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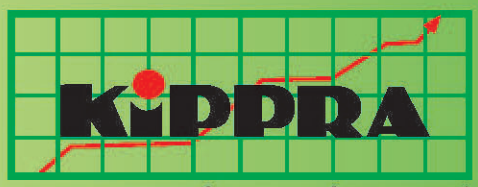

The KENYA INSTITUTE for PUBLIC POLICY RESEARCH and ANALYSIS

Towards Human Vaccine Production in Kenya: Exploring Key Pathways to Sufficient Production

Peris Mwangi and Boaz Munga

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THE KENYA INSTITUTE FOR PUBLIC POLICY RESEARCH AND ANALYSIS (KIPPRA)

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Abstract

This study examines human vaccine production in Kenya, focusing on key drivers, policies, and regulatory frameworks, while suggesting pathways for sufficient manufacturing through 2040. Employing future foresight methodology, it analyzes data from systematic literature reviews and expert interviews. Vaccine production is vital for Kenya due to the high morbidity and mortality from vaccine preventable diseases; the experiences from the COVID-19 pandemic; and the accelerated phase-out of vaccine supply support from the Vaccine Alliance (Gavi) before 2030. The study finds that strong government support and robust partnerships are essential for successful human vaccine production based on the experiences of leading countries. The key factors include funding from the exchequer, supported by favourable policies, regulatory frameworks, infrastructure, and R&D capabilities. It emerges that there are many opportunities for Kenya to leverage financial and technical support from global and regional organizations in its efforts to establish a vaccine industry, including the African Union. On the legal and regulatory front, Kenya faces a lack of harmony between domestic and international legal frameworks, and gaps in the adoption of international standards. These factors may hinder efforts in human vaccine production. The study recommends that the government, in collaboration with other stakeholders, enhance support for R&D and infrastructure development through national budgeting and public-private partnerships. Essential infrastructure includes formulation and fill-finish facilities, along with advanced equipment for vaccine production. It also highlights the need to identify skills gaps and implement human capital development programmes to build a skilled workforce while creating attractive work environments to prevent brain drain. Additionally, the regulatory framework should be strengthened by supporting the Pharmacy and Poisons Board (PPB) to establish a stable, integrated system capable of effectively regulating vaccines. Regulatory reforms are also needed to harmonize domestic and regional or international legal landscapes by adopting international standards. Kenya has opportunities to leverage global and regional goodwill to secure support from various actors, including the African Union and Gavi.

Abbreviations and Acronyms

ACDC	Africa Centre for Disease Control
AIDS	Acquired Immuno Deficiency Syndrome
AU	African Union
AVAREF	African Vaccine Regulatory Forum
AVEC	Advancing Vaccine End-to-End Capabilities
BETA	Bottom-up Economic Transformation Agenda
CEPI	Coalition for Epidemic Preparedness Innovations
CIA	Cross Impact Analysis
CRC	Centre for Clinical Research
DALYs	Disability-Adjusted Life-Years
DHHS	Department of Health and Human Services
EAC	East African Community
F&F	Fill and Finish
FFF	Form, Fill, and Finish
GAVI	Global Alliance for Vaccines and Immunization
GBT	Global Benchmarking Tool
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
HPV	Human papillomavirus
ISO	International Organization for Standardization
IVI	International Vaccines Institute
KAVI	Kenya AIDS Vaccine Initiative (KAVI)
KBI	Kenya BioVax Institute
KEMRI	Kenya Medical Research Institute
KNBS	Kenya National Bureau of Statistics
MDI	Matrix of Direct Influence
MICMAC	Multiplication of Cross Impact Matrices Applied to Classification
MOH	Ministry of Health
mRNA	Messenger RNA
NMRA	National Medicine Regulatory Authority
NQCL	National Quality Control Laboratory
NTD	Neglected Tropical Disease
PATH	Programme for Appropriate Technology in Health
PAVM	Partnerships for African Vaccine Manufacturing
PESTLE	Political, Economic, Social, Technical, Legal, and Environmental
PPB	Pharmacy and Poisons Board
PPP	Public Private Partnership
R&D	Research and Development
RNA	Ribonucleic Acid
SADC	Southern African Development Community
SDG	Sustainable Development Goal
SEZ	Special Economic Zone (SEZ)
SSA	Sub-Saharan Africa
STI	Science, Technology, and Innovation
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TRIPS	Trade-Related Aspects of Intellectual Property Rights

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1. Introduction

Vaccine-preventable diseases (VPDs) continue to have significant negative impacts across the globe and particularly in Africa. These diseases include infectious diseases, which are a major contributor to global morbidity and mortality. Diseases such as diarrhoea, influenza, and malaria are prevalent in many parts of the world, affecting millions of people simultaneously. Their rapid spread has often led to epidemics and pandemics, resulting in high mortality rates. These diseases have significant economic and social repercussions, including disruptions to trade, travel, and education; increased healthcare costs; loss of productivity; and death. In 2019, infectious diseases were estimated to have caused 8.7 million deaths worldwide, representing around 15 per cent of all deaths globally (Zhang, Fu, Liu, Zhao, Wang, 2023).

Expanding access to human vaccines is vital and among the most effective interventions in combating infectious diseases. Recognizing the importance of immunization or vaccines, the 73rd World Health Assembly (in 2020) endorsed the Immunization Agenda 2030 (IA2030), which is a comprehensive global strategy aimed at ensuring individuals of all ages worldwide fully benefit from vaccines for their health and well-being (WHO, 2021).

However, despite these ambitious goals, Africa has the highest number of unvaccinated and under-vaccinated children, with 12.7 million children falling into this category in 2021, including 8.7 million who did not receive any dose (UNICEF, 2023). Moreover, Africa, including Kenya, finds itself overly reliant on external sources for human vaccines. This dependence poses several risks and challenges to the country and the continent, including supply chain vulnerability and limited control over human vaccine availability. Relying heavily on external sources makes countries susceptible to supply chain disruptions, which can result in shortages. Additionally, limited control over availability, pricing, and distribution of human vaccines can lead to delays, especially during global shortages.

A combination of the aforementioned and other factors provides compelling reasons for establishing a vaccine industry in Kenya. One of the key reasons for establishing local human vaccine production is that it aligns with global efforts to achieve the Sustainable Development Goals (SDGs), particularly SDG3 (on good health and well-being) and SDG9 (on industry, innovation, and infrastructure). Vaccine production also aligns with the strategic plan for the Africa Centre for Disease Control (ACDC) referred to as the 'African CDC 2040', which aims at transforming public health across the continent by the year 2040. In this ambitious plan, one of the key goals and initiatives is for African countries to manufacture 60 per cent of its pharmaceutical and human vaccine requirement.

In addition to alignment with international, regional, and national goals, a second compelling reason to establish a vaccine industry in Kenya is the country's ongoing transition from support by the Global Alliance for Vaccines and Immunization (GAVI). This is as a result of Kenya's transition to a lower-middle-income economy. Currently, the country is in an accelerated phase of this transition, which includes a 25 per cent annual increase in co-financing that began in 2023/24. This means

that by 2027/28 the country will be paying 100 per cent of the vaccines previously supported by GAVI, which will increase the governments obligation tenfold.

Further, the establishment of a human vaccine industry is likely to stimulate economic growth by attracting investment, manufacturing infrastructure, and creating job opportunities. Importing human vaccines is also expensive, thus straining national healthcare budgets and creating challenges related to human vaccine quality and safety. Investing in local vaccine production fosters technological innovation, knowledge transfer, and skill development in biotechnology, pharmaceuticals, and related fields. Collaborations with international partners and technology transfer agreements facilitate the exchange of expertise, best practices, and cutting-edge technologies, enhancing Kenya's scientific capabilities and competitiveness in the global marketplace.

Locally produced vaccines are more likely to be tailored to local disease burdens and public health needs (Rodrigues and Plontkin, 2020). This is relevant for vaccines of existing diseases and new vaccines for emerging diseases such as COVID-19. This is particularly pertinent for Kenya and other Sub-Saharan Africa (SSA) countries, which face the challenge of neglected tropical diseases (NTDs). Examples in Kenya include bilharzia (schistosomiasis), chikungunya, dengue fever, elephantiasis (lymphatic filariasis), Rift Valley fever, and sleeping sickness, which may all require effective and universally safe vaccines to prevent outbreaks.

A local vaccine industry will enhance Kenya's sovereignty and self-reliance in healthcare services. Local production will also improve access to affordable vaccines for populations in Kenya and the region. In addition, local vaccine production addresses the need for pandemic preparedness. For instance, the COVID-19 pandemic underscored the critical importance of having local vaccine manufacturing capabilities to respond swiftly to emerging infectious diseases and health crises.

Studies indicate that investment in human vaccine production is likely to yield high returns. For instance, World Bank analysis shows that regional investment in vaccine manufacturing, research and development (R&D) and regulatory capacity building will cost less than 1.0 per cent of total government health expenditure while providing cost-benefit ratios four times higher than national-level investments (Mutasa et al., 2023). Additionally, a study published in The Lancet Global Health addressed a critical evidence gap regarding the business case for investing in vaccine and therapeutics manufacturing in South Africa, Kenya, and India. The study estimated that the required investments range from 1.5 billion to 1.7 billion US dollars and could significantly impact mortality and disability-adjusted life-years (DALYs) averted in these regions (Lancet, 2023).

This study examines the necessary measures to establish and achieve sufficient human vaccine production in Kenya. The starting point is an outline of the ideal goals for vaccine production in Kenya and the steps required to reach these goals within the current context. The study charts a pathway towards local vaccine production by identifying feasible interventions based on lessons learnt from around the world. Therefore, this study aids in assessing the key drivers for human vaccine production in Kenya. It also provides a review and suggests improvements

to the policy and regulatory frameworks in the human vaccine industry in Kenya. Lastly, the study identifies interventions that can facilitate the development of human vaccine production in Kenya through 2040.

This study is organized into six sections, with the first section introducing the human vaccine industry and discussing the Kenyan context. Section two reviews the global, regional, and local contexts of the human vaccine industry, examining the various gaps in the regulatory framework and recommendations specific to Kenya. Section three presents the methodology, while section four employs futures foresight to explore the key drivers of human vaccine manufacturing and develops potential scenarios for the industry in Kenya through 2040. Section five proposes pathways for human vaccine manufacturing in Kenya, and section six provides the conclusion of the study.

2. Overview of the Human Vaccine Industry

This section examines the key activities of the human vaccine production process, including research and development (R&D) and other pre-manufacturing activities, production or manufacturing, exports, imports, and growth of demand of vaccines. It also examines human resource requirements for vaccine production, capacity development, and other development initiatives by various actors, including governments.

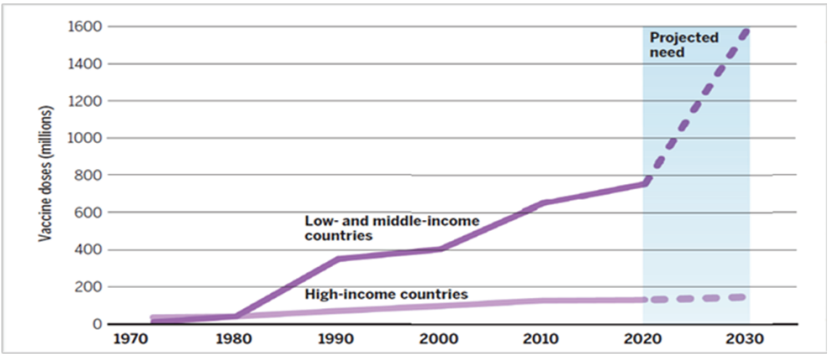
2.1 Global Context

Global research and development (R&D) vary significantly across different regions. Most R&D investments are associated with North America and European governments and private sectors. This has resulted in cutting edge technologies such as mRNA, vector based, and protein subunit vaccines. There is also increased R&D activity from Asia, particularly China and India while Africa continues to face significant challenges, including limited funding for vaccine R&D.

In terms of production, the European Union, the United States, and India are the three largest producers of human vaccines. Approximately 5.5 billion doses of human vaccines are produced globally each year. The European Union leads in both volume, accounting for 44 per cent of total global exports, and value, contributing 60.3 per cent. Other significant contributors include India and the United States, which account for 24.7 per cent and 22.0 per cent of the total global value traded, respectively (Guetta-Jeanrenaud, Poitiers and Veugelers, 2021). Additional key players in vaccine production include Indonesia, Japan, South Korea, and Russia (Evenett et al., 2021).

On the demand side, the vaccine market has seen significant growth since the 1970s, primarily driven by demand in low- and middle-income countries. Prior to the COVID-19 pandemic, projections suggested that the global vaccine market would exceed 62 billion US dollars by 2027 (Top 10 vaccine manufacturers, 2020). The global vaccine trends from 1970 to the present, along with projections from 2020 to 2030, are illustrated in Figure 2.1.

Figure 2.1: Projection of global vaccine trends



Source: Rappuoli et al. (2019)

As for human resources, the global setup is skewed such that there is often brain drain where skilled researchers from developing countries move to regions with better opportunities.

2.2 African Context

Africa's involvement in human vaccine pre-manufacturing activities, including R&D, lags the rest of the world. For example, clinical trials in Africa account for less than 1.0 per cent of the global trials (Editorial, 2022). As part of the efforts to address this issue, on 13th April 2021, African leaders agreed on an ambitious plan to construct facilities and fund research and development to increase the proportion of vaccines manufactured in Africa from 1.0 per cent in 2021 to 60.0 per cent by 2040. Moreover, the African Development Bank has plans to finance at least two technology platforms for vaccine production while the Africa Centre for Disease Control has plans to establish five new vaccine manufacturing facilities across the continent. These developments suggest that individual countries such as Kenya can leverage these emerging signals to set up vibrant vaccine industries.

Presently, less than 0.1 per cent of the world's vaccine supply is manufactured in Africa. Even so, the production of vaccines in Africa has seen significant advancements in recent years, with efforts focused on building local capacity and reducing dependency on foreign supplies. These initiatives received further impetus following the outbreak of the COVID-19 pandemic, which highlighted the urgent need for local vaccine manufacturing. Some of the key initiatives include significant financial commitments from global health organizations. These include GAVI and WHO, which support African vaccine manufacturing, pandemic preparedness, routine immunization catch-up efforts, and technology-transfer, particularly for mRNA vaccines.

Although Africa's capacity to participate in the final stages of vaccine production, referred to as 'form, fill, and finish' (FFF) has increased tremendously, a lot needs to be done to move up the value chain (Box 2.1). The continent's capacity for FFF surpasses the continent's demand and is approximately two (2) billion doses annually, which exceeds the average annual demand of 1.3 billion doses (Wellcome, 2023). There are also plans to expand this capacity further and it is projected to double by 2030. Part of what needs to be done by African countries, including Kenya is to move beyond the 'form, fill, and finish' process. An example of a process that can be taken up by African countries is the production of antigens (the active component in vaccines), which remains underdeveloped. This means that much of the continent's vaccine manufacturing is still dependent on importing antigens from other regions.

Box 2.1: About 'form, fill, and finish' (FFF)

Form or in full formulation involves mixing the bulk vaccine antigen (the active ingredient that triggers an immune response) with other components, such as stabilizers, preservatives, and adjuvants. The goal is to create a stable and effective vaccine formulation that can be stored and transported safely. Filling is the process of placing the vaccines into vials, syringes, or other containers. This step must be conducted under sterile conditions to prevent contamination and ensure the vaccine's safety and efficacy. Finishing includes sealing the vials or syringes, labelling, and packaging them for distribution. It also involves quality control checks to ensure that each batch of the vaccine meets the required standards before it is shipped to healthcare providers.

Africa imports 99 per cent of its vaccine needs, despite the presence of manufacturers with headquarters in Egypt, Morocco, Senegal, South Africa, and Tunisia. There are 13 operational vaccine companies and organizations across Africa. Ten have developed Fill and Finish (F&F) capacity, five have demonstrated Drug Substance (DS) capabilities, and three conduct research and development (R&D). It is projected that this would expand to 23 manufacturing facilities, including 12 end-to-end facilities and 11 F&F-only facilities, supplying 22 priority products by 2040 (Ekstrom et al., 2021). Thus, the Africa continent, which contributes 17 per cent of the global population and 25 per cent of the global burden of disease, is disproportionately impacted by vaccine nationalism, stockpiling and low economic status (Aderinto, Oladipo, Amao, Omonigbehin, 2023). The low production contributes to an expanding trade deficit and the poor availability of necessary vaccines.

Consequently, regional development organizations are now working together to expand local production in Africa as a part of their plans to boost the population's health. Examples include the Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action spearheaded by the AU (Africa CDC, 2021), the East African Community (EAC) Regional Pharmaceutical Plan of Action (2017-2027) and the Southern African Development Community (SADC) amended Pharmaceutical Business Plan. The policies acknowledge, among other things, that domestic pharmaceutical production is a strategic requirement and a viable potential for growth because it can be less expensive than imports and would improve the trade balance.

However, there are still challenges including limited local scientific capacity and unreliable supply chains, the lack of competent national medicine regulatory authorities (NMRAs); and unclear demand commitments of technology transfer agreements. There are also significant challenges with respect to infrastructure and funding for vaccine R&D. Even after successful production, there is need to unlock the structure of vaccine markets in Africa and infuse a dedication and backing to purchase vaccines made in Africa (Ekstrom et al., 2021; Aderinto et al., 2023).

2.3 The Context of Vaccine Industry in Kenya

Kenya aspires to position itself as the regional hub for specialized health products and technologies, focusing particularly on vaccines for children, adolescent girls, and maternal immunization. Presently, the country relies on imports for 70 per cent of its finished pharmaceutical commodities and 100 per cent of raw materials, consuming a significant portion of both government and private sector health expenditure (MOH, 2022). Moreover, Kenya, along with the broader African continent, imports over 98 per cent of its vaccine requirements, emphasizing the importance of achieving self-sufficiency in vaccine production for cost-effective public health interventions.

The Government of Kenya has over time put in place initiatives to promote the development of the vaccine industry in the country. This has been through various initiatives, including providing tax incentives and investing in supportive infrastructure. The Government has provided vaccine manufacturing companies with Special Economic Zone (SEZ) status, which grants these companies preferential policies, incentives, and infrastructure support. This intends to foster an environment conducive to industrial development and investment. In addition, the government offers tax incentives for vaccine manufacturers by waiving withholding tax and interest on payments to foreign entities undertaking human vaccine manufacturing in Kenya. This was introduced in the Finance Act, 2023 and is expected to incentivize multinational pharmaceutical companies to invest in local production.

A related incentive is the exemption from the 16 per cent value added tax (VAT) on the purchase of plant and machinery, which further reduces the cost burden for vaccine manufacturers. Corporate tax reduction of 10 per cent is another incentive for companies engaged in vaccine manufacturing. This was reduced from the standard 37.5 per cent for foreign entities. This is expected to attract investment in human vaccine production under the Special Economic Zone status.

Kenya, in collaboration with international organizations and partners has been actively engaged in vaccine research and development. Recently, the country submitted a request to the International Vaccines Institute (IVI), hosted by the Republic of Korea, seeking support in developing, manufacturing, and delivering vaccines through joint research, training, and education initiatives to enhance vaccine production capacity. Additionally, Kenya had been chosen as one of the recipients of global mRNA technology transfer by Moderna. Although the support was withdrawn, there is room for further engagement and support towards embracing innovative vaccine production methods.

Kenya's vaccine research capacity is on the rise. To this effect, the Science, Technology, and Innovation (STI) Act No. 28 of 2013, the main Act governing research activities in Kenya, put in place frameworks for the establishment of Kenya Medical Research Institute (KEMRI). KEMRI, the main government body conducting human health research in Kenya, has a strong track record in conducting clinical trials and developing new animal vaccines, boasting a national platform for clinical trials research with key sites in Nairobi, Kisumu, Thika, and Kilifi. Through its biotechnology programme, KEMRI actively supports the application of biotechnology in healthcare and medicine, with a focus on vaccine and diagnostic development. Another private R&D centre is the Kenya AIDS

Vaccine Initiative (KAVI), based at the University of Nairobi, which is licensed by the Pharmacy and Poisons Board (PPB) under the STI Act No. 28 of 2013. The research unit has contributed significantly to HIV vaccine trials, drug trials, epidemiological and basic research projects. The KAVI research unit has pioneered advancements in mucosal sampling and immune assay standardization.

Under KEMRI, Kenya is set to establish a 'form and fill' vaccine facility in the first phase of establishing the vaccine industry. Fill and finish (F&F) facilities are imperative since they include relatively fewer regulatory requirements, shorter project durations, have a chance to build a track record with partners and suppliers and finally are flexible in that they can process more types of vaccines as opposed to bulk facilities. By focusing on F&F facilities, the country can leverage existing infrastructure and expertise, establish partnerships, and build a track record in vaccine manufacturing, laying the foundation for further expansion into bulk vaccine production.

As part of a long-term strategy, the Kenyan government is committed to developing its capacity for manufacturing human vaccines to achieve self-sufficiency. Kenya established the Kenya BioVax Institute, which is mandated to manufacture, package, and commercialize specialized health products and technologies, including vaccines and therapeutics. The Government has also put in place additional initiatives, including human capacity building through training scientists and researchers in vaccine development and clinical trials and clinical trial sites. Some of the human vaccine development work ongoing in the country are as illustrated in Table 2.1.

Table 2.1: Human vaccine development status in Kenya

Type of vaccine	Study description	Partners
CRC HIV trials for RV460	Adjuvant study for a DNA/ protein prime /boost HIV vaccine using gp145	CRC/KEMRI
HIV/AIDS vaccine trial, HIVconsVX	A chimeric vaccine that can target a wide range of HIV mutants	KAVI/Oxford University
ChAdOx1 nCoV-19 vaccine (AstraZeneca Vaccine)	Evaluation of toxicity and efficacy of ChAdOx1 nCoV-19 vaccine	Welcome Trust/ KEMRI/ Oxford University
Malaria RTS, S/AS01 vaccine	Phase three evaluation of toxicity and efficacy RTS, S/AS01 vaccine	KEMRI/GSK/PATH
Phase III R21/Matrix-M malaria vaccine trial	Assessment of the malaria vaccine's, efficacy, its safety, and tolerability among infants and young children	KEMRI/University of Oxford/Serum Institute
Single dose HPV vaccine	Evaluation of efficacy of single dose Gardasil HPV vaccine as compared to current two or three doses	KEMRI/University of Washington/ Merck

Source: KEMRI

Notably, despite all the above efforts, and the established key equipment and facilities for research and development and a pool of experts in its research institutions such as KEMRI, Kenya is yet to produce its own human vaccine. However, four major efforts have been put in place to aid human vaccine production. This includes the establishment of Kenya Biovax Institute, Smart Vaccine Facility Project, Dawa (K) Limited Initiative and Moderna-Kenya Initiative. The Biovax Institute has already established a manufacturing plant at Embakasi, Nairobi County. The Institute anticipates producing two to three antigens by 2029, when GAVI will have fully withdrawn their support to the Kenyan government on the purchase of vaccines.

Kenya's reliance on external vaccine sources stems from various factors, including financial constraints and regulatory challenges. The country is experiencing various challenges that necessitate strategies to overcome them – for instance, the need to acquire sophisticated technology and expertise. Vaccine production also demands a reliable supply chain for raw materials, which can be difficult to establish and maintain. Furthermore, there is a pressing need to invest in essential research from both the public and private sectors. Despite this, the capacity for research and development remains limited, resulting in reduced local innovation in vaccine development. While international collaborations exist, local research institutions often encounter challenges in participating in global R&D efforts due to funding and resource limitations.

Furthermore, the vaccine market in Kenya and the region is relatively small, making it less attractive for large scale vaccine production investments. This is made much more difficult owing to the fluctuating demand and purchasing power hence posing a challenge in planning for vaccine production.

Intellectual property and technology transfer has been a constant barrier to local production. Effective technology transfer requires not only the physical equipment but also the know-how and skills, which can be challenging to acquire. Programmes such as the Global Alliance for Vaccines and Immunization (GAVI), COVID-19 Vaccines Global Access (COVAX) and bilateral donations play significant roles in providing vaccines, but this can also encourage dependency on external sources. In the political front, there is need for robust national strategies, which are essential to reduce Kenya's dependency on external sources of vaccines.

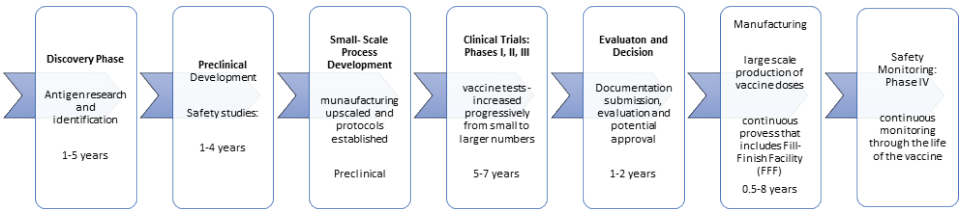
Brain drain has been a thorny issue for Kenya and other developing countries across numerous sectors, including the medical sector. Studies call for political, economic and social reforms to make Africa attractive to skilled manpower both at home and in the diaspora. Some of the identified causes for the human flight include low wages, poor working conditions, inadequate career opportunities and ethnic and tribal discrimination in employment. Other cited reasons include corruption, nepotism, elitism, inadequate incentives and research possibilities (El-Khawas, 2004; Mills, 2011; Mlambo, Harris and Mandla, 2019).

2.4 Exploring the Vaccine Development Pipeline and Vaccine Value Chain (VVC)

The vaccine value chain is complex and encompasses all the steps involved in the development, production, distribution, and administration of vaccines. The processes encompass conception, manufacture, distribution and usage (Sanae et al., 2022). The value chain includes actors, relationships, power dynamics and governance that exist within the chain. These include producers or manufacturers, input suppliers, operations, processors, retailers and buyers. These primary actors are supported by a range of technical, business and financial services providers, including regulatory bodies and healthcare providers to ensure safe, effective and accessible vaccines. The vaccine development process and the value chain are illustrated in Figures 2.2 and 2.3.

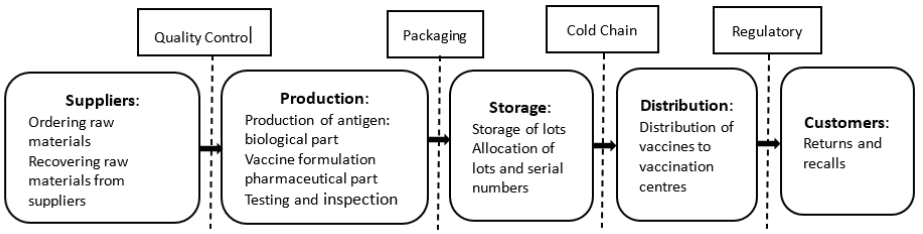
The entire vaccine production process, from development to consumption, can be delineated into five principal stages (Bown and Bollyky, 2022). These phases include pre-clinical phase, clinical trials, manufacturing, inspection, and distribution. The pre-clinical phase involves research and development (R&D) to ascertain methods that stimulate the human immune system to respond to antigens akin to its reaction to viruses. The R&D process encompasses efforts to understand the disease and identify potential vaccine candidates. This process culminates in pre-clinical testing, which is conducted in laboratories and on animal models to evaluate the safety and immune response of the vaccine candidate. It is estimated that these two phases can take two (2) to nine (9) years (Figures 2.2 and 2.3).

Figure 2.2: Components of the vaccine development pipeline



Source: Marcia Garcia Bengoa (2020)

Figure 2.3: Components of the vaccine development pipeline



Source: Sanae et al. (2022)

The subsequent stage encompasses multiple rounds of clinical trials, which usually include several phases: Phase I or small scale trials on a limited number of healthy volunteers to assess safety and dosage; Phase II include expanded trials with more participants to evaluate efficacy and side effects, and Phase III entails large-scale trials involving thousands of participants to confirm effectiveness and monitor adverse reactions. The trials pave way for regulatory approval in which the data from all trials are compiled and submitted to regulatory bodies for review. The products are approved if the vaccines are found to meet safety and efficacy standards and this ushers in the manufacturing processes.

The third stage revolves around vaccine manufacturing, encompassing primary manufacturing involving active ingredient production or bulk production, and secondary manufacturing involving the amalgamation of the drug substance with additional components such as excipients, adjuvants, and preservatives (Kis et al., 2020). In the large scale production of vaccines, there is rigorous testing throughout the process to ensure standards are met. The manufacturing process includes numerous activities and encompasses growing of the vaccine components such as viruses or bacteria, formulating the vaccine, filling vials or syringes, and packaging the final product. Each vaccine requires scores of ingredients such as bioreactors, filters, vials, cell cultures, chemicals for formulation and packaging materials, which support a large value chain (Hatchett et al, 2021).

The fourth stage in the vaccine production process focuses on preparing the vaccines for distribution. The formulated vaccine or drug product is filled into various containers such as vials, plastic tubes, ampoules, or syringes. This 'fill-finish' phase takes place in specialized manufacturing facilities under stringent temperature and sterility controls. Notably, this stage follows a broadly similar process for most vaccines, allowing multiple types of vaccines to be formulated and filled within the same facility (UNIDO, 2017). In the vaccine manufacturing process, FFF stands for formulation/ill/finish and it is a critical stage where the product is filled into vials, syringes, or other containers and then finished by sealing, labelling and packaging (Figure 2.2).

Vaccine manufacturing is dependent on three important players, including, research institutions, pharmaceutical laboratories and for-profit pharmaceutical giants. The research institutions are funded to come up with an innovation, but it is the pharmaceutical companies that has the capacity and experience that will transform the medical innovation through laboratory development, clinical trials, regulatory approval and finally administration to the consumer. The government also plays a critical role in that it can fund the research institutions through push-funding and purchase the developed vaccines through pull-funding.

In the fifth and final stage, the filled vials undergo inspection for final quality control and testing before vaccine distribution and delivery. Some vaccines, due to their characteristics, are transported in a frozen and concentrated form, necessitating on-site dilution before public administration. Vaccine value chains require effective distribution and logistics after their production that include cold chain management. This is followed by administration of the vaccine, which requires training of the healthcare professionals. The process is effective if there are adequate public campaigns to educate the public about the benefits and safety

of the vaccine to encourage uptake. This process is crucial in reducing vaccine hesitancy. The vaccine value chain requires strong post-market surveillance to monitor the vaccine performance and identify any adverse effects. This surveillance include ongoing research to improve the vaccine and adapt it to emerging variants or new strains of the disease.

The vaccine value chain plays a crucial role in the success of public immunization efforts and in ensuring that the target population receives necessary vaccinations. It comprises various levels and stakeholders that are interdependent. Nonetheless, for the vaccine value chain to thrive, a crucial support system is imperative, complementing the primary components mentioned earlier. This support framework encompasses human capital equipped with the requisite skills, knowledge, and competence, adequate financing, robust regulatory capacity, stringent quality assurance measures, progressive technology development, and sound company infrastructure. The vaccine value chain distinguishes itself from other value chains due to the specialized expertise and knowledge essential for vaccine development and manufacturing, involving a multitude of stakeholders. Moreover, vaccines demand meticulous attention to specific details and are extremely sensitive, setting them apart from conventional goods. The execution process is intricate, entailing multiple steps that are susceptible to variations triggered by swift changes in the market and demand, especially during epidemics. Lastly, the regulatory aspect within the Vaccine Value Chain (VVC) is stringent, imposing numerous constraints on vaccine development.

2.5 Regulatory and Policy Review of the Vaccine Industry

Policy and regulatory framework is vital in supporting human vaccine production. Effective frameworks facilitate the entire process, from research and development to distribution, and help maintain public trust in vaccination programmes. Policies can provide incentives for research and development, such as grants, tax credits, and intellectual property protections, encouraging innovation in vaccine development. This review examines the current regulations and policies governing each segment of the vaccine industry, which encompasses all stages from research and development to the delivery of vaccines to end users. Legislation, regulations and policies affecting local manufacturing, procurement, and taxation is an important enabler to securing the vaccine value chain. The review identifies policies and legal frameworks, gaps and areas for improvement or recommendations.

With respect to R&D, Kenya has internationally recognized institutions with capacity for vaccine research. These include the Kenya Medical Research Institute (KEMRI). Although research and development is important for the vaccine industry, private sector investment is hindered by high risks and low returns associated with vaccine R&D and production. This points to the need to support these initiatives and/or create financial incentives, such as low-interest loans and tax breaks, to attract private investment. Regarding policies, Kenya has put in place policies and institutions supporting innovation, but these are not specific to vaccine R&D. The National Research Fund offers grants for research, but these may not be adequate to support vaccine related research and in any case, these

grants are not designed to support the entire phase of this research that may take one (1) to five (5) years.

With respect to production, the country has put in place incentives to sustain and attract investment in vaccine manufacturing. Some of the key incentives include a 15 per cent margin applied to evaluation of bids in public procurement of pharmaceuticals in favour of local industry; faster timelines for registration and inspection; and reduced taxation rate for local manufacturers. The Finance Act of 2022 exempts pharmaceutical manufacturers from VAT on plant and machinery, imported inputs and raw materials. One of the concerns within the industry is the perceived instability in the tax regime and related exemptions. For instance, the VAT exemption regime is hampered by delays and bureaucratic processes for reimbursement and bears additional administrative costs.

The Kenya Pharmaceutical Industry Diagnostic Report 2020, states that the country is currently operating its pharmaceutical sector sub-optimally owing to regulatory and organizational gaps. One of the aspects identified as a gap is the disharmony between the domestic and regional legal landscapes in the context of national medicines regulatory authorities (NMRA). There is also need for more clarity for the responsibilities bestowed to the diverse stakeholders, including the National Quality Control Laboratory (NQCL) and the Pharmacy and Poisons Board (PPB) – particularly the gaps in communication and data sharing between the entities. This can lead to inefficiencies, delayed responses, and lack of cohesive action in the regulatory process. Poor coordination among players can affect the overall effectiveness of the pharmaceutical or vaccine regulatory framework.

In Kenya, the Pharmacy and Poisons Board (PPB) regulates the approval and monitoring of vaccines, and ensures compliance with international standards. It is responsible for the safety, efficacy, and quality of medical products, including vaccines. Even so, the Board has yet to achieve WHO maturity level III, which signifies a stable, well-functioning, and integrated regulatory system capable of effectively regulating vaccines (see Box 2.2). The approval process is perceived as complex and slow and could be improved through policy reforms and the adoption of international best practices. Quality control and assurance is also recognized as a weak link, partly to the limited capabilities of the National Quality Control Laboratory with respect to testing equipment and the facility's inability to manage large volumes. Proposed policy reforms in this area would include the need to achieve WHO maturity level III or IV for the PPB. Key informants highlighted the need for reforms to harmonize regulatory standards for vaccines.

Box 2.2: About the WHO maturity level

The WHO Global Benchmarking Tool (GBT) is used to assess and classify the maturity level of national regulatory systems. The GBT defines four levels of maturity:

- Maturity Level I: Some elements of a regulatory system exist;
- Maturity Level II: Systematic implementation of most elements – however, major gaps remain;
- Maturity Level III: A stable, well-functioning, and integrated system; and
- Maturity Level IV: A regulatory system operating at an advanced level of performance and continuous improvement.

Kenya's journey towards achieving maturity level III will involve developments across several institutions. One essential aspect will be enhancing the capacity of the PPB to encompass all areas of vaccine regulation and guidelines, including evaluation, approval, and post-marketing surveillance. Key informants noted that this can be attained by establishing and maintaining International Organization for Standardization (ISO/IEC 17025) accreditation for testing and calibration laboratories to ensure compliance with international standards.

In terms of manufacturing, there are limited facilities for large-scale vaccine production. Current incentives for pharmaceutical manufacturing are not specifically tailored to vaccines. Kenya needs to invest in developing state-of-the-art vaccine manufacturing facilities, and the support provided to the BioVax facility is commendable. There is also a need to offer specific incentives for vaccine manufacturers, such as subsidies for raw materials and machinery, and to implement policies that attract foreign investment in local vaccine production.

In relation to supply chain logistics, cold chain infrastructure is underdeveloped, particularly in rural areas. This may result from supply chain policies that prioritize general pharmaceuticals over vaccines. There is a need to develop and implement a comprehensive plan to strengthen cold chain infrastructure and improve logistics and distribution networks to ensure the efficient delivery of vaccines nationwide. The country need to introduce policies that specifically address the unique requirements of vaccine supply chains.

Table 2.2: Policy review of the vaccine industry

Issues	Policy and legal framework	Policy and other gaps	Recommendations
Discovery phase and preclinical trials	• Industrial Property Act, 2001 (administered by the Kenya Industrial Property Institute) • Science, Technology, and Innovation Act of 2013 • Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)	• Weak promotion of technology transfer from foreign entities • Weak mechanisms to support local researchers and innovators to navigate the patent system • Weak enforcement mechanisms of intellectual property owing to lack of resources, training, and coordination among enforcement agencies • Delays in granting of patents • Resource constraints	The broader innovation ecosystem, including funding for research and development, infrastructure, and collaboration between academia and industry, needs strengthening to fully leverage the patent system

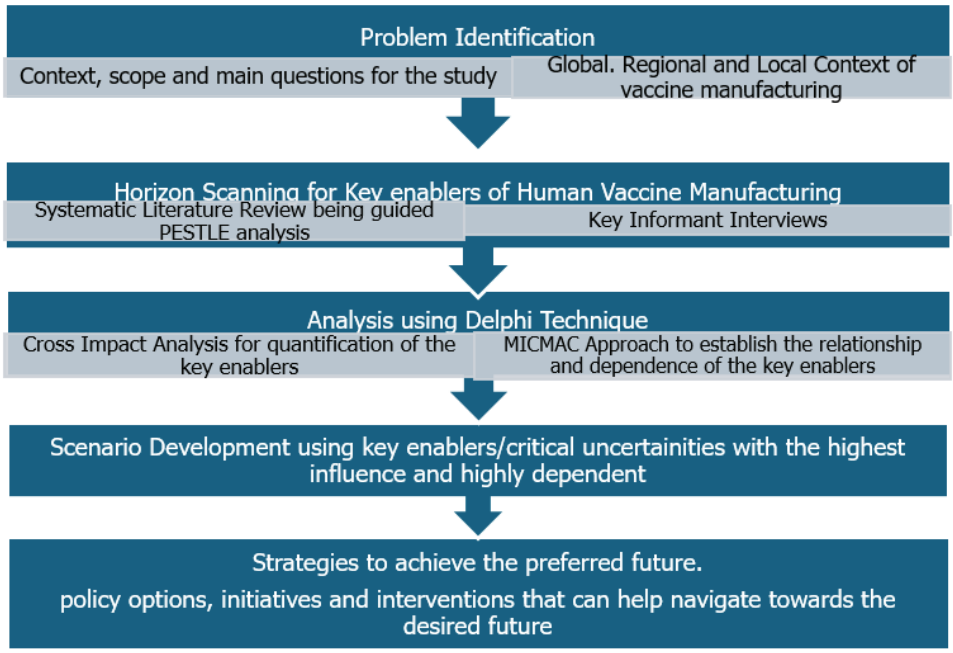
	Science, Technology, and Innovation Act of 2013	• Focuses on promoting, coordinating, and regulating the progress of science, technology, and innovation within the country – for example, through the creation of the National Research Fund • Gaps include the lack of formalized support for collaborative research with international institutions; lack of policies that are specific to vaccine R&D; and limited funding for vaccine research	• Active engagement in partnerships and establish more formal partnerships with international research institutions • Create incentives for vaccine- related innovations through policies, including tax breaks and grants • Increase dedicated funding for vaccine R&D
Small scale process development	Science, Technology, and Innovation Act of 2013	• Does not provide clear guidelines for vaccine production • Not harmonized with international standards	• Outline specific regulations and guidelines for vaccine research, development, and manufacturing • Align with global standards, for example, WHO to facilitate international collaboration
	Kenya Pharmaceutical Sector Development Strategy of 2012	Addresses access to finance for the growth of the pharmaceuticle industry but lacks comprehensive implementation programme	• Advocate for special financial products for the pharmaceutical industry • Advocate for the reduction of high interest rates especially on short term loans
Clinical trials; phases I, II, III Evaluation and decision	Pharmacy and Poisons Act (Cap 244)	• Compliance with international standards, such as WHO prequalification, is required but the process is lengthy and resource intensive • The PPB yet to achieve a higher maturity level (WHO maturity level III for vaccines) and NQCL is relatively weak	• Streamline regulatory approval processes to be more efficient while maintaining ambitious standards • Enhance capacity of the PPB through training and resources • Strengthen the PPB and NQCL to provide regional pharmaceuticals quality assurance and quality control (WHO maturity level III for vaccines) • Foster alignment with regional regulatory frameworks to facilitate smoother cross-border collaboration

Manufacturing	Procurement regulations/laws	• Policies, legislation, and regulations affect local manufacturing – these include procurement regulations and the tax regime • Production remains a risky venture especially with respect to securing markets	• A key aspect is the need to derisk vaccine production through purchase agreements that could be supported by supportive public sector procurement regulations, for example, special treatment provisions in the regulations/laws • Leading human vaccine producing firms overcome the market related risks through diversification of products beyond vaccine manufacturing to include production of other specialized medicinal products such as the production of insulins, antivenoms, rapid test kits, and pharmaceuticals
Safety monitoring – Phase IV	Pharmacy and Poisons Act (Cap 244)		Strengthen collaboration between academia, regulatory authorities, research and development organizations and industry
Crosscutting interventions	East African Countries (EAC) Regional Pharmaceutical Plan for Action 2017-2027	Kenya pharmaceutical companies have only occupied 30% of the total allocated one (1) billion US dollars in the Kenyan pharmaceutical market	Need to create a conducive macroeconomic environment that has good returns to attract investors
	Public Private Partnership Act 2021	• Makes it mandatory for all PPPs to prioritize local content, which might be difficult in a new industry such as the human vaccine manufacturing • Introduces direct procurement processes considering the procurement scandals previously experienced in the country	• Have flexibility in human vaccine industry PPPs to allow transfer of technologies and build a skilled workforce and infrastructure • Form a taskforce to control procurement processes
	Kenya National Guidelines for Safe Management of Health Care Waste, 2011	Provide limited guidance on the management of electronic and electrical waste	Provide robust information on this guidance especially with the country going towards 5th revolution

3. Methodology

The study employed futures methodologies, which refer to systematic approaches used to anticipate and plan for potential future scenarios. By using this approach, the study aimed to develop plausible and preferred scenarios and discuss the implications of achieving an ideal state. As outlined in numerous studies, including WEF (2024) and Gatune and Cloette (2022), the futures methodology followed the steps defined in Figure 3.1.

Figure 3.1: The methodological tools for analyzing vaccine production in Kenya



3.1 Problem Identification

The study process began by conceptualizing the problem. Through the Bottom-up Economic Transformation Agenda, the government intends to improve affordable healthcare by promoting human vaccine production in the country. Therefore, through extensive literature review and understanding the human vaccine manufacturing, the study's context, scope and objectives were clearly defined.

3.2 Horizon Scanning for Key Enablers in the Vaccine Industry

Horizon scanning essentially involved conducting a thorough assessment of the environment surrounding human vaccine manufacturing to identify the

key trends and drivers that influence human vaccine production. The study employed Political, Economic, Social, Technical, Legal, and Environmental (PESTLE) analysis to pinpoint the driving forces behind sufficient human vaccine production in the country. Two steps were undertaken in this process: a systematic literature review of published scientific journals in the human vaccine industry to understand the human vaccine value chain, its context, and the key drivers of human vaccine production; and key informant interviews were conducted with experts in human vaccine manufacturing to validate the key drivers identified in the literature review. The key informants' interactions included a roundtable meeting with senior stakeholders drawn from manufacturing companies such as The Kenya Biovax Institute, research firms such as the Kenya Medical Research Institute (KEMRI), academia, pharmaceutical companies, the regulatory body – Pharmacy and Poisons Board, civil organizations, international bodies such as the WHO, and the Ministry of Health. Additionally, semi-structured questionnaires were employed to gather more contextual factors and confirm previously identified factors. The semi-structured questionnaires were presented to a cohort of human vaccine experts from the cadres identified earlier in this text. Purposive and snowball sampling techniques were used to identify the key informants. A total of twenty (20) key informants were engaged through both virtual and physical interactions.

3.3 Key Drivers of the Human Vaccine Industry

PESTLE analysis was employed to identify the key drivers of human vaccine industry as summarized in Table 3.1.

Table 3.1: PESTLE analysis on key drivers of the human vaccine industry

PESTLE framework	Critical uncertainty	Key findings	Source
Political (P)	Geopolitical alignment and stability (P1)	Geopolitical stability plays a crucial role in enhancing collaboration with other countries in terms of trade relations, supply chains, sharing of intellectual property and technology transfer	Aggarwal and Reddie, 2021; Ottersen et al., 2014; Maziar et al., 2021; Khubchandani et al., 2020
	Political alignment and stability (P2)	Lack of political will and commitment in countries contributed to the slow growth of vaccine industries in Africa	Ekström et al., 2021; Gostin et al., 2019; Evenett et al., 2021; Gawande et al., 2015; Blanchard et al., 2017; Baldwin, 2018; Krugman, 2018; World Bank, 2020;

Economic (E)	Economic stability - financing mechanisms (E1)	• Vaccine production complexities, high costs, and the monopoly in the vaccine supply market were the key factors of the low presence of vaccine manufacturing companies • Sustainable and innovative financing are most important and influential variables that are prominent in vaccine development	Batson et al., 2006; WHO, 2011; Gavi the Alliance, 2022; Mutasa et al., 2023; Maziar et al., 2021; Khan et al., 2016; Plotkin et al., 2016; Wellcome-Biovac, 2023; Kis et al., 2020; Mutasa et al., 2023; Guignard et al., 2021
	Public-private partnership (E2)	The vaccine industry requires collaborations right from financing (pull and push funding), technology transfer, regulatory bodies, research and development and the entire value chain	Khan et al., 2016; WHO, 2011; Jadhav et al., 2008; Meyer, 2021; Douglas and Sarmant, 2018; Happi and Nkengasong, 2022; United Nation Vaccine Research, 1997; Gupta et al., 2013; Homma et al., 2013; Nohynek et al., 2013; Hardt et al., 2016; Ekström et al., 2021; Gavi the Alliance, 2022; Plotkin et al., 2016; Mutasa et al., 2023; Guignard et al., 2021; Maziar et al., 2021; Kettler H. and Towse A., 2002; Luter et al., 2017; Fu et al., 2021; Rwanda Press release, 2023
Social (S)	Public perception and vaccine hesitancy (S1)	The reduction in vaccine hesitancy and more confidence in medical professionals will increase demand for vaccines, which in turn increases the production of vaccines	Saied, 2022
Technological (T)	Evolution of technological innovations, advancements and transfer (T1)	To increase manufacturing capacity, quickly and effectively, technical and knowledge transfer is necessary. It will be essential for partners from developed and developing countries to prioritize adjuvant technology as a key asset for vaccine development efforts	Khan et al., 2016; Happi and Nkengasong, 2022; Hendricks et al., 2010; WHO, 2021; Bown 2021; Fu et al., 2021; Fox, 2017; Barton, 2006; WHO, 2011; Ekström et al., 2021; Gavi the Alliance, 2022; Grohmann et al., 2016; Kis et al., 2020;

	Skilled personnel (T2)	• Most low-income countries have not established their vaccine manufacturing due to lack of human resource • Lack of the ability to recruit and retain qualified personnel is a challenge associated with technology transfer	African Union and Africa CDC, 2022; Saied, 2022; Traicoff et al., 2019; Arias et al., 2019; Leopold et al., 2017
Legal (L)	Regulatory environment (L1)	Policies guiding vaccine industry should be purposefully developed to allow accessibility of cheaper financing from donors, technology transfer and attract investors by creating an enabling business environment	Ekström et al., 2021; Blin, 2021; Mutasa et al., 2023; Duclos et al., 2011; Baylor, 2017
	Restrictions on intellectual property (L2)	Waiver on intellectual property right will catalyze manufacturing where it is lacking, create greater self-sufficiency and ensure vaccines reach the most vulnerable quickly	Editorial, 2022; Ekström et al., 2021; Fu et al., 2021
Environmental (EV)	Safe environments (EV1)	Vaccine industry is prone to contribute to ecological imbalance through the production and accumulation of biohazardous waste	Abbasi et al., 2020
	Emerging global health threats (EV2)	Emerging and re-emerging epidemics will continue to increase the demand for vaccines	Gouglas et al., 2019

3.4 Assumptions of the Study

It is important to note that during this comprehensive review and our interactions with experts in the initial stages of the study, we analyzed the strengths, weaknesses, opportunities, and threats (SWOT) related to human vaccine manufacturing in Kenya. This SWOT analysis serves as the baseline for the general assumptions made by the study, as shown in Table 3.2.

Table 3.2: Assumptions based on SWOT analysis of the vaccine industry in Kenya

SWOT	Assumption
Strength	• There will be a stable allocation of funds by the Kenyan government to the human vaccine industry • Presence of the Kenya BioVax Institute, KEMRI, Kenya Primates Research Institute and Pharmacy and Poison Board (PPB), National Quality Control Laboratory (NQCL) • Some staff at Kenya BioVax Institute (KBI) have already been trained on human vaccine production biotechnology at International Vaccine Institute in Seoul, Korea
Weakness	• Insufficient capacity of specialized human resource • The specialized staff may move to other countries to seek better renumeration • Weak regulatory framework for vaccine manufacturing • Lack of WHO prequalification in Kenya's regulatory body (PPB), which inhibits regulation of human vaccine manufacturing in Kenya hence delay in manufacturing
Opportunities	• The Government will allocate funds and grants to human vaccine development to actualize the Bottom-up Economic Transformation Agenda (BETA) • Donors might come in and fund R&D, for intance, the case of WHO introducing mRNA in South Africa • Use of media to create trust for locally manufactured vaccines among residents to prevent vaccine hesitancy
Threats	• Disruptive events such as new epidemics might erupt and interfere with the vaccine production process • Rumours and misinformation about locally made vaccines • Apprehension by the local citizens about locally manufactured vaccines; lack of trust in the locally made vaccines • Lack of buy-in by private investors for locally manufactured human vaccine

3.5 Analysis using Delphi Technique

The Delphi technique is an iterative forecasting method that involves consulting a panel of experts through systematic feedback rounds. The consultations identified the key drivers that would have the highest impact on human vaccine production. Cross impact analysis (CIA) was employed to ascertain the direct effects of interactions between variables. Cross impact analysis (CIA) is a methodology designed to determine how relationships between events influence resulting events and reduce uncertainty about the future (Gordon, 1994). These relationships were categorized based on their relative impact and were used to ascertain which events or scenarios were most probable or likely to occur within a given time frame. The variables' impact on each other was classified as high, moderate, or low. The overall probability score was obtained by calculating the mean score for each variable from all the responses.

The Multiplication of Cross Impact Matrices Applied to Classification (MICMAC) tool was employed to conduct a structural analysis to establish the relationship's

key drivers. MICMAC analysis facilitated the development of a graph that classifies factors based on their driving and dependence power. Four clusters were identified in this graph, namely: Cluster I: Autonomous Factors, which are factors that are relatively isolated from the system and exhibit weak or no dependence on other factors; Cluster II: Dependent Factors, which are primarily reliant on other factors; Cluster III: Linkage Factors, which serve as the connecting factors and are unstable, exerting the most influence on others; and Cluster IV: Independent Factors or key drivers, which are characterized by weak influence from other factors and warrant maximum attention due to their significant impact. This classification was used to categorize the factors and validate the interpretive structural model factors in the study, leading to their results and conclusions.

3.6 Scenario Development and Recommended Strategies

The key drivers and critical uncertainties that had the highest influence and low dependence were used to develop the scenarios likely to occur in the vaccine industry in Kenya in the future. The forecast year considered was 2040, which the Africa CDC has identified as the target year for African countries to produce their pharmaceuticals and vaccines sufficiently. These scenarios were developed in consultation with experts from the human vaccine industry.

The process concluded with the development of strategies to achieve the preferred future. This included identifying policy options, initiatives, and interventions that can facilitate navigation towards the desired future. A discussion of the implications and pathways was also conducted. These steps helped refine the country's preferred future by selecting the most desirable outcomes. Subsequently, the independent key drivers were used to develop scenarios likely to occur in the vaccine industry in Kenya in the future.

4. Scenario Analysis for the Human Vaccine Industry in Kenya

Depending on global and regional developments and local interventions, the futures methodology acknowledges that several scenarios are possible. These may include a business-as-usual scenario, where the current situation persists; a better-than-current scenario; an ideal or desired scenario; and the preferred scenario. This chapter illustrates the outputs of the study process, from a systematic literature review to Cross Impact Analysis and scenario development.

4.1 Scenario Matrix

The study reviewed several factors influencing the vaccine industry using a literature review, as summarized in Table 4.1. Furthermore, stakeholder engagement was incorporated to complement and refine the review findings. The review and engagement employed the Political, Economic, Social, Technological, Legal, and Environmental (PESTLE) analysis. The identified factors were subsequently classified as primary trends, secondary elements, or critical uncertainties within the vaccine industry. Primary trends encompassed factors anticipated to significantly impact the vaccine industry but could be managed; secondary elements involved factors that had a minimal effect on the vaccine industry, while critical uncertainties captured elements that carry significant unpredictability and could majorly influence the vaccine industry. The following factors were identified:

Political factors

Political will and commitment are key factors that have long been impediments in Kenya and many African countries. However, this is now changing, with strong signals of political will emerging across the continent, specifically Kenya. These signals include Kenya's recent accession to membership in the International Vaccine Institute (IVI), led by the President's Office. Additionally, IVI is set to open an office in Nairobi, which will serve as the headquarters for IVI's Advancing Vaccine End-to-End Capabilities (AVEC) initiative in Africa and will collaborate closely with local partners, including the Kenya BioVax Institute. Nonetheless, in Kenya, it is necessary to transcend business-as-usual and move towards allocating a premium (through higher budgetary allocations) to successfully manufacture human vaccines.

Geopolitical stability is also critical for the success of the vaccine industry, as it significantly enhances collaboration with other countries in Africa and globally in areas such as trade relations, supply chains, and the sharing of intellectual property and technology transfer. Countries are keen to enforce intellectual property rights and restrict the use of patent waivers, which can hinder access to vaccines.

Economic factors

Vaccine manufacturing is capital intensive and requires a lengthy investment period to stabilize. Therefore, for the vaccine industry to thrive, a stable economic

environment is essential, one that can offer grants and financing and promote economic growth. In 2017, the African Union declared that the region should invest 1.0 per cent of its Gross Domestic Product (GDP) in research and development. However, in 2020, Africa's share of R&D investment was 0.9 per cent, compared to 2.2 per cent in South America and 44.3 per cent in Asia. Kenya's share is equally meagre, and developing innovative financing mechanisms through public-private partnerships will aid in financing vaccine R&D and manufacturing, thereby achieving self-sufficiency. The need to reduce reliance on imports of raw materials for fill/finish to decrease operational costs is a crucial economic factor.

Social factors

The populations eligible for vaccination will continue to rise in line with natality rates, alongside emerging and re-emerging epidemics such as COVID-19. This indicates that there will always be a substantial demand for vaccines, particularly for paediatric use. According to the Kenya National Bureau of Statistics (KNBS, 2023), Kenya's population is projected to surpass 70 million by 2045. Nevertheless, Kenya is grappling with vaccine hesitancy, which must be confronted through health education and the production and distribution of safe products to foster acceptance and maintain demand.

Technological factors

The world is transitioning into the fifth industrial revolution; therefore, new technological innovations and advancements are emerging to aid in the efficient and effective production of vaccines. Innovations such as the use of mRNA, which is in the process of being adopted, offer several advantages, including broader applicability across various diseases and rapid development. However, despite having a relatively skilled workforce, the country has yet to capitalize on this advantage to drive the development of its vaccine industry. Kenya can still benefit from the organizational skills of well-developed countries by sharing knowledge with emerging vaccine manufacturers through technology transfers and freedom of intellectual property, especially during outbreaks of pandemics.

Environmental factors

The vaccine industry is prone to contributing to ecological imbalance through the production and accumulation of biohazardous waste. The discarded vials contain thimerosal, a mercury-based preservative that is hazardous to aquatic ecosystems and humans when released haphazardly into water bodies. Disposing of packaging and personal protective equipment as a preventive measure adds to the microplastic fibres in the environment. Cold chain storage of vaccines has significantly increased carbon dioxide greenhouse gas in the atmosphere. These factors complicate the establishment of a vaccine production ecosystem for Kenya.

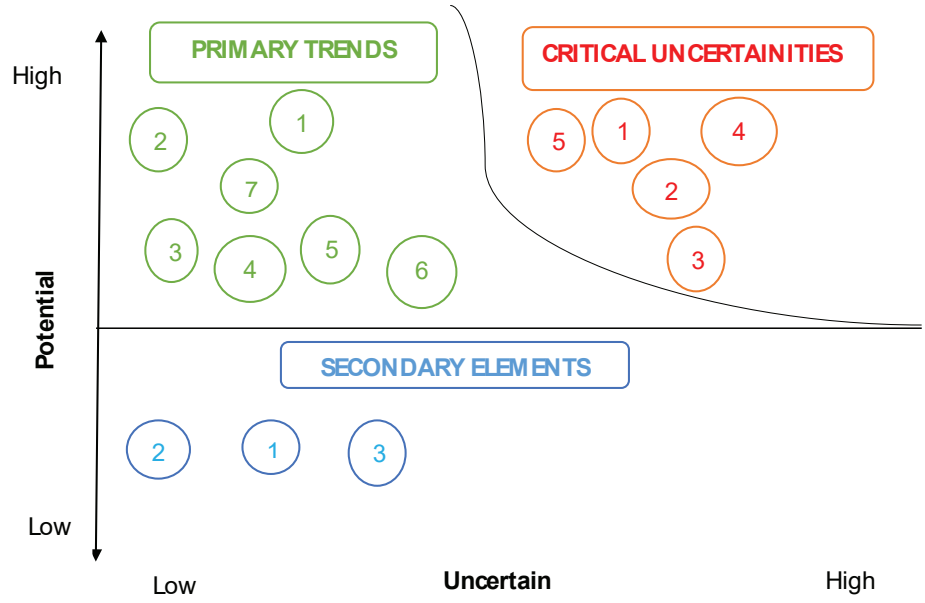
Legal factors

These include regulations, policies, property rights, liability, and risks within the vaccine industry. A robust ethics and regulatory body is essential for overseeing vaccine development and manufacturing. Countries need to collaborate in establishing vaccine regulation by, for instance, signing membership with

the WHO regulatory body (AVAREF) or seeking approval from nations with existing regulatory frameworks. Policies guiding the vaccine industry should be deliberately developed to facilitate access to cheaper financing from donors, enable technology transfer, and attract investors by creating a supportive business environment. Patent licencing can also present a business opportunity, allowing small biotechnology firms in the vaccine industry, which may struggle to penetrate larger markets sufficient to recoup their R&D investments, to licence their patents to larger firms and benefit from economies of scale in marketing. Kenya has yet to establish policies and regulations specific to human vaccine manufacturing, resulting in a lagging regulatory process.

The factors discussed above were grouped as shown in the scenario matrix (Figure 4.1), which isolated the critical uncertainties from the primary trends and secondary elements.

Figure 4.1: Scenario matrix: PESTLE analysis for the vaccine industry in Kenya



The factors used in the matrix are grouped as shown in Table 4.1.

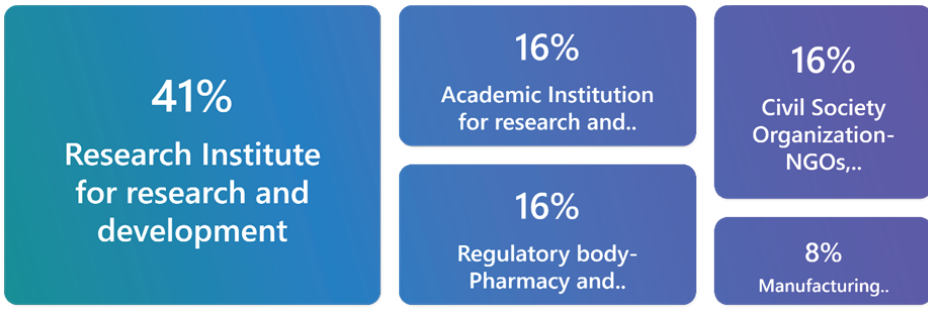
Table 4.1: Horizon scanning output for the factors affecting vaccine manufacturing

PESTEL	Primary trends	Critical uncertainties	Secondary elements
Political		• Geopolitical alignment and stability • Political will	
Economic	• Rate of economic growth • High taxation • Economic stability • Policies in the vaccine industry • Increase in operation cost		Age Gender Supply chain resilience
Sociological		Public perception and vaccine hesitancy	
Technological		Technology innovations/ advancements and transfer	Technology connections
Legal		• Regulatory environment • Restrictions on intellectual property	
Environmental	• Changing trends in disease • Environmental regulations		

4.2 Cross Impact Analysis

The Cross Impact Analysis (CIA) Matrix was employed to assess how various critical uncertainties – key drivers of vaccine manufacturing — interact within the vaccine ecosystem. As the name suggests, the CIA method evaluates how different variables (including events or trends) may impact each other. It is utilized to understand the interplay between multiple factors and to facilitate more informed decision-making. The data gathered came from a group of 20 experts in various fields associated with human vaccine manufacturing, from whom interviews were conducted (Figure 4.2).

Figure 4.2: Percentage of experts interviewed from various fields



A table was created in which the rows and columns represented the various drivers, with each cell detailing one variable's impact on another. The influence of each driver was determined by calculating the average score, as illustrated in Table 4.2.

Table 4.2 was also created, where the rows and columns represented the various drivers, with each cell detailing one variable's impact on another. The influence of each driver ranged from zero (0) to three (3), where 0 represented no influence, 1 represented weak influence, 2 represented moderate influence, and 3 represented strong influence. Each cell's value was derived by calculating the average impact score reported by all 20 respondents, as illustrated in Table 4.2. For instance, the intersection of the third row (P2: Enhancing strong political will and stability) and various columns (including E1 and E2) suggests that the respondents deemed enhancing strong political will and stability to strongly influence innovative financing mechanisms and strengthened public-private partnerships.

Table 4.2: Cross impact analysis

		P1	P2	E1	E2	S1	T1	EV1	EV2	L1	L2
Political	P1: Strengthened geopolitical stability	0	3	3	3	2	3	3	3	3	3
	P2: Enhancing strong political will and stability	3	0	3	3	2	3	3	2	3	3
Economic	E1: Innovative financing mechanisms	2	2	0	3	2	3	2	2	3	3
	E2: Strengthening public private partnership	2	3	3	0	2	3	2	3	3	3
Social	S1: Vaccine hesitancy	1	2	1	2	0	1	2	2	2	2
Technological	T1: Promoting technology transfer	2	2	2	2	2	0	2	2	2	2

Environmental	EV1: Promoting safe manufacturing environment	2	2	2	3	2	2	0	2	3	2
	EV2: Emerging global health threats like pandemics	3	2	2	3	2	3	3	0	3	3
Legal	L1: Fostering effective regulatory capacity	3	3	2	3	3	2	3	3	0	3
	L2: Promoting sharing of Intellectual Property Rights	2	2	2	3	2	3	2	2	2	0

Notes:

1. *P1 and P2 are political factors; E1 and E2 are economic factors; T1 is a technological factor; EV1 and EV2 are environmental factors; while L1 and L2 are legal factors*

   P1: Strengthened geopolitical stability

   P2: Enhancing strong political will and stability

   E1: Innovative financing mechanisms

   E2: Strengthening public private partnership

   T1: Promoting technology transfer

   L1: Fostering effective regulatory capacity

   L2: Promoting sharing of intellectual property rights

   EV1: Promoting safe manufacturing environment

   EV2:Emerging global health threats like pandemics

   S1:Vaccine hesitancy

2. *Influences range from zero (0) to three (3):*

   0: no influence; 1: weak ; 2: moderate influence; 3: strong influence

4.3 Direct Influence/Dependence Graph

The data from the cross-impact analysis was later used to develop the matrix of direct influence (MDI). This matrix aids in visualizing interactions and dependencies, assisting in scenario planning and strategic decision-making by highlighting potential effects and interactions between factors. The drivers with the highest influence and low dependence were utilized in scenario development.

Geopolitical influence (P1), political will and stability (P2), public-private partnership (E2), and the presence of global health threats were identified as the key drivers of human vaccine manufacturing, exerting the highest influence with low dependence on other factors required for sufficient human vaccine production.

Fostering regulatory capacity, innovative financial mechanisms, sharing intellectual property rights, and promoting a safe manufacturing environment were classified as linkage factors that exhibit strong driving forces and significant dependence on other factors. Technology transfer was classified as a dependence factor with strong reliance and weak driving force, whereas vaccine hesitancy was categorized as an autonomous factor (Figure 4.3).

Figure 4.3: Direct influence/dependence graph

Notes:

P1: Strengthened geopolitical stability

P2: Enhancing strong political will and stability

E1: Innovative financing mechanisms

E2: Strengthening public-private partnership

T1: Promoting technology transfer

L1: Fostering effective regulatory capacity

L2: Promoting sharing of intellectual property rights

EV1: Promoting safe manufacturing environment

EV2: Emerging global health threats like pandemics

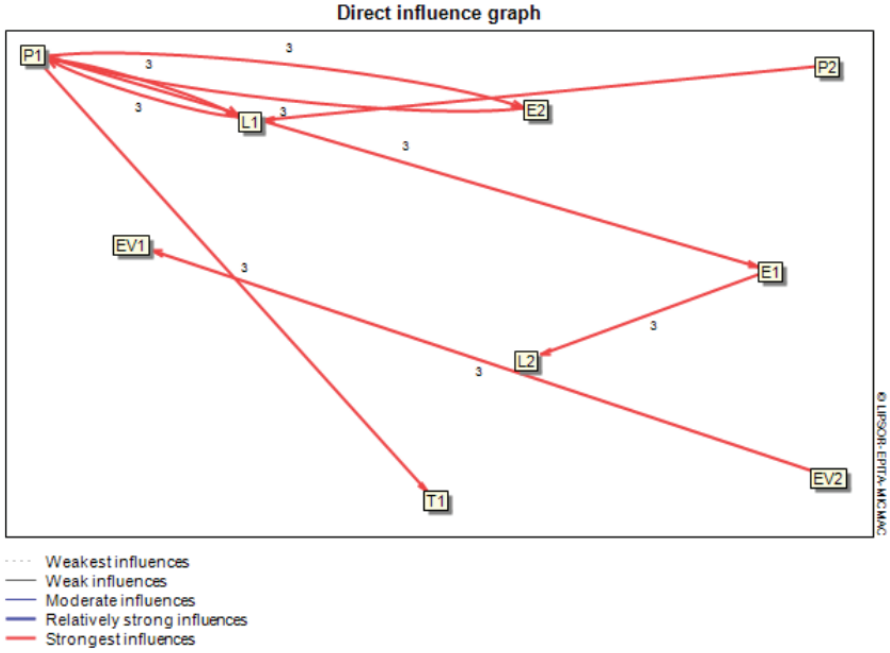
S1: Vaccine hesitancy

4.4 Direct Influence Graph

Subsequently, a direct influence graph was created to visually represent how various drivers interact and influence each other. Each node, such as P1 (strengthened geopolitical stability), denotes a variable, while the arrows indicate the direction of influence from one node to another. Thus, the graph illustrates both the direction and level of influence, with the arrows weighted to reflect the

strength of the influence. As shown in Figure 4.4, the prevailing perspective is that geopolitical factors (P1) significantly influence public-private partnerships (E2) as a driver for human vaccine manufacturing in Kenya. The presence of innovative financial mechanisms (E1) is strongly affected by political will and stability (P2) and global health threats (EV2). Furthermore, technology transfer (T1) is also strongly influenced by geopolitical stability (P1).

Figure 4.4 Direct influence graph



Notes:

P1: Strengthened geopolitical stability

P2: Enhancing strong political will and stability

E1: Innovative financing mechanisms

E2: Strengthening public-private partnership

T1: Promoting technology transfer

L1: Fostering effective regulatory capacity

L2: Promoting sharing of intellectual property rights

EV1: Promoting safe manufacturing environment

EV2: Emerging global health threats like pandemics

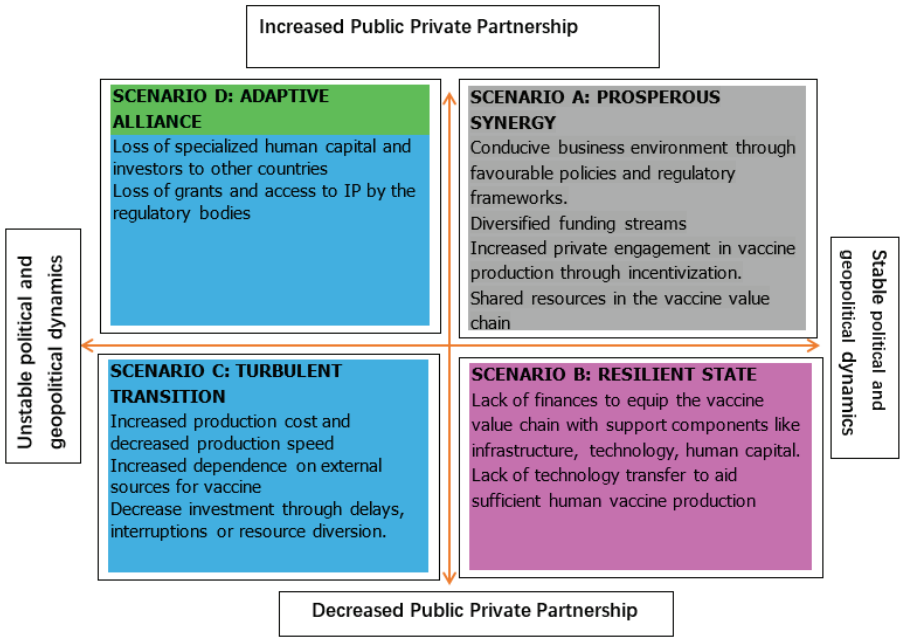
S1 : Vaccine hesitancy

4.5 Scenarios Development: Based on Identified Critical Uncertainties

The results of the analysis highlighted public-private partnerships, along with political and geopolitical stability, as critical drivers that can help shape the human vaccine industry. The process began by determining the crucial factors influencing human vaccine production in Kenya, including economic, social, technological, environmental, and political variables. This was followed by developing a graph or matrix of influences and evaluating these factors. A qualitative scale was employed (e.g., weak, moderate, strong). The most influential variables were identified, and their relationships were mapped out. The insights gained from the structural analysis were utilised to construct different scenarios. The scenario construction was also informed by discussions with various experts in academia, research institutes, public-private bodies, civil society organisations, pharmaceutical manufacturers, and the NQCL.

Using the critical uncertainties in the vaccine industry in Kenya, the following four scenarios were identified as the most likely to occur in the vaccine industry by 2040. These scenarios are termed: 'Prosperous synergy', 'Resilient state', 'Turbulent transition', and 'Adaptive alliance', as illustrated in Figure 4.5.

Figure 4.5: Four possible scenarios towards 2040 based on PPP and the geopolitical and political status



Scenario A: Prosperous synergy

This represents the ideal scenario envisioned for Kenya, assuming sufficient human vaccine manufacturing capabilities. In this scenario, a conducive business environment for investors will be established, governed by appropriate policies and a regulatory framework. The increased public-private partnerships (PPP) will result in diversified funding streams for research and development (R&D), alongside enhanced private engagement in vaccine production through incentivization. Ultimately, the resources along the vaccine value chain can be shared among member states within a regulatory framework, such as the pooled purchasing of raw materials, thus reducing operational costs.

Scenario B: Resilient state

This scenario depicts a better human vaccine industry than the current situation. It may result in a thriving vaccine manufacturing industry in Kenya, albeit facing sustainability challenges. Despite the political stability in the country and existing international treaties, the rate of public-private partnerships (PPP) is expected to decline, thereby negatively impacting the rate of adequate human vaccine production. Insufficient funding will hinder governmental efforts in vaccine development, which is inherently capital-intensive. Additionally, there is limited transfer of technology to the Kenyan vaccine industry from established manufacturers with the required human capital and mass production capabilities. Consequently, this will lead to a shortage of necessary skills and expertise in emerging technologies in the vaccine industry in Kenya.

Scenario C: Turbulent transition

This scenario shares many similarities with the current state of human vaccine manufacturing in Kenya, which has yet to commence. The human vaccine production ecosystem is marked by vaccine nationalism. In this situation, vaccine-producing countries prioritize securing vaccines for their populations through stockpiling, export restrictions, and pre-purchase agreements, partly due to unstable political and geopolitical dynamics. The hoarding of certain materials in vaccine production is likely to result in increased production costs and decreased production speed. It will also lead to inequitable distribution, prolonged pandemics, and heightened geopolitical tensions. As this scenario is expected to persist into the future, initiating human vaccine production in Kenya and promoting vaccine-sharing agreements can help address the issue.

This scenario is also characterized by low or decreased PPP, which would result in inadequate technology and human capital. This state will also depend on the importation of vaccines due to the strained economic conditions stemming from unstable political and geopolitical circumstances. This is likely to increase the number of unvaccinated individuals, thus hindering the attainment of herd immunity. Lastly, investors will be reluctant to invest in vaccine development within the country, and resources will either be delayed, interrupted, or diverted to uses other than the vaccine industry. This is the status quo. This scenario can be proactively avoided through several interventions, including building and sustaining strong political will and enhancing incentives alongside PPP.

Scenario D: Adaptive alliance

In this scenario, the increased rate of PPP exposes the country to numerous financial grants, technology transfers, specialised human capital, and regulatory collaborations. However, all these advantages may be undermined due to the unstable political and geopolitical climate. This situation implies that a sustainable human vaccine production rate will not be achievable. The scenario underscores the significance of political will in fostering adequate human vaccine production in Kenya. For both scenarios, C and D, competition among countries and recognizing vaccines as strategic assets suggest that geopolitics will serve as a crucial variable or uncertainty.

5. Pathways to Human Vaccine Manufacturing in Kenya

The study's first objective was to assess the key drivers of human vaccine production in Kenya. The study reviewed literature from around the globe and identified that the key drivers for human vaccine production include a mix of government policies, funding, infrastructure, research and development (R&D) capabilities, human resources, and global geopolitics. Findings indicate that public-private Partnerships (PPPs), political will and stability, and the presence of global health threats are also key drivers. Nearly all vaccine production activities in leading countries are initiated with strong government support and partnerships with other stakeholders. Also crucial is funding backed by favourable government policies and regulatory frameworks.

The country needs to implement multifaceted interventions, including:

(i) Leveraging the global and regional goodwill to cement partnerships and funding from international organizations such as GAVI, Coalition for Epidemic Preparedness Innovations (CEPI), the African Union and the World Health Organization.

(ii) Fostering deeper collaborations with key actors, including international research institutions and pharmaceutical companies as a way of building PPPs.

(iii) Strengthening political will and, even more importantly, securing public sector support through consistent budget allocations.

The second objective was to review and recommend improvements to the policy and regulatory frameworks. Kenya has established policies and institutions that support innovation; however, these are not specifically tailored to human vaccine research and development. The government should address several issues, including the need to:

(i) Enhance political commitment as a viable pathway to elevate the vaccine industry to the forefront of discussions to improve the regulatory framework. This will facilitate the development of relevant policies, plans, and legislation that should be promoted at the national level rather than being solely a Ministry of Health issue. The policies and regulations should provide incentives to encourage and support investments in the human vaccine industry. Political commitment has played a pivotal role in India's success in the vaccine sector.

(ii) Formalize collaborative research with international institutions in laws, regulations and institutional plans, for instance, by adding clauses specific to vaccine R&D and patenting in the Science, Technology, and Innovation Act of 2013.

(iii) Support the Pharmacy and Poisons Board (PPB) to attain WHO maturity level III and later IV, which represents a stable, well-functioning, and integrated regulatory system capable of effectively regulating vaccines. This will improve the time taken for vaccine approval through the adoption of international best practices.

(iv) Enhance coordination among players to improve the effectiveness of the pharmaceutical and vaccine regulatory framework. This can be achieved by introducing greater clarity regarding the responsibilities assigned to various stakeholders, including the National Quality Control Laboratory (NQCL) and the Pharmacy and Poisons Board (PPB), particularly addressing the gaps in communication and data sharing between these entities.

(v) Address the disharmony between the domestic and regional legal landscapes regarding national medicines regulatory authorities (NMRA). This can be achieved through regulatory reforms that adopt international standards, which in turn will facilitate smoother cross-border collaboration.

(vi) Adopt initiatives for ethics and integrity – corruption poses a significant governance challenge in Kenya, with repercussions in the manufacturing sector. Enhancing ethics and integrity standards in manufacturing can be crucial in addressing this issue. As the Kenya Association of Manufacturers leads the UN Global Compact Initiative, the Code of Ethics should be disseminated widely throughout the manufacturing sector.

Based on the scenarios discussed in the study, a pathway for Kenya to realize human vaccine production is proposed. This pathway encompasses strategic planning, infrastructure development, skilled personnel, regulatory oversight, research and development, international collaboration and partnerships, manufacturing and packaging, supply chain management, and ultimately consumption. This can be achieved through reverse integration, which involves beginning the process with tail-end activities and gradually moving up the value chain. The pathways or key steps arising from our discussions that can facilitate the development of human vaccine production in Kenya through 2040 are:

(i) Implement multifaceted interventions, including advocacy, to boost investment in vaccine infrastructure and research and development. Through the Ministry of Health and its agencies such as the BioVax Institute, the government can allocate more resources to infrastructure development and vaccine research and development via the national budget; maintain tax incentives, including tax breaks for firms investing in vaccine research; and streamline regulatory support. Critical elements will include full budgetary support for the completion of the Kenya BioVax Institute. Systematic support is essential for establishing supportive infrastructure, including equipped laboratories with advanced technology; manufacturing plants with formulation and fill-finish (FFF) facilities; quality control and assurance laboratories; cold chain storage facilities; documentation systems; information technology systems; affordable and reliable utilities (particularly electricity and water); and waste management systems.

    The country can enhance existing FFF activities as a precursor to advancing into human vaccine formulation activities in the medium term and product development in the longer term. One of the higher-value activities the country can pursue is the production of antigens, which remain underdeveloped.

(ii) Foster collaborations through PPPs to support technology transfers and

investments in human vaccine production. PPPs for vaccine manufacturing have a successful track record in other regions, such as Brazil (Bio-Manguinhos) and Indonesia (Instituto Butantan). These PPPs provide opportunities for upgrading infrastructure, including research facilities and laboratories, to meet international standards. Leveraging regional efforts to form an industrial cluster with other vaccine-manufacturing African countries can be a key avenue for accessing funding, supplies, and technologies in human vaccine production. In the African context, the African Development Bank and the Africa Centre for Disease Control (along with GAVI and the WHO) would be essential allies, as these institutions have plans to establish new vaccine manufacturing facilities across the continent.

(iii) Invest in human capital development while safeguarding against brain drain. This includes creating appealing career pathways and work environments, providing appropriate salaries and responsibilities, and enabling employees to progress within the organization and enhance their expertise. A variety of financial incentives, such as competitive remuneration, performance-based monetary rewards, and bonuses for returning to the home country, along with non-financial incentives, such as a supportive work atmosphere, positive employer-employee relationships, and developmental opportunities through training, promotion, recognition, and innovation, should be incorporated into comprehensive brain drain management strategies (WHO/DHHS, 2012). Lessons can be learned from South Africa, which in 2001 developed a national biotechnology strategy to cultivate expertise in biotechnology. The project had a significant positive impact, positioning the country as a leader in vaccine production in Africa. These efforts can be reinforced by investments in training programmes for researchers and scientists in the field of vaccine development, and by providing grants and funding to universities and research institutions for vaccine research.

The following are crosscutting interventions:

(i) The government can implement interventions to enhance coordination between governmental agencies and institutions, particularly academia, regulatory bodies, and manufacturers of human vaccines. It is essential to establish a task force that includes representatives from all stakeholders in the VVC. This will promote innovative and cost-effective methods for vaccine manufacturing in the country, leading to self-sufficiency.

(ii) Introduce flexibility within the Public Private Partnership Act 2021 to facilitate the transfer of technologies and to develop a skilled workforce and infrastructure.

(iii) Offer comprehensive details on managing electronic and electrical waste within the Kenya National Guidelines for Safe Management of Health Care Waste, 2011, which offers limited guidance.

(iv) Make it mandatory for all PPPs to prioritize local content progressively.

Table 5.1: Proposed pathway interventions, timeline and responsible agency

	Proposed pathway	Timeline	Responsible agency(s)
	Preliminary – *need to establish the current and evolving status of human vaccine production*		
1	Implement comprehensive evaluation of the specific human vaccine needs for Kenya's population	Continuous	Ministry of Health and BioVax
2	Develop a strategic plan (informed by needs evaluation and feasibility study) that outlines goals, timelines, partnerships, and funding sources for human vaccine production to the year 2040	Immediate	BioVax in collaboration with other actors
	Infrastructure – *state of the art infrastructure is required to support vaccine production*		
3	Upgrade and build human vaccine manufacturing facilities that meet good manufacturing practices standards	Continuous	MOH, BioVax and PPP partners
4	Acquire state of the art equipment and technology for vaccine production, including bioreactors, fermenters, and quality control instruments	Immediate	MOH, BioVax and PPP partners
5	Establish a reliable supply chain of raw materials and components needed for vaccine production	Continuous	MOH, BioVax and PPP partners
	Human resources		
6	Identify skill gaps and implement training programmes to develop a skilled workforce for all aspects of vaccine production	Continuous	MoE, MOH, Universities, BioVax
	Research and development		
7	Enhance R&D facilities to develop and test new vaccines	Immediate	MOH, Universities, BioVax, PPP partners
8	Foster collaborations with international research institutions and pharmaceutical companies	Continuous	MOH, Universities, BioVax, PPP partners
9	Leverage global partnerships and funding from international organizations such as WHO, GAVI, CEPI, and the African Union	Immediate and continuous	MOH, BioVax, PPP partners
	Regulatory framework		
10	Strengthen the capacity of regulatory authorities like the Pharmacy and Poisons Board (PPB) to oversee vaccine production, approval, and distribution	Immediate	PPB, MOH, National Assembly
11	Support the PPB to achieve maturity level III status	Immediate	PPB and MOH
	Distribution and storage		
12	Establish an efficient distribution network to deliver vaccines to healthcare facilities across the country		MOH and PPP partners
13	Run public awareness campaigns to educate the population about the importance and safety of vaccines		MOH, BioVax
14	Engage with community leaders and healthcare providers to build trust and encourage vaccine uptake		MOH, BioVax

6. Conclusion

The study explores the vaccine industry and the factors that can lead to a thriving human vaccine industry in the country. A PESTLE analysis has clearly identified key drivers such as geopolitical and political stability, the presence of innovative financing mechanisms, public-private partnerships (PPP), the emergence of global threats, a safe manufacturing environment, technology transfers, the sharing of intellectual property rights (IPR), and a skilled workforce. Further analysis involving vaccine manufacturing experts in Kenya indicated that PPP, global threats, and political and geopolitical stability are the crucial driving forces for sufficient vaccine manufacturing, exhibiting high influence with low dependency on other variables. Therefore, there is a need to explore how these factors can enhance the status of human vaccine manufacturing in Kenya. Political commitment to allocating finances and formulating policies and legislation that create a conducive macroenvironment is essential to attract investors in human vaccine manufacturing while establishing market links for the vaccines. PPPs are also critical in assisting the country in accessing financing, technology transfers to improve workforce skills, and sharing patents, thereby widening the range of vaccines, particularly in line with WHO prequalification standards and access to regulatory bodies. All these efforts represent clear pathways the country should adopt to achieve sufficient human vaccine manufacturing by 2040.

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