenya Biovax is set for a prosperous future

(Cibati,

Mr Mugo Kıbati, MBS

Report of the Chief Executive Officer

Kenya was reclassified as a lower-middle income country (LMIC) in 2019 setting the stage for it to transition from donor support of the already established and successful childhood immunization programme. To sustain the gains of this important public health programme, the Government of Kenya began its journey to establish capacity to locally manufacture human vaccines and other biologics though the incorporation of Kenya Biovax Institute as a state-owned company in September 2021

Kenya Biovax mandate to manufacture and commercialize vaccines and related health technologies and products places us at the apex of the regional and continental aspirations to locally manufacture 60% of vaccines by the year 2060 and aligns with National and Cohesion Values on Universal Health Coverage In the FY2022 2023, the process of developing Kenya Biovax Strategic Plan 2023 2028 was started and is scheduled for completion in the course of the next accounting period.

During the period to 30 June 2023, the development methodology at KBI has been approached through phased implementation, in consideration of the complexity embedded in the vaccines production and manufacturing processes, the costly technological outlay, identification of technical personnel, and the complex research and development activities, all of which could have been potential barriers to entry. This 3-phase approach was deployed to ensure establishment of a state-of-the-art vaccine manufacturing facility that will aim to achieve product commercialization by end of financial year 2025/2026 and operationalization as a fully-fledged bulk production facility by start of year 2027.

The Embakasi facility was refurbished for administrative functions and preparation for installation of manufacturing modules. Within the financial year 2022 2023, additional refurbishment works including structured cabling, security systems installation and office equipment installation were undertaken enabling the relocation of KBI operations to Embakasi. The installation of Enterprise Resource Planning system has progressed with successful procurement of the service provider. The enabling works, including water-treatment facilities and connection to local utilities has been delayed but are scheduled for implementation in the financial year 2023 2024.

Kenya BioVax Institute signed agreements with local and international stakeholders and established strategic partnerships and collaboration frameworks for potential engagements in the areas of technology transfer, market analyses, WHO pre-qualification, knowledge transfer and personnel capacity building. This will secure the necessary skills for establishing vaccine manufacturing capacity in Kenya as well as to promote the development of the vaccine ecosystem in regulatory affairs (Pharmacy and Poisons Board and National Quality Control Laboratory), research and development (Kenya Medical Research Institute, Kenya Institute of Primate

Research, the local universities and other related research institutes) and specialized supply chain management for products requiring cold chain storage. A major achievement was that Kenya has ratified the African Medical Agency (AMA) treaty which will serve to enable access to the Africa vaccine market. Additionally, the institute took a lead position in the process of ensuring that Kenya joins the International Vaccine Institute.

Kenya Biovax implemented the Presidential directives during the period FY2022 2023 and has actively engaged specialized institutions to address key cross cutting issues including corruption prevention, disability, gender and road safety mainstreaming, and prevention of alcohol and drug abuse.

While challenges such as inadequate allocation and delays in accessing funding for development and operations and delays in requisite approvals for recruitment of critical staff to support operations were experienced in this year, the Institute explored innovative ways to address them through continuous engagements with relevant Government Agencies to unlock the delays.

On behalf of the Institute Board and staff, I would like to take this opportunity to thank the Government of Kenya for its unequivocal support during the year under review. I also appreciate the financial, material and moral support of our strategic partners, collaborators and friends during the year. And it is because of the understanding and guidance of the Chairman of the Board as well as the cooperation of the entire staff that we have ended the year with success.

I look forward to the coming financial year and the years ahead.

Dr. Michael Lusiola

Chief Executive Officer / Director-General.

6. Statement of Performance against Predetermined Objectives for FY 2022 2023

The Kenya BioVax Institute was established in September 2021 following a feasibility study conducted by the Kenya Medical Research Institute (KEMRI) and the subsequent recommendation by a multi-agency committee on human vaccine production that developed the foundational institutional framework documents (feasibility study, concept note) that have been used by the Institute.

Kenya Biovax Institute has five (5) strategic pillars within the current Draft Strategic Plan for the FY 2023- FY 2028. These strategic pillars are as follows:

Strategic Pillar 1: Resource mobilisation and facility readiness

Strategic Pillar 2: Human Resource establishment and capacity building

Strategic Pillar 3: Partnerships and Technology Transfer

Strategic Pillar 4: Vaccine Market shaping

Strategic Pillar 5: National interest and values.

Kenya Biovax Institute develops its annual work plans based on the above five (5) pillars/Themes/Issues. Assessment of the Board's performance against its annual work plan is done on a quarterly basis. Kenya Biovax Institute achieved its performance targets set for the FY 2022 period for its five (5) strategic pillars, as indicated in the diagram below:

Strategic Pillar/Theme/Issue s	Objective	Key Performance Indicators	Activities	Achievements
Strategic Pillar 1:	Human	Percentage	1. NEMA	Awarded NEMA
Resource	Vaccine	completion	certification	certification.
mobilisation and	Filll-and-	rate of	process for	The Institute
facility readiness	Finish	human	Environmen	undertook a
	facility	vaccine fill-	tal Health	strategic direction
	established		and Safety	to

		and-finish	2.	Design	comprehensively
		facility		workshops	develop a plan for
				with	enabling works
				consultants	and to
				from the	concurrently
				State	expand available
				Department	office space which
				of Public	would
				Works for	accommodate
				enabling	recruited. GMP
				works and	Contract signed
				office space	
				expansion	
Strategic Pillar 2:	Personnel	Number of	1.	Engagement	The Institute
Human Resource	trained in	staff		of	recruited a
establishment and	administrativ	recruited		Governmen	procurement
capacity building	e functions	and trained		t Agencies	manager in that
	and	in		for approval	period and trained
	specialised	administrati		of	all of its staff in
	HPT	ve and		recruitment	operational
	manufacturi	technical		process	management
	ng	functions	2.	Training	procedures.
				workshops	Technical staff
				and	were trained in
				seminars	biomanufacturing
					and

					biosafety/biosecuri
					ty processes
Strategic Pillar 3:	Establishing	Number of	1.	Engage	Engagement with
Partnerships and	partnerships	technology		ment	Government and
Technology	and	transfer		meetin	non-
Transfer	collaboration	agreements		g with	Governmental
	for	signed, and		local	partners, both
	knowledge	strategic		and	locally and
	exchange	partnership		interna	internationally.
	and	formed		tıonal	MoU signed with
	technology			stakeh	the Kenya
	transfer			olders	Institute for
			2.	Onboa	Primate Research.
				rding	Technology
				the	Transfer
				Institu	Agreement under
				te to	the WHO mRNA
				the	technology
				Techn	transfer program
				ology	submitted to the
				Transf	Office of the
				er	Attorney General
				Agree	for review
				ment	
				under	
				the	
				WHO	

			mRNA	
			techno	
			logy	
			transfe	
			r	
			progra	
			m	
Strategic Pillar 4:	Establishing	Number of	1. Engagement	*
Vaccine Market	mechanisms	engagement	meetings	Draft strategic
shaping	to create and	meetings	with	plan developed
	sustain	held.	Governmen	
	product		t Agencies	
	demand		on market	
			access	
			strategies	
			held.	
			2. Drafting of	
			the	
			Institute's	
			first	
			Strategic	
			Plan	
Pillar/ theme/ issue	Enhancing	Number of	Induction and	Training sessions
5: National interest	measures	training	training sessions on	held on national
and values.	aimed at	sessions held	national interest	values and interest
	fulfilling the		and values	
	Institute's			

mandate that		
will promote		
national		
security,		
prosperity		
and well-		
being		

7. Corporate Governance Statement

The Kenya Biovax Institute held five (5) board meetings in the Financial Year 2022 2023 with board members diligently attending all these board meetings.

The Institute, in its decision-making processes, observed the highest ethical standards and benchmarks on best practices in compliance with the applicable legal principles, its vision, mission and core values.

i) Board Charter

The Board of charter for KBI was drafted for consideration and subsequent enactment by the Board of Directors. Once adopted, it will clearly state the respective roles, responsibilities and the authorities of the Board and its Committees. The Mwongozo Code of Governance for State Corporations guided the Board's operations.

ii) Process of appointment and removal of directors

The appointments to the Board, and removal from the Board, were in accordance with the Company's Act 2015, and the Memorandum and Articles of Association. The Chairperson was appointed by His Excellency, the President of the Republic of Kenya, while the directors were appointed by the Cabinet Secretary, for the time being responsible for health, to serve for a term of 3 years each from the date of appointment and may, subject to performance evaluation, be appointed for a further and last term of 3 years. The Board consisted of the Chairperson, 5 Directors and the CEO / D-G as ex-officio, by the period ending 30 June 2023.

Some of the roles that the Board of Directors undertook during the period ending 30 June 2023 included the following:

- a) Set and oversaw the overall strategy and approve significant policies of the organization;
- b) Ensured that the strategy was aligned with the purpose and the long-term goals of the organization on sustainability;

- c) Engaged with relevant Government Agencies to expedite approval of recruitment processes;
- d) Approved the annual budget of the organization;
- e) Monitored the organization's performance and ensured sustainability;
- f) Ensured availability of adequate resources for the achievement of the organization's objectives;
- g) Hired the procurement manager, on such terms and conditions of service as were approved by the relevant government organ(s)

The Chairperson:

- a) Provided overall leadership to the Board,
- b) Played a key role in setting the agenda for Board meetings;
- c) Conducted efficient Board meetings and guided the Board's decision-making process;
- d) Encouraged Board members to participate fully in Board deliberations;
- e) Harnessed the collective skills of the Board and its committees:
- f) Monitored the performance of the CEO, maintained close, but independent working relationship with the CEO, ensured appropriate balance of power between the CEO and the Board and was available for consultations with Board members; and
- g) Encouraged a culture of transparency and teamwork among Board members

Each Board member:

- a) Exercised the highest degree of care, skill and diligence in discharging their duties,
- b) Acted in the best interest of the organization and not for any other purpose;
- c) Acted honestly at all times and did not place themselves in a situation where their personal interests conflicted with those of the organization;
- d) Exercised independent judgment at all times;
- e) Understood and accepted the principle of collective responsibility;
- f) Devoted sufficient time to carry out their responsibilities;

- g) Promoted transparency and accountability at Board level; and
- h) Promoted teamwork within the Board and the organization.

8. Management Discussion and Analysis

(Operational and financial performance of the organisation for the last three-to-five-year period).

The Kenya BioVax Institute's Board of Directors was inaugurated in December 2021. This submission covers KBI performance over the last two years.

a) Entity's key projects or investments decision implemented or ongoing.

During the period ending 30 June 2022, the key project that management undertook was the refurbishment works at the Embakasi Warehouse for administrative functions and preparation for installation of manufacturing modules. Within this financial year, refurbishment works including structured cabling, security systems installation and office equipment installation were undertaken enabling the relocation of KBI operations to Embakasi.

The roofing works were uncompleted due to delays in receiving the special material order, onset of rainy season and overlapping national duties of contractor (National Youth Service). The enabling works, including water-treatment facilities and connection to local utilities has been delayed but are scheduled for implementation in the next FY2023 2024 Management has initiated other projects within the accounting period including the installation of Enterprise Resource Planning system and development of KBI Strategic Plan 2023 2028.

b) Entity's compliance with statutory requirements,

The Institute complied with statutory requirements and remitted payroll statutory deductions as required. Further, the Institute initiated processes for submission of statutory monthly and quarterly reports to relevant Government Agencies for Presidential directives and cross cutting management issues such as corruption prevention, disability, gender and road safety mainstreaming, and prevention of alcohol and drug abuse.

c) Major risks facing the organisation,

These have included:

- 1. Instability of the financial markets, hence affecting FOREX and currency value, hence purchasing power;
- Funding delays in accessing funding for development and operations; delayed disbursement of funds from the Government;
- Technical expertise the manufacturing activities for the Institute require highly-skilled personnel and highly-advanced technology, machinery and equipment, all of which are challenging to find; and
- 4.Regulatory a high regulatory threshold is required for manufacture of these specialized HPTs, especially for human vaccines. Having a suitable regulatory framework for instance supported by a 'Maturity Level 3' for the local regulatory agency) is key in efforts to operationalize.

d) Material arrears in statutory and other financial obligations,

The Institute did not have any loan default, pending bills, tax default, outstanding staff and Pension obligation/actuarial deficit during the period ending 30 June 2023.

e) Future developments and anticipated desired results.

a. Manufacturing, Research and Development

A major achievement in the FY2022 2023 period was the pronouncement of Kenya Biovax as the regional spoke for the WHO mRNA Technology Transfer Programme. This means that Kenya Biovax will be one of the recipients of the WHO-mRNA technology transfer and engagement is ongoing with the relevant stakeholders to align on the next steps. The process will involve performing a gap assessment to ascertain the current infrastructure, workforce, clinical research and regulatory capacity. KBI management will work with WHO and partners to develop the roadmap and necessary activities like training and resources required to support the actualization of mRNA technology transfer.

b. Partnerships

KBI management signed an agreement (MOU) with Kenya Institute of Primate Research and initiated discussions with Kenya Medical Research Institute to also sign an MOU. Additionally, there are ongoing discussions with the Ministry of Health Programme for Immunization, UNICEF and GAVI in regard to advance purchase agreements for our products.

We engaged Africa CDC, Africa Vaccine Manufacturing Initiative and Partnerships for African Vaccine Manufacturing (PAVM) in the ongoing discussions for pooled vaccine procurement. Similarly made contacts made with Eastern Central and Southern Africa Health Community and IGAD on market shaping for vaccines. A major achievement was that Kenya has ratified the African Medicines Agency (AMA) treaty which will serve as an enabler to access to the Africa vaccine market. We have taken a lead position in the process of ensuring that Kenya joins the International Vaccine Institute..

c. Human Resource Establishment and Capacity building

KBI management did not succeed in recruitment of technical staff due to delays occasioned by approval from National Treasury and Economic Planning and Salaries Remuneration Commission but manage med to recruit the Manager, Supply Chain and procurement. However the recruitment process will continue in the next accounting period.

Progress in establishment of Kenya BioVax Institute (KBI).

S/No.	DATE	IMPLEMENTATION STATUS
1	Continuous	 Partnership and business development. Nomination as Kenya's recipient for the WHO mRNA technology transfer program KBI successfully engaged multiple partners to support its establishment. These have included global pharmaceutical manufacturers (for instance AstraZeneca, Johnson & Johnson, CanSino Biologics, Aspen Pharmacare, Serum Institute), regulatory agencies and development partners (such as the World Health Organization, the African Union) and

S/No.	DATE	IMPLEMENTATION STATUS
		supporting research institutions (for instance KEMRI, UoN,
		KIPRe).The institute has leveraged these partnerships and has been
		successful in obtaining contractual arrangements and
		agreements for drug substances and drug products, which will
		be key in developing the product pipeline.

Current Areas of Focus

- a. Refurbishing of the premises continues;
- b. Resource mobilisation;
- c. Developing Kenya Biovax Strategic Plan 2023 2028;
- d. Development of operational policies;
- e. Planning on acquiring and installing machinery and equipment, and materials and inputs in preparation for production; and
- f. Recruitment and personnel capacity building.

9. Environmental and Sustainability Reporting

i) Sustainability strategy and profile

The Institute has set out the development of its sustainability strategy and profile and has sought strategic partners, both locally and internationally to support its functionality especially in technology and knowledge transfer.

In addition, the Institute plans to establish a state-of-the-art modular sterile product manufacturing facility that is WHO-prequalified and has engaged key partners, e.g., the World Health Organisation, the Pharmacy and Poisons Board, the National Quality Control Laboratory. The Institute intends to adopt and deploy 'green manufacturing' practices as part of its contribution to the attainment of national climate change action objectives.

ii) Environmental performance

Sustainability requirements focus on ensuring that its activities will be continued and do not tamper with the environment. It entails fulfilling presidential directives as well as societal expectations as far as environmental and sustainability requirements are concerned.

During the 2022/23 Financial year, KBI undertook tree planting at Uplands, Kiambu county where KBI staff planted 400 trees.



Kenya Biovax CEO, Dr. Michael Lusiola led the team in a tree planting exercise in Uplands, Limuru

iii) Employee welfare

Kenya BioVax Institute has developed a Human Resource Policy which has considered the gender ratio, disability and regional balance in its recruitment process. The Institute engaged a recruitment agency in hiring of its staff with guidelines on inclusion of gender, regional and disability inclusion.

Training and development being an integral part of the Human resource development activity in all organisations, Kenya BioVax has strived in improving the skills of its employees by ensuring staff are trained in their areas of specialisation as well as in advancement of their professionalism. In the FY 2022/2023 all staff received training in operational management processes and technical staff were trained on biomanufacturing processes.

The Institute currently has majority of its staff deployed from various MDAs to assist in its operationalisation and therefore staff appraisal is undertaken by the parent MDAs. However, requisite policies are under development to ensure a robust, performance-based appraisal system is instituted in FY 2023/24.

iv) Market place practices-

The organisation should outline its efforts to

a) Responsible competition practice.

The Institute undertook its procurement processes, including assignment of specific tenders for AGPO, in compliance with the Public Procurement and Asset Disposal Act of 2015 and attendant regulations.

b) Responsible Supply chain and supplier relations

The Institute's procurement processes were conducted in compliance with the Board approved procurement plan and budget and available resources from the National Treasury and Planning.

Timely responses to suppliers and processing of payments were executed within this year

c) Responsible marketing and advertisement

All tenders were placed on the Institute's website www.biovax.go.ke

v) Corporate Social Responsibility / Community Engagements

During the 2022/23 Financial year, KBI undertook tree planting at Uplands, Kiambu county where KBI staff planted 400 trees and intends to plant over 5000 trees in the community within the next 5- years.

10. Report of the Directors

The Directors submitted their report together with the audited financial statements for the year ended June 30, 2023, which showed the state of KBI's affairs.

i) Principal activities

The principal activities of the entity are to manufacture and commercialise specialised human HPTs, including human vaccines, biotherapeutics and diagnostics.

ii) Results

The results of the entity for the year ended June 30, 2022, are set out in Section XIII below.

iii) Directors

The members of the Board of Directors who served during the year are shown in Section II above, in accordance with the Articles of Association

iv) Auditors

The Auditor-General is responsible for the statutory audit of the *Kenya BioVax Institute Limited* in accordance with Article 229 of the Constitution of Kenya and the Public Audit Act 2015.

By Order of the Board

Name: Bernard Kuria

Corporation Secretary/Secretary to the

Board

11. Statement of Directors Responsibilities

Section 81 of the Public Finance Management Act, 2012 and section 14 of the State Corporations Act require the Directors to prepare financial statements in respect of Kenya Biovax Institute Limited which give a true and fair view of the state of affairs of Kenya BioVax Institute at the end of the financial year/period and the operating results of Kenya BioVax Institute for that year/period. The Directors are also required to ensure that KBI keeps proper accounting records which disclose with reasonable accuracy the financial position of KBI. The Directors are also responsible for safeguarding the assets of Kenya BioVax Institute

The Directors are responsible for the preparation and presentation of KBI's financial statements, which give a true and fair view of the state of affairs of KBI for and as at the end of the financial year (period) ended on June 30, 2023. This responsibility includes:

- (1) Maintaining adequate financial management arrangements and ensuring that these continue to be effective throughout the reporting period;
- (ii) Maintaining proper accounting records, which disclose with reasonable accuracy at any time the financial position of the Entity;
- (iii) Designing, implementing and maintaining internal controls relevant to the preparation and fair presentation of the financial statements, and ensuring that they are free from material misstatements, whether due to error or fraud;
- (iv) Safeguarding the assets of Kenya BioVax Institute Limited
- (v) Selecting and applying appropriate accounting policies, and
- (vi) Making accounting estimates that are reasonable in the circumstances

The Directors accept responsibility for Kenya BioVax Institute's financial statements, which have been prepared using appropriate accounting policies supported by reasonable and prudent judgements and estimates, in conformity with International Public Sector Accounting Standards (IPSAS), and in the manner required by the PFM Act, 2012 and Company's act (2015). The Directors are of the opinion that the *Entity's* financial statements give a true and fair view of the

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state of Kenya BioVax Institute's transactions during the financial year ended June 30, 2023, and of KBI's financial position as at that date. The Directors further confirms the completeness of the accounting records maintained for Kenya BioVax Institute Limited, which have been relied upon in the preparation of Kenya BioVax Institute financial statements as well as the adequacy of the systems of internal financial control.

In preparing the financial statements, the Directors have assessed the entity's ability to continue as a going concern.

Nothing has come to the attention of the Directors to indicate that the Institute will not remain a going concern for at least the next twelve months from the date of this statement.

Approval of the financial statements

The Kenya BioVax Institute Limited financial statements were approved by the Board on G Day

_, 2023 and signed on its behalf by:

Name: Mugo Kibati EBS

Chairman of the Board

Name: Dr. Michael Lusiola

Accounting Officer

REPUBLIC OF KENYA

Telephone: +254-(20) 3214000 E-mail: info@oagkenya.go.ke Website: www.oagkenya.go.ke



HEADQUARTERS
Anniversary Towers
Monrovia Street
P.O. Box 30084-00100

NAIROBI

Enhancing Accountability

REPORT OF THE AUDITOR-GENERAL ON KENYA BIOVAX INSTITUTE LIMITED FOR THE YEAR ENDED 30 JUNE, 2023

PREAMBLE

I draw your attention to the contents of my report which is in three parts:

- A. Report on the Financial Statements that considers whether the financial statements are fairly presented in accordance with the applicable financial reporting framework, accounting standards and the relevant laws and regulations that have a direct effect on the financial statements.
- B. Report on Lawfulness and Effectiveness in Use of Public Resources which considers compliance with applicable laws, regulations, policies, gazette notices, circulars, guidelines and manuals and whether public resources are applied in a prudent, efficient, economic, transparent and accountable manner to ensure Government achieves value for money and that such funds are applied for the intended purpose.
- C. Report on Effectiveness of Internal Controls, Risk Management and Governance which considers how the entity has instituted checks and balances to guide internal operations. This responds to the effectiveness of the governance structure, the risk management environment and the internal controls, developed and implemented by those charged with governance for orderly, efficient and effective operations of the entity.

An unmodified opinion does not necessarily mean that an entity has complied with all relevant laws and regulations, and that its internal controls, risk management and governance systems are properly designed and were working effectively in the financial year under review.

The three parts of the report are aimed at addressing the statutory roles and responsibilities of the Auditor-General as provided by Article 229 of the Constitution, the Public Finance Management Act, 2012 and the Public Audit Act, 2015. The three parts of the report, when read together constitute the report of the Auditor-General.

REPORT ON THE FINANCIAL STATEMENTS

Opinion

I have audited the accompanying financial statements of Kenya Biovax Institute Limited set out on pages 1 to 14, which comprise of the statement of financial position as at 30 June, 2023, and the statement of financial performance, statement of changes in net assets, statement of cash flows and statements of comparison of budget and actual

amounts for the year then ended, and a summary of significant accounting policies and other explanatory information in accordance with the provisions of Article 229 of the Constitution of Kenya and Section 35 of the Public Audit Act, 2015. I have obtained all the information and explanations which, to the best of my knowledge and belief, were necessary for the purpose of the audit.

In my opinion, the financial statements present fairly, in all material respects, the financial position of Kenya Biovax Institute Limited as at 30 June, 2023, and of its financial performance and its cash flows for the year then ended, in accordance with International Public Sector Accounting Standards (Accrual Basis) and comply with the Public Finance Management Act, 2012 and Medical Practitioners and Dentists Act, Cap.253 Laws of Kenya.

Basis for Opinion

The audit was conducted in accordance with International Standards of Supreme Audit Institutions (ISSAIs). I am independent of the Kenya Biovax Institute Limited Management in accordance with ISSAI 130 on Code of Ethics. I have fulfilled other ethical responsibilities in accordance with the ISSAI and in accordance with other ethical requirements applicable to performing audits of financial statements in Kenya. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Key Audit Matters

Key audit matters are those matters that, in my professional judgment, are of most significance in the audit of the financial statements. There were no key audit matters to report in the year under review.

REPORT ON LAWFULNESS AND EFFECTIVENESS IN USE OF PUBLIC RESOURCES

Conclusion

As required by Article 229(6) of the Constitution, based on the audit procedures performed, except for the matters described in the Basis for Conclusion on Lawfulness and Effectiveness in Use of Public Resources section of my report, I confirm that, nothing else has come to my attention to cause me to believe that public resources have not been applied lawfully and in an effective way.

Basis for Conclusion

1. Non-Maintenance of an Asset Register

During the year under review, the Institute did not provide for audit an asset register which contain key information such as historical cost of assets, date of acquisition and physical location of the asset as required in an asset register. This was contrary to Regulation 143 (1) of the Public Finance Management (National Government) Regulations, 2015 which provides that the Accounting Officer shall be responsible for maintaining a register of assets under his or her control or possession as prescribed by the relevant laws.

In the circumstances, Management was in breach of the law.

2. Non-Deduction and Remittance of Statutory Deductions

During the year under review, the Institute did not deduct nor remit National Social Security Fund deductions amounting to Kshs.5,600 and National Health Insurance Fund deductions amounting to Kshs.53,450. Further, Management did not provide evidence of remission of Pay As You Earn (PAYE) estimated at Kshs.3,384,853. Non-remission of taxes to respective Authorities may result in imposition of penalties and interests.

In the circumstances, Management was in breach of the law.

3. Lack of Strategic Plan

As previously reported, during the year the Institute has not put in place a strategic plan to guide on future milestones in its endeavor to fulfil its mandate, this was contrary to Section 68 of the Public Finance Management (National Government) Act, 2015 which states that an Accounting Officer shall prepare a strategic plan for the entity in conformity with the medium term fiscal framework and fiscal policy objectives of the national government.

In the circumstances, Management was in breach of the law.

4. Lack of Board Charter

As previously reported, during the year under review, the Institute operated without a charter contrary to the provisions of Section 1.11(1,2) of Mwongozo Code on management of state corporations.

In the circumstances, Management was in breach of the law.

The audit was conducted in accordance with ISSAI 4000. The standard requires that I comply with ethical requirements and plan and perform the audit to obtain assurance about whether the activities, financial transactions and information reflected in the financial statements are in compliance, in all material respects, with the authorities that govern them. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my conclusion.

REPORT ON EFFECTIVENESS OF INTERNAL CONTROLS, RISK MANAGEMENT AND GOVERNANCE

Conclusion

As required by Section 7(1)(a) of the Public Audit Act, 2015, based on the audit procedures performed, except for the matters described in the Basis for Conclusion on Effectiveness of Internal Controls, Risk Management and Governance section of my report, I confirm that, nothing else has come to my attention to cause me to believe that internal controls, risk management and overall governance were not effective.

Basis for Conclusion

1. Wrong Computation and Remittance of Taxes

Note 14 to the financial statements reflects property, plant and equipment balance of Kshs.29,047,643. The balance includes an amount of Kshs.13,838,800 in respect of motor vehicle while the purchase price was Kshs.11,930,000 and hence resulting to a tax

overpayment of Kshs.1,908,800 to Kenya Revenue Authority. Though Management has initiated the process of claiming the amount, the refund had not been received as at 30 June, 2023.

In the circumstances, the internal controls on tax computations could not be confirmed.

2. Weakness in Internal Controls

The Kenya Biovax Institute Limited was established in September, 2021 as a State Corporation under the Ministry of Health, by the Companies Act, 2015 to have a comprehensive framework for the manufacture and commercialization of vaccines, therapeutics and diagnostics; support technology transfer and commercialization of outputs on Healthcare Products and Technologies (HPTs) from research institutions, and universities.

However, the Institute is not fully operational and the following deficiencies were noted;

No.	Observation	Guiding Law/Principle	Risk
1	Lack of an Internal Audit Department	Section 73 (1)(a) of the Public Finance Management Act, 2012 states that every national government entity shall have appropriate arrangements in place for conducting internal audit according to the guidelines of the Accounting Standards Board. Further, Sub-sections 4 and 5 states that a national government entity shall ensure that internal audits in respect of the entity are conducted in accordance with international best practices.	may lead to ineffective internal controls and non-compliance with the relevant laws, rules
2	Lack of Risk Management Policies	Public Finance Management Regulations 2015 Section 165-part (1) states that the accounting officer shall ensure that the national government develops a) risk management strategies which include fraud prevention mechanism and b) a system of risk management and internal control that builds robust business operations.	policies in place to manage the risks in
3	Lack of Policy Framework	Review of the organization's records revealed the Institute did not have a Human Resource Policy as required by Section B2 of the Human Resource Policies and Procedures Manual for Public Service, 2016. Further the Institute lacked Finance Policy, Asset Management Policy and Transport Policy to guide in decision making.	framework could lead to poor decisions due to

No.	Observation	Guiding Law/Principle	Risk
4	Failure to Carry out Risk Assessment	Treasury Circular No. 3/2009 of 23 February 2009 provided a broad policy framework for developing and implementing customized Risk Management Strategies in Public Institutions. The circular required all heads of Public Institutions to develop and implement a Risk Management Framework as a fundamental step towards establishing an accountable and innovative public service. The circular requires that all Public Institutions develop an Institutional Risk Management Policy Framework (IRMPF). The circular also requires accounting officers and other to put in place structures and systems to manage their identified risks, considering their legal obligations, policy decisions, business objectives and public sector expectations.	Failure to ensure that there is an effective risk-based internal audit system may lead to lack of a procedure in combating any risks that arises.
5	Failure to have ICT Policy	Regulation 101 part 1 of the Public Finance Management (National Government) Regulations, 2015 requires the Accounting Officer of a national government entity to institute appropriate access controls needed to minimize breaches of information confidentiality, data integrity and loss of business continuity.	operations coming to a complete shut down in the event of a disaster in the absence of a back-

The audit was conducted in accordance with ISSAI 2315 and ISSAI 2330. The standards require that I plan and perform the audit to obtain assurance about whether effective processes and systems of internal controls, risk management and overall governance were operating effectively, in all material respects. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my conclusion.

Responsibilities of Management and Board of Directors

Management is responsible for the preparation and fair presentation of these financial statements in accordance with International Public Sector Accounting Standards (Accrual Basis) and for maintaining effective internal controls as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error and for its assessment of the effectiveness of internal controls, risk management and overall governance.

In preparing the financial statements, Management is responsible for assessing the Institute's ability to sustain services, disclosing, as applicable, matters related to sustainability of services and using the applicable basis of accounting unless the Management is aware of the intention to dissolve the Institute or to cease operations.

Management is also responsible for the submission of the financial statements to the Auditor-General in accordance with the provisions of Section 47 of the Public Audit Act, 2015.

In addition to the responsibility for the preparation and presentation of the financial statements described above, Management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities which govern them, and that public resources are applied in an effective way.

The Board of Directors is responsible for overseeing the Institute's financial reporting process, reviewing the effectiveness of how Management monitors compliance with relevant legislative and regulatory requirements, ensuring that effective processes and systems are in place to address key roles and responsibilities in relation to governance and risk management, and ensuring the adequacy and effectiveness of the control environment.

Auditor-General's Responsibilities for the Audit

The audit objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes my opinion in accordance with the provisions of Section 48 of the Public Audit Act, 2015 and submit the audit report in compliance with Article 229(7) of the Constitution. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISSAIs will always detect a material misstatement and weakness when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

In addition to the audit of the financial statements, a compliance audit is planned and performed to express a conclusion about whether, in all material respects, the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities that govern them and that public resources are applied in an effective way, in accordance with the provisions of Article 229(6) of the Constitution and submit the audit report in compliance with Article 229(7) of the Constitution.

Further, in planning and performing the audit of the financial statements and audit of compliance, I consider internal control in order to give an assurance on the effectiveness of internal controls, risk management and governance processes and systems in accordance with the provisions of Section 7(1)(a) of the Public Audit Act, 2015 and submit the audit report in compliance with Article 229(7) of the Constitution. My consideration of the internal control would not necessarily disclose all matters in the internal controls that might be material weaknesses under the ISSAIs. A material weakness is a condition in

which the design or operation of one or more of the internal control components does not reduce to a relatively low level the risk that misstatements caused by error or fraud in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

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Because of its inherent limitations, internal controls may not prevent or detect misstatements and instances of non-compliance. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

As part of an audit conducted in accordance with ISSAIs, I exercise professional judgement and maintain professional skepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal controls.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the applicable basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Institute's ability to continue as a going concern or to sustain its services. If I conclude that a material uncertainty exists, I am required to draw attention in the auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my audit report. However, future events or conditions may cause the Institute to cease to continue to sustain its services.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information and business activities of the Institute to express an opinion on the financial statements.
- Perform such other procedures as I consider necessary in the circumstances.

I communicate with Management regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that are identified during the audit.

I also provide Management with a statement that I have complied with relevant ethical requirements regarding independence and to communicate with them all relationships and other matters that may reasonably be thought to bear on my independence and where applicable, related safeguards.

FCPA Nancy Gathungu, CBS AUDITOR-GENERAL

Nairobi

01 March, 2024

13. Statement of Financial Performance for the year ended 30 June 2023

	Notes	2022-2023	2021-2022
		Kshs	Kshs
Revenue from non-exchange transactions			
Transfers from other governments entities	6	58,333,332	90,605,000
		58,333,332	90,605,000
Revenue from exchange transactions			
Finance income	7	12,049,720	399,819
		12,049,720	399,819
Total revenue		70,383,052	91,004,819
Expenses			
Use of goods and services	8	43,158,897	18,713,718
Employee cost	9	11,524,173	- ,
Board Expenses	10	2,660,934	-
Repair and Maintenance	11	2,487,083	-
Depreciation and amortization	14	1,988,731	-
Total expenses		61,819,818	18,713,718
Surplus/ (deficit) before tax		8,563,234	72,291,101

The notes set out on pages 6 to 13 form an integral part of these Financial Statements. The Financial Statements set out on pages 1 to 5 were signed on behalf of the Board of Directors by:

Name: Dr. Michael Lusiola

Name: CPA Evelyn Wangeci

Name: Mugo Kibati EBS

Accounting Officer

Head of Finance

Chairman of the Board

ICPAK M/No:15404

Date 06 | 03 | 2024

Date 06 03 2024

Date \$6/03/2124

15 Statement of Financial Position as at 30 June 2023

Statement of Financial Position as	Notes 2022-2023 2021-2022					
	Notes	Kshs	Kshs			
Assets		KSIIS	KSIIS			
Current Assets						
Cash and Cash equivalents	12	453,352,382	465,127,396			
Receivable	13	100,000,000				
Total Current Assets		553,352,382	465,127,396			
Non-Current Assets						
Property, Plant and Equipment	14	29,047,643	11,930,000			
Total Non- Current Assets		29,047,643	11,930,000			
Total Assets		582,400,025	477,057,396			
Liabilities						
Current Liabilities						
Trade and Other Payables	15	1,545,690	4,766,295			
Total Current Liabilities		1,545,690	4,766,295			
Net Assets						
Accumulated Surplus		80,854,335	72 201 101			
Capital Fund		500,000,000	72,291,101			
Total Net Assets		580,854,335	400,000,000			
Total Net Assets and Liabilities		582,400,025	472,291,101 477,057,396			

16. Statement of Changes in Net Assets for the year ended 30 June 2023

Statement of Changes in Net Assets for the year ended 30 June 2023				
Description	Fund balance	Retained earnings	Total	
	Kshs	Kshs	Kshs	
Capital/development grants received during the year	400,000,000	-	400,000,000	
Surplus/ (deficit) for the year	-	72,291,101	72,291,101	
As at June 30, (2022)	400,000,000	72,291,101	472,291,101	
As at July 1, (2023)	400,000,000	72,291,101	472,291,101	
Surplus/ (deficit) for the year	-	8,563,234	8,563,234	
Capital/development grants received during the year	100,000,000	·	100,000,000	
As at June 30, (2023)	500,000,000	80,854,335	580,854,335	

(Indicate actual name of the entity)
Annual Report and Financial Statements
for the year ended June 30, 2023

17. Statement of Cash Flows for the year ended 30 June 2023

		2022-2023	Fy 2021-2022
	Note s	Kshs	Kshs
Cash flows from operating activities			
Receipts			
Transfers from other governments entities	6	58,333,332	90,605,000
Finance income	7	12,049,720	399,819
Total receipts		70,383,052	91,004,819
Payments			
Use of goods and services	8	43,158,897	13,947,423
Employee costs	9	11,524,173	-
Board Expenses	10	2,660,934	-
Repairs and maintenance	11	2,487,083	-
Working capital adjustment-Decrease in payables	15	3,220,605	-
Total payments		63,051,692	13,947,423
Net cash flows from/(used in) operating activities		7,331,360	77,057,396
Cash flows from investing activities			
Purchase of PPE and Intangible assets	14	19,106,374	-11,930 ,000
Net cash flows from (used in) investing activities		19,106,374	11,930,000
Cash flows from financing activities			
Proceeds of Grants from National Government		-	400,000,000
Net cash flows from financing Activities		-	400,000,000
Net increase/(decrease) in cash & Cash equivalents		11,775,014	465,127,39
Cash and cash equivalents at 1 July		465,127,396	465,127,39
Cash and cash equivalents at 30 June		453,352,382	465,127,39

Annual Report and Financial Statements

for the year ended June 30, 2023

18. Statement of Comparison of Budget and Actual amounts for the year ended 30 June 2023

	Original budget	Adjustmen ts	Final budget	Actual on comparable basis	Performance difference	% of utiliz ation
	2022-2023	2022-2023	2022-2023	2022-2023	2022-2023	2022
Revenue	Kshs	Kshs	Kshs	Kshs	Kshs	%
Transfers						70
from the	400,000,000	-	400,000,000	58,333,332	1_	
Government						15%
Finance	-	-	-	12,049,720	-	100%
income						10070
Total income	400,000,000		400,000,000	70,383,052	-	18%
Expenses				,,,,,,,,,		16%
Compensatio n of employees	20,000,000	-	20,000,000	11,524,173	8,475,827	58%
Use of goods and services	50,000,000	-	50,000,000	43,158,897	6,841,103	86%
Other payments	30,000,000	-	30,000,000	5,148,017	24,851,983	17%
Total expenditure				59,831,087		85%
Surplus for the period				10,551,965		3370
Capital Expenditure				0		

The financial statements set out on pages 1 to 5 were signed on behalf of the Board of Directors:

Name: Dr. Michael Lusiola

Name: CPA Evelyn Wangeci

Name: Mugo Kibati EBS

Accounting Officer

Head of Finance

Chairman of the Board

ICPAK M/No:15404

Date 06 103 2024 Date 06 03 2024

Date 06/03/2024

19. Notes to the Financial Statements

1. General Information

Kenya Biovax Institute Limited is established by and derives its authority and accountability from Company's Act (2015). The entity is wholly owned by the Government of Kenya and is domiciled in Kenya. The entity's principal activity is the manufacture and commercialisation of human HPTs, including vaccines, biotherapeutics and diagnostics.

For Kenyan Companies Act reporting purposes, the balance sheet is represented by the statement of financial position and the profit and loss account by the statement of profit or loss and other comprehensive income in these financial statements.

2. Statement of Compliance and Basis of Preparation

The financial statements have been prepared on a historical cost basis except for the measurement at re-valued amounts of certain items of property, plant and equipment, marketable securities and financial instruments at fair value, impaired assets at their estimated recoverable amounts and actuarially determined liabilities at their present value. The preparation of financial statements in conformity with International Public Sector Accounting Standards (IPSAS) allows the use of estimates and assumptions. It also requires management to exercise judgement in the process of applying the Kenya BioVax Institute's accounting policies. The areas involving a higher degree of judgement or complexity, or where assumptions and estimates are significant to the financial statements, are disclosed in Note 5 of these financial statements.

The financial statements have been prepared and presented in Kenya Shillings, which is the functional and reporting currency of KBI *The* financial statements have been prepared in accordance with the PFM Act, the State Corporations Act, and International Public Sector Accounting Standards (IPSAS). The accounting policies adopted have been consistently applied to all the years presented

6. Transfers from Other Government entities

Description	2022-2023 KShs	Fy 2021-2022 KShs
Unconditional Grants		
Operational Grant	58,333,332	90,605,000
Total Unconditional Grants	58,333,332	90,605,000

(Explain the purpose of funding)

Transfers from Ministries, Departments and Agencies (MDAs)

Name of The Entity Sending The Grant	Amount recognized to Statement of Financial performance.*	Amount deferred under deferred income.	Amount recognised in capital fund.	Total transfers (Current FY)	Insert Comparative FY
	KShs	KShs	KShs	KShs	KShs
Ministry of Health	58,333,332	-	100,000,000	158,333,332	490,605,000
Total	58,333,332	-	100,000,000	158,333,332	490,605,000

(Ensure that the amount recorded above as having been received from the Ministry fully reconciles to the amount recorded by the sending Entity Ministry. An acknowledgement note/receipt should be raised in favour of the sending Ministry. The details of the reconciliation have been included under appendix xxx) *Amount recognised in the statement of financial performance should be the recurrent grant and the development grant to the extent that there are no conditions attached. Total of column 1 should tie to note 6(the part on unconditional grants).

7. Finance Income

Description	2022-2023 Kshs	Fy 2021-2022 Kshs	
Interest from commercial banks and financial institutions	12,049,720	399,819	
Total finance income	12,049,720	399,819	

(Interest accrued in the Institutes Bank Account)

8. Use of Goods and Services

Description	2022-2023	Fy 2021-2022
	Kshs	Kshs
Subscriptions	709,660	_
Advertising	1,420,758	-
Audit Fees	696,000	-
Conferences and Delegations	1,407,052	-
Consulting Fees	4,505,440	-
Hospitality	2,439,845	-
consumables	255,000	-
Fuel and Oil	2,760,768	-
Licenses and Permits	1,350,900	-
Telecommunication	1,235,199	-
Travel, Subsistence & Other Allowances*	25,746,138	-
Bank charges	98,537	84,621
Other operating expenses	533,600	18,629,097
Total Costs	43,158,897	18,713,718

Notes to the Financial Statements (Continued)

9. Employee Costs

Employee Costs		
Description	2022-2023	Fy

		2021-2022
	Kshs	Kshs
Salaries and wages	11,282,846	0
Overtime payments	241,327	0
Employee costs	11,524,173	0

10. Board Expenses

Description	2022-2023 Kshs	Fy 2021-2022 Kshs
Chairman/Directors' Honoraria	672,000	0
Sitting Allowances	1,916,534	0
Travel and Subsistence	72,400	
Total	2,660,934	0

11. Repairs and maintenance

Description	2022-2023	Fy 2021-2022	
	Kshs	Kshs	
Vehicles	2,487,083	-	
Total Repairs and Maintenance	2,487,083	-	

Annual Report and Financial Statements for the year ended June 30, 2023

12. Cash and Cash Equivalents

Description	2022-2023 Kshs	2021-2022 Kshs
Bank and Cash Balances	453,352,382	465,127,396
Total Cash And Cash Equivalents	453,352,382	465,127,396

12 (b). Detailed Analysis of the Cash and Cash Equivalents

Financial Institution	Account number	2022-2023 Kshs	Fy 2021-2022 Kshs
a) Current Account			
NCBA - Upper Hill Branch	5462760018	453,352,382	465,127,396
Sub- Total		453,352,382	465,127,396
Grand Total		453,352,382	465,127,396

13. Receivables from Non-Exchange Transactions

Description	2022-2023 Kshs	Fy 2021-2022 Kshs
Ministry of Health	100,000,000	-
Total receivables from non- exchange transactions	100,000,000	-

Cost	Buildings	Motor vehicles	Furniture and fittings	Computers	Total
	Kshs	Kshs	Kshs	Kshs	Kshs
As At 1July (2021)	0	-	-	-	-
Additions	0	11,930,000		-	11,930,000
Disposals	0	-	-	-	-
Transfers/Adjustment s	0	-	-	-	-
As at 30 th June (2022)	0	11,930,000	-	-	11,930,000
Additions	9,397,970	1,908,800	4,973,000	2,826,604	19,106,374
Disposals	0	-	-	-	_
Transfer/Adjustments	0	-	-	-	-
As at 30 th June (2023)	9,397,970	13,838,800	4,973,000	2,826,604	31,036,374
Depreciation And Impairment					-
At 1July (2022)	0	-	-	-	-
Depreciation	0		-	-	-
Impairment	0	-	-	-	-
Transfers/ Adjustments	0	-	-	-	-
As At 30th (2023)	0	-	-	-	-
Depreciation	0	1,988,731	-	-	1,988,731
Disposals	0	-	-	-	-
Impairment	0	_	-	-	_
Transfer/Adjustment	0	-	-	-	-
As at 30 th June (2023)	9,397,970	11,850,069	4,973,000	2,826,604	29,047,643
Net Book Values					-
As at 30 th June (2022)	0	11,930,000	-	-	11,930,000

(Indicate actual name of the entity)

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for the year ended June 30, 2023

1 1	1				
As at 30 th June (2023)	9,397,970	11,850,069	4,973,000	2,826,604	29,047,643

15. Trade and Other Payables

Description	2022-2023 Kshs	Fy 2021-2022 Kshs
Trade payables	1,545,690	4,766,295
Total trade and other payables	1,545,690	4,766,295

16. Events after the Reporting Period

There were no material adjusting and non- adjusting events after the reporting period.

17. Ultimate and Holding Entity

Kenya BioVax Institute is a State Corporation under the Ministry of Health. Its ultimate parent is the Government of Kenya.

18. Currency

The financial statements are presented in Kenya Shillings (Kshs) rounded to the nearest Kshs.

Appendices

Appendix 1: Implementation Status of Auditor-General's Recommendations

The following is the summary of issues raised by the external auditor, and management comments that were provided to the auditor.

Reference No. on the external audit Report	Issue / Observations from Auditor	Management comments	Status: (Resolved / Not Resolved)	Timeframe: (Put a date when you expect the issue to be resolved)

Guidance Notes:

- (i) Use the same reference numbers as contained in the external audit report;
- (ii) Obtain the "Issue/Observation" and "management comments", required above, from final external audit report that is signed by Management;
- (iii) Before approving the report, discuss the timeframe with the appointed Focal Point persons within your Entity responsible for implementation of each issue;
- (iv) Indicate the status of "Resolved" or "Not Resolved" by the date of submitting this report to National Treasury.

Director General/C.E.O/M.D (enter title of head of Entity)

Date:

Appendix II: Projects implemented by *Kenya Biovax Institute*Projects implemented by the State Corporation/ SAGA Funded by development partners and/
or the Government.

oject itle	Project Number	Dono r	Period/ duratio n	Donor commitmen t	Separate donor reporting required as per the donor agreement (Yes/No)	Consolidated in these financial statements. (Yes/No)

Status of Projects completion

(Summarise the status of project completion at the end of each quarter, i.e. total costs incurred, stage which the project is etc)

SN	Project	Total project Cost	Total expended to date	Completion % to date	Budget	Actual	Sources of funds

Appendix IV: Transfers from Other Government Entities

					Where Reco				
Name of the MDA/Donor Transferring the funds	Date received as per bank statement	evelopment/ Amou	Total Amount - KES	ount - Financial	Capital Fund	Deferred Income	Receivables	Others - must be specific	Total Transfers during the Year
Ministry of									
Health	12/12/2022	Recurrent	-	58,333,332	-	-	-	-	58,333,332
Total				58,333,332	-	-	-	-	58,333,332

Appendix V- Inter-Entity Confirmation Letter

[Insert your Letterhead]

[Insert name of beneficiary Entity] [Insert Address]

The [insert SC/SAGA/Fund name here] wishes to confirm the amounts disbursed to you as at 30th June 20xx as indicated in the table below. Please compare the amounts disbursed to you with the amounts you received and populate the column E in the table below Please sign and stamp this request in the space provided and return it to us.

Confirmation of amounts received by [Insert name of beneficiary Entity] as at 30th June (Current FY)												
		Amounts Disbu	Amounts Disbursed by [SC/SAGA/Fund] (KShs) as at 30th June (Current Amount Received									
			FY)			by [beneficiary						
						Entity]	Differences					
Reference	Date Disbursed	Recurrent (A)	Development (B)	Inter-	Total	(KShs) as at 30th	(KShs)					
Number				Ministerial	(D)=(A+B+C)	June (Previous FY)	(F)=(D-E)					
				(C)		(E)						
Total												

In confirm that the amounts shown above are correct as of the date indicated.

Head of Accountants department of beneficiary Entity:

Appendix VI: Reporting of Climate Relevant Expenditures

Project Name	Project Description	Project Objectives	Project Activities	Quarter				Source of Funds	Implementing Partners	
Name				Q1	Q2	Q3	Q4			

Appendix VII: Reporting on Disaster Management Expenditure

Column I	Column II	Column III	Column IV	Column V	Column VI	Column VII
Programme	Sub- programme	Disaster Type	Category of disaster related Activity that require expenditure reporting	Expenditure item	Amount (Kshs.)	Comments
			(response/recovery/mitigation/preparedness)			