Biotechnology Journal International

Volume 30, Issue 1, Page 97-115, 2026; Article no.BJI.148194
ISSN: 2456-7051
(Past name: British Biotechnology Journal, Past ISSN: 2231–2927, NLM ID: 101616695)

Sustainable Pharmaceutical Manufacturing and Supply Chain Diversification for Economic Growth in Africa: Barriers, Opportunities, and Policy Pathways

Ernest Tambo [a,b*]

[a] *Institute for Global Health Equity Research, University of Global Health Equity, Butaro/Kigali, Rwanda.*
[b] *Africa Institute for Disease Intelligence, Preparedness and Response (AIDIPaR), Yaounde, Cameroon.*

Author's contribution

The sole author designed, analyzeed, interpreted and prepared the manuscript.

Article Information

DOI: https://doi.org/10.9734/bji/2026/v30i1824

Open Peer Review History:
This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here: https://pr.sdiarticle5.com/review-history/148194

Review Article

Received: 28/09/2025
Published: 21/01/2026

Abstract

While Africa continent has high potential due to its large and youthful population, manufacturing remains underdeveloped, with only 2% of global manufactured goods originating from Africa. Inadequate and unreliable infrastructure is one of the most critical barriers to manufacturing implementation and broad growth. Little is documented on biomanufacturing readiness and supply

**Corresponding author: E-mail: tambo0711@gmail.com, etambo@ughe.org;*

Cite as: *Tambo, Ernest. 2026. "Sustainable Pharmaceutical Manufacturing and Supply Chain Diversification for Economic Growth in Africa: Barriers, Opportunities, and Policy Pathways". Biotechnology Journal International 30 (1):97-115. https://doi.org/10.9734/bji/2026/v30i1824.*

chain systems performance and robustness that are essential for safe and efficacious vaccines, medicine and other diagnostic products. This review article highlights biopharmaceutical manufacturing and supply chain management regulatory ecosystem and engagement, workforce and infrastructure capacities implementation strategies. Findings showed that pharmaceutical manufacturing in Africa is a rapidly growing, strategic focus for health sovereignty, aiming to shift from importing over 99% of its vaccines to producing 60% locally by 2040 through massive workforce development, strategic partnerships, and targeted investments. This review article highlights the biomanufacturing regulatory ecosystem and policies implementation to targeted capacity building strategies in enhancing sustainable production and supply chain systems resilience, efficiency and access and uptake effectiveness for economic growth and well-being, Addressing implementation barriers and knowledge gaps is crucial in harnessing and fast-tracking vaccines and medical products scale production and wide availability against preventable infectious diseases and non-communicable diseases among under-served and vulnerable populations across Africa and global south. Findings revealed that key barriers and challenges include a shortage of skilled labor, complex and inconsistent regulatory environments, inadequate and unreliable infrastructure like geopolitics power increasing operational costs and limits production, fragmented markets, transportation, inefficient roads and ports, which drives up freight costs and causes significant supply chain management bottlenecks, and limited allocation domestic finance. Key strategies in national and regional diversification of manufacturing are highlighted to significantly impact socio-economic growth by fostering innovation, creating jobs, and enabling sustainable production of various goods. Advancing biomanufacturing basic and advanced research to industrial-scale production and sustainability approaches. Africa's development and transformation relies on biomanufacturing actionable outcomes which is crucial for a thriving bioeconomy immense opportunities driven by the Africa Union Platform for Harmonized African Health products Manufacturing (PHAHM) to build capacity for vaccines, diagnostics, and therapeutics. This calls for the urgent need for integration and sustainability drivers and evidence-based biomanufacturing policies and regulations, productivity and economic development strategies. Fostering public-private biomanufacturing partnerships and co-investment actions plans. Boosting integrative vaccines biomanufacturing national regulatory and ethics engagement, licensure pathways and hamonized reliance approaches through advancing data sharing and standard practice for programmatic vaccine biomanufacturing decision-making and resilience across borders. Data-driven and evidence-informed decisions safe and effective biomedical products development, scale production, availability,low-cost and uptake compliance have shown signifficant global and public health benefits and returns impact. Biopharmaceutical manufacturing and biotechnologies skilled workforce development and programmatic plans including risk mitigation and supply chain capabilities across Africa have potential social and pubic health impact and driving "the Africa w Want", while addressing manufacturing regulatory processes and high cost investment and global supply chain complexities and vulnerabilities issues and gaps is core across Africa and worldwide.

Keywords: Pharmaceutical, Manufacturing; maturity; financing, reliance, supply chain; Implementation; sustainable; efficiency; economic; benefit, Africa.

1. Introduction

Manufacturing continues to play a key role in the economic growth of developing countries, though challenged with dwindling financing, economic volatility and geopolitical shocks alongside growing inequities across the global south (Sinumvayo et al., 2024; Mynhardt & Ndembi, 2023). Biomanufacturing utilizes biological systems to produce biomaterials, vaccines and medicines those potentially drive significant economic growth by creating new industries and markets innovations (Mynhardt & Ndembi, 2023; Wohlgemuth, 2025). It has been noted that nearly half of Africa's 1.5 billion people lack regular access to essential medicines, building a robust, home-grown pharmaceutical industry can ensure the health security of all Africans, as COVID-19 pandemic revealed life-threatening gaps in the availability of essential medical products (Mynhardt & Ndembi, 2023; Wohlgemuth, 2025).

Investing in robust and sustainable biomanufacturing and biotechnologies industries is esential to promote local manufacturing of pharmaceuticals and healthcare products scale production and increasing accessibility to

medical commodities and healthcare goods. This offers a new paradigm shift in, reducing import dependency, reliance on fossil fuels and minimizing environmental impact. Implementation of contextual biomanufacturing supply chain solutions are evolving with key African countries maturity level 3 accreditation (Rwanda, Egypt, Ghana, Nigeria, South Africa, Kenya and Morrocco) focusing on enhanced national pharmaceutical regulatory process, and domestic financial mobilization and increasing market visibility, risk mitigation, and sustainable practices. Key strategies include leveraging technology for real-time tracking, implementing robust business continuity plans, and building strong, diversified supplier relationships (Mynhardt & Ndembi, 2023; Ogwu et al., 2025; Ali et al., 2024; Carter, 2025). Supply chain diversification approach reduces risk by relying on multiple suppliers, locations, and transportation methods and, increases supply chain resilience, agility, and the ability to adapt to disruptions like natural disasters, geopolitical instability, or pandemics. Key benefits include risk mitigation, potential cost savings through competitive sourcing, access to new markets, and enhanced innovation (Saha & Roy, 2021; Lokko et al., 2018).

The necessity for investment in local pharmaceutical production is critical to improve availability, affordability, safety and the stability of supply, especially for critical products like vaccines, antibiotics and diagnostics. Moreover, in navigating this storm demands clear, science-based evidence to help policy-makers make smart, localized decisions that make the most of increasingly limited resources as Africa local vaccine production capacity meets less than 1 percent of the local demand and over 70% import of all pharmaceuticals consumed,(Akegbe et al., 2023). The shortfalls in COVID-19 vaccine demand production, crisis-induced supply chain disruptions, and inequitable distribution and, government intervention commitment require to accelerate vaccine and medicines production and availability, both manufacturing value-added and job creation/employment opportunities across Africa. These have potential in revamping biomanufacturing sector development changes and exploitation of potential new opportunities and scale productivity. (Drury et al., 2019; Shokoohi & Attar, 2024; Aguilar et al., 2019).

Continuous deployment of emerging AI-powered biomanufacturing uses artificial intelligence, machine learning, and robotics to optimize biological production processes, improve efficiency, and reduce costs in the creation of products like life-saving therapeutics, vaccines, and sustainable materials. This integration allows for data-driven decision-making and automation that surpasses traditional methods further enhance productivity and reduce costs (Sinumvayo et al., 2024). Africa biomanufacturers and biotechnologies firms should focus on enhancing the digital maturity of their processes and facilities by adopting advanced automation, data analytics, evidence-driven or knowledge translation management, and modeling tools, as outlined in the BioPhorum Digital Plant Maturity Model (Sinumvayo et al., 2024; Drury et al., 2019; Timmis et al., 2017; Kristensen, 2025; Shokoohi & Attar, 2024; Clomburg et al., 2017). While engineering science suppliers have been creating new software, automation technologies, sensors, and analytical tools, the consumables used in these processes are still largely analog (Josephson et al., 2021; Wohlgemuth, 2025; Pandey et al., 2024).

Little is documented on pharmaceutical biomanufacturing and supply chain performance and robustness inadequacies and gaps that are not just limited to vaccines, medicine, diagnostics and others sector products (Mynhardt & Ndembi, 2023; Drury et al., 2019; Josephson et al., 2021). Bio-pharmaceutical manufacturing issues and problems are systemic, plaguing all emerging biologics-based therapies from cells and gene therapies (CGTs), engineered tissues and organoids (ETOs), to next-generation vaccines. Similar to the COVID-19 vaccines, thousands of patients are waiting for cell therapies and transplants to treat their cancer (Akegbe et al., 2023; Rubin Thompson et al., 2023). With the rapid growth, necessitating robust and adaptable biomanufacturing supply chains. Most industry's increasing complexity and the need for high-quality, consistent products demand sophisticated solutions to manage the flow of materials, information, and processes" (National Research Council et al., 2015; Pandey et al., 2024). "The growing number of countries in pharmaceutical manufacturing's maturity level will significantly impact vaccine and medical products scale production and production and consequential economic growth. Moreover, fostering innovation, creating jobs, and enabling sustainable production and supply chain improvements of various health goods.

Advancing biomanufacturing research and innovation to industrial-scale production and productivity is crucial for a thriving bioeconomy, which offers an alternative against the traditional, often unsustainable industrial practices. The lack of appropriate advanced biomanufacturing infrastructure, logistics and supply-chain management solutions and a highly qualified bio-pharmaceutical workforce is a key barrier for widespread and equitable access and uptake of these emerging therapies. A rapid regulatory and policy reforms and leadership engagement will be critical fundamental for national and global helth policy and health diplomacy across Africa" (Rubin Thompson et al., 2023; Ramin et al., 2024; Rasor et al., 2021; Lopes, 2015).

Achieving Africa bio/pharmaceutical reliance and health financing sovereignty roadmaps requires a robust policy and resilient regulatory frameworks enabling environment coupled with vaccines and essential medicines supply chains systems. This is essential in ensuring timely and efficient scale production, accessibility and uptake strategies implementation of biological products (e.g.: vaccines,diagnostics). Adopting diversification of biomanufacturing technologies, tools and supply chain management require fostering multisectorial partnership and multistakeholders collaboration. Advanced biomanufacturing and supply chain solutions involve using biological systems like cells and enzymes to synthesize bioproducts, offering sustainable and efficient alternatives for various pharmaceutical and biotech-industries. The increasing interest and need for gene therapies to cure inherited diseases and improved lifestyle illnesses has be on the scale in the global south, while only a privileged few patients can access these therapies in the global north" (Rubin Thompson et al., 2023; Thomas, 2024).

Key contextual and practical biopharmaceutical and biotechnologies strategies include integrating digital and circular economy principles require leveraging emerging humanoid AI, blockchain and robotics technologies like synthetic biology, genetic engineering, and multiomics in optimizing bio-based products. Embedding digital platforms connected features and smart digital supply chain management logistics is essential for efficient decision and fast distribution and uptake coverage monitoring and mapping imapct design to enhance biopharmaceutical manufacturing regulation and reliance practical performance and benefits and return of investment. But also boosting production processes efficiency and effectiveness. Also, addressing local biomanufacturing process optimization and quality assurance, data inter-operatibility to local investment key barriers and challenges is paramount by implementing strategic alternative initiatives, the biomanufacturing sector builds more resilient and efficient supply chains, fostering innovation and ensuring the availability of critical medical and biological products to under-served and vulnerable groups. While addressing regulatory compliance, procurement and supply chain vulnerabilities, material shortages, and ensuring making life-saving therapies more accessible and cost-effective, the availability of skilled workforce with combined expertise in data science, AI, and life sciences to implement and manage these advanced technologies effectively.

This review article highlights biopharmaceutical manufacturing and supply chain management regulatory ecosystem and engagement, workforce and infrastructure capacities implementation strategies, in enhancing effective and sustainable production flow and supply chain management performance indicators metrics for scale access and uptake effectiveness in emergencies public health threats and in advancing economic growth and well-being across Africa.

2. Key Findings and Discussions

2.1 Integration and Sustainability Drivers and Evidence-Based Advancing Biomanufacturing Policies and Regulations Engagement Implementation for Economic Development

Findings reported Africa's bio-manufacturing high-level policy and regulatory leadership commitment and engagement pathways, building local infrastructure and workforce capacity for health products production through several initiatives. These include the Partnerships for African Vaccine Manufacturing (PAVM), now the Platform for Harmonized African Health products Manufacturing (PHAHM), which aims to boost local production of vaccines, therapeutics, and diagnostics. Interestingly, documented key actions and pathways include strengthening regulatory frameworks and domestic financing mechanisms implementation. Fostering the enabling business environment, pharmaceutical

Table 1. Trend and progress in Africa manufacturing ecosystems of vaccines, health products and other essential health commodities in Africa

Key Phase	Actions	Significance
Africa Union manufacturing Act and roadmap adoption and implementation	Transforming Africa local manufacturing landscape, policy, regulatory and implementation guide aligned Au vision 2063	Significant progress towards local vaccine and other health products manufacturing
	Expansion and coordinated local manufacturing of not only vaccines, but other health products, medicines and diagnostics. progress and challenges	Securing funding for manufacturers, Improving regulatory instruments and mobilizing support to establish local bio-pharmaceutical markets and free trade zones.
National Regulatory Authority maturity level 3 NRA- ML3) accrediation and Reliance agreement	National Regulatory Authorities (NRAs) from seven African countries-Ghana, Rwanda, Egypt, South Africa, Tanzania, Nigeria, Zimbabwe, Senegal, -signed a Memorandum of Understanding (MoU)	This marked a significant milestone in strengthening regulatory systems across the continent Fostering more harmonized regulatory landscape,collaboration and mutual reliance on regulatory decisions among signatory agencies that strengthens local manufacturing and improves access. while also creating an enabling environment for the local production of medical products. Collaborating with a common goal of ensuring timely access to safe, quality and effective medical products across Africa Streamlining approval processes, the MoU will ensure that Africa is better equipped to respond to public health emergencies and reduce dependence on international suppliers.
African Manufacturing Landscape survey	A total of 574 manufacturers were active in Africa, and 25 of them were involved in producing vaccines and over $5.5 billion in pledged investments	Africa's growing commitment to self-efficiency in manufacturing of all health products to ensure care delivery access equity and reflection of sheer-determination to create a resilient healthcare system. Egypt plays a central role in the ongoing transformation of production and procurement patterns, with 20% of Africa's vaccine manufacturing capacity and plans to produce 380 million doses annually by 2030 Toward self-sufficiency in vaccine and health products manufacturing in Africa is no longer a vision – it is a necessity inspired by the experiences gained and

Key Phase	Actions	Significance
		lessons learned from the COVID-19 pandemic havoc. Hence, Africa's capacity to produce high-quality health products, including vaccines and value-based procurement and supply chain efficiency foster economic growth, sustainability, and local industrial innovation.
African Pooled Procurement Mechanism (APPM)	equitable access to essential health products efforts to combat these problems are being complicated by climate change, risk of deliberate use of biological knowledge, and the spread of misinformation linked outbreaks such mpox, cholera, Marburg, measles, and many others, as well as humanitarian crises	It highlighting its transformative impact on market sustainability and demand certainty. By consolidating procurement across African nations, APPM enables manufacturers to scale production, advancing Africa's self-sufficiency in vaccine and health product manufacturing
African Continental Free Trade Area (AfCFTA)	AfCFTA refined strategy, plan, and vision for regional manufacturing of essential health products vibrant, sustainable, commercial and market-driven vaccine sector,	AfCFTA policy documents creating the right policy environment for manufactures and investors. Fostering local production, harmonizing regulations, and creating pooled procurement systems to reduce import reliance, lower costs, and strengthen supply chains for essential medicines. Creating common frameworks and joint purchasing mechanisms to increase buying power and lower prices, enhancing trust and market access for African products. Developing regional hubs (e.g., Rwanda, Egypt, South Africa) for APIs, generics, and biologics to build production capacity, and building resilient systems better prepared for future health crises. Adjusting rules to incentivize local production, though simpler procurement rules for pharma could further benefit the sector and boosting financial independence in health. Promoting African leadership, full commitment, and stronger capacity and support our goal of producing 60% of Africa's vaccines by 2040,noting that

Key Phase	Actions	Significance
		African market for vaccines and medicines is valued at over USD 50 billion annually, yet the continent imports most of the healthcare products that it consumes. Enabling greater self-sufficiency and bargaining power in global markets including financing local manufacturing, reducing tariffs for compliant producers, and leveraging economies of scale via collective purchasing

reliance, free trade zones and financial local and regional sovereignty solutions through public-private partnerships bringing together government agencies, industries, researchers, and international donors, investing in human capital through skills development, piloting phase 1 projects and creating an enabling policies and regulatory pathways.

Biomanufacturing offers immense opportunities and transformative force in health,agriculture, climate and environment, regulatory environment and innovation, aligning with continental goals like the African Union's New Public Health Order and Agenda 2063 to address health security and economic development. With the African Vaccine Manufacturing Accelerator (AVMA) was launched. Such innovative and sustainable financial sovereignty strategies and mechanisms will accelerate the expansion of commercially viable and much needed vaccine and essential drugs, building the necessary regulatory and ethics capacities at all levels, Strengthening human resources and self reliance in secured raw bio/pharmaceutical materials, appropriate demand using an established Pooled Procurement Mechanism (PPM) to improve affordability, availability and equitable access to high-quality medical supplies across the Africa continent (Table 1).

We showed that recent NRA-ML3 and reliance progress in biomanufacturing ecosystems improvements such as strengthening national regulatory agencies (NRAs), harmonizing national regulations to streamline processes for health product. For example,investing in education and training programs, such as the Master and Doctorate (PhD) programs in biotechnology and expertise in biomanufacturing in Rwanda will build a skilled local workforce and play a key growth driver in industrialization and emerging engine of economic development in most developing African countries. Of late, an emphasis has been placed on the role of a robust pharmaceutical and biomanufacturing industries infrastructure and capabilities to boost in real economy as a drive for youth massive employment and economic development and growth (Ramin et al., 2024; Fleck-Vidal et al., 2025).

Evidence-based biomanufacturing policies and regulations implementation should now focus reliance and financial sovereignty modalities by which industrialization takes place and, in particular, on the integration and sustainability drivers (Duga et al., 2025). Strengthening robust and resilient research and innovation collaboration and partnership of scientific, technological, clinical, infrastructure, and policy fields would increase resiliency and preparedness to meet the increasing demand for vaccine and medical products including diagnostic kits. While also empowering citizen, while also understanding the trade-offs, costs and benefits of each option in their specific context and evidence-based solutions to build a safer and prosperous future for all. Collective regional and partners efforts to tackling investment gaps requires refocusing on research and development (R&D) much broader infrastructure,accredited biotechn-/pharma regulatory and skills training programs, particularly strengthening vocational education, providing internships, and developing the local capacity to run clinical trials is needed to support local manufacturing, rather than just rely on fill and finish, with insufficient technology transfer and documented unmet critical gaps.

Hence, effective investment and Mobilizing financial resources and developing new financing mechanisms to support biomanufacturing projects. Ample funding mobilization and allocation in biopharmaceutical manufacturing research and development policies is crucial in technology and digital innovation sector will help African countries to enhance the rate of reliance, patient-providers communication and collaboration, medication adherence and efficient supply chain management for vaccine production and delivery for economic prosperity. It is recommended that policy makers should invest in those policies that can enhance the socioeconomic and financial growth. Also, increasing biotechnological and pharmacecutical manufacturing productivity create new job opportunities for sustainable, healthy and competitive economic development in future larger markets.This will attract capital diversification of all types of sectors with more effective resource allocation to investment in R& I and large markets driven opportunities and shared prosperity as well (Duga et al., 2025).

Fostering greater firms and governments accountability and more efficient resource use in customizable and modular platforms could provide unprecedented dynamics to develop new vaccines for evolving viruses against climate change, and tailored therapies to treat disparate diseases across diverse populations. For example, BioNTech initially targeted cancer with

its technology platform and was able to pivot to COVID-19 vaccines in 2020 (Privor-Dumm et al., 2023; Wagstaffe et al., 2025). “For example, the rapid development and emergency use authorizations in 2020 in the U.S. of vaccines from Moderna and Pfizer-BioNTech” (and perhaps Novavax later in 2021), as well as the role that government regulation and policies have played in ramping up vaccine production, purchase, distribution, and manufacturing governance and management capabilities.

Currently, very few biopharmaceutical firms can be customized to reach and treat hundreds of rare diseases and cancers (Mynhardt & Ndembi, 2023; Adebisi et al., 2022). However, despite multibillion- markets with recent double-digit annual growth for both vaccines biomanufacturing, efforts remain siloed and fragmented amongst local private firms sector and external partners.

2.2 Fostering Public-Private Biomanufacturing Partnerships and Co-Investment Actions

Findings showed that smart and strategic collaboration between the private sector, government, industries, and research institutions is vital for sharing knowledge for sustainable and coordinated pharmaceutical manufacturing efforts, which aligns with African Union’s framework for action, the New Public Health Order, explicitly calls for governments, multilateral organizations, philanthropies, private sector, and civil society organizations to support increased investment to support local pharmaceutical manufacturing ecosystem.

The pharmaceuticals is a fast-growing market in Africa and is expected to reach a business opportunity of $50 billion in 2030 from $20.8 billion in 2013. The private sector investment and partnerships can help respond by shifting from importing finished products to producing Active Pharmaceutical Ingredients (APIs), vaccines, and treatments innovation in local biomanufacturing firms. Given the large investment needs, incentivizes country-led solutions to expanding access to immunizations, including local vaccine manufacturing investors by GAVI and WorldBank groups in technology capabilities and knowledge transfer to achieve the ambition, public-private sector partnership and engagement is key in unlocking the biopharmaceutical value chain investment in increasing access to high-quality medicines and vaccines across Africa and strengthening Africa’s commercial medicine market and foster economic development.

Strengthening partnerships and collaborations for stronger multifaceted industries and local supply chains, free trade and economic zones, harmonized regulation, and investment incentives.It can result in result in scalable healthcare products production and, job creating ecosystems capable of consistently delivering affordable, high-quality medicines and exporting them across Africa borders. Also, boosting bio-supplier and other actors relationships and reliance consolidation across public, suppliers and firms will be beneficial, provide fairness and healthcare delivery equity. Galvanizing open and effective biopharmaceutical quality data generation and shariing, and knowledge syhthesis are essential ingredients in targeted bio-pharmaceutical skills building, know-how transfer and exchange on best practices. Integrating susttainable, context- and resilient business processes and solutions iis crucial in increasing returns of investment, mutual benefits and well-being enhancements across Africa.

Strategic partnerships and investments in Africa's biotechn and pharmaceutical manufacturing sector focus on building local capacity through finance, infrastructure, training, local and regional regulatory engagement and policy paths alignment,. This is aiming to achieve greater health sovereignty and social impact.

Key actions include securing funding for manufacturing facilities and research, establishing regional training networks, and creating collaborative frameworks creation and implementation between public and private entities like the African Union, Africa CDC, WHO, and the International Vaccine Institute, that align stakeholders and leveraging on domestic and external co-investments effectively across multisectors and geographies.

There is an urgent need to scale investment in the pharmaceutical and biotech sectors is essential in establishing robust manufacturing infrastructure facilities,building strong health systems,transfer of technology and expertise to local manufacturers. For example establishment of BioNTech's BioNTainers in Rwanda is increasing the production of vaccines and potentially Active Pharmaceutical Ingredients (APIs) in supporting end-to-end manufacturing capabilities, rather than just "fill and finish”, and

to build a sustainable and strategic industry-based local products patent and intellectual property rights. .Another example is Biovac in South Africa boosting vaccine manufacturing capacity and exchange programs is empowering African nations to collectively advance their manufacturing capabilities and in strengthening regulatory systems to support local production and innovation supply chain management efficiencies. In Rwanda is also pursuing a place in Africa's pharma manufacturing ecosystem as the government constructs a home-grown industry and quality standards with private sector support, enhancing regulaatory and ethics compliance,working in collaboration with BioNTech paved the way for Africa's first end-to-end mRNA facility in 2023, and investing a lot in staff training and enhancing our laboratory facilities to meet international standards.Rwanda planned investments in infrastructure such as the construction and equipping of a One Health Laboratory in Kigali, which will strengthen local capabilities for disease surveillance and response while contributing to the country's broader pharmaceutical ecosystem.

Senegal built multi-vaccine production facility, along with other stakeholders mobilizing public and philanthropic support for different aspects of the project. When fully operational, the facility will have the capacity to produce up to 300 million vaccine doses annually comapred to Cote d'Ivoire factory of capacity to produce 5 billion tablets annually amd 1,000 direct and indirect job opportunities, supplying African markets with essential vaccines and increase its pandemic-ready capacities and creation of high-value jobs. Also has targeted producing 50 percent of its pharmaceutical products locally by 2035. Private-sector collaboration is key in pursuing of national health security. Similarly, South Africa Regional Biomanufacturing Training Hub can holst 300 to 800 individuals annually, with a particular focus on young people and women, fostering long-term sustainability throughout the region's biomanufacturing industry.

Fostering procurement, engineering, regulatory and standards reliance and harmonization partnerships efforts offers further advantage of collaborative manufacturing reliance and harmonization platforms for knowledge exchange and technologies transfer capacity building spirit as shown within the global scientific community in 2020 COVID-19 pandemic research and innovation ecozone, demonstrated in the surge in the circulation of preprints and sequences for new safe and efficacious mRNA vaccines.

Biomanufactured products can be quintessential public goods (e.g., vaccines) or the ultimate bespoke therapy tailored patient. Incentivation that enable flexibility and interconnection to easily navigate these markets variabilities and business models would lead to a public-private infrastructure that responds rapidly to variable demands for both types of products have all gained significant momentum (Akegbe et al., 2023; Rubin Thompson et al., 2023; Duga et al., 2025).

"Galvanizing new public-private Bio-pharmaceutical and biotechnologies partnerships are also needed to keep the global community prepared and stocked, especially to develop the next generation of digital and AI-data-driven infrastructure that combines fundamental research, data science, supply chain optimization, and feedback-driven biomanu-facturing resilience with technology advancements and flexibility. The Strategic National Stockpile of therapeutics" (Adebisi et al., 2022; Fonjungo et al., 2012) in the event of a nuclear or chemical attack is an example of partnering across this public-private divide. "Similar preparedness and urgency could address less punctuated but nonetheless urgent vaccines or medical products demands. Pre-ordering products and stockpiling is part of a broader strategy to provide increased access to capital, knowledge, and intellectual property locally and regionally. These actions are all necessary, and given sufficient political will, they could have further energy if organized under a large effort like the Manhattan Project or moonshot solution for biomanufacturing in the Cancer Moonshot Initiative is an antecedent of future accelerated efforts" (Mahoney et al., 2023).

2.3 Boosting Integrative Vaccines Biomanufacturing Reliance and Regulatory Engagement Approaches

Findings showed that African governments political will and leadership commitment in local and regional Biomanufacturing enabling regulatory and partnerships through the establishment of the African Medicines Agency (AMA) and agreements among national authorities to foster an integrative vaccines manufacturing ecosystem. These efforts aim to

achieve self-sufficiency and meet 60% of the continent's vaccine needs by 2040, a goal set by the Partnerships for African Vaccine Manufacturing (PAVM) initiative. AMA continues to provide continent-level guidance and harmonization of regulatory standards in 29 AU members countries have ratified the AMA treaty, moving it toward full operation through providing hands-on training in Good Manufacturing Practice (GMP) and regulatory science. It supported and bolster National Regulatory Authority (NRA) Collaboration a landmark ML3 accreditation Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Zimbabwe and jointly signed an agreement to cooperate on medicine and vaccine regulation review and shared inspection processes.

The growth of the domestic pharmaceutical manufacturing sector especially the production of generics promises to help narrow health disparities. Local pharmaceutical production enhances secure access to safe vaccines and medicines by improving both the quantity and quality of supply, reducing reliance on imports, mitigating the fast-expanding scourge of counterfeit and substandard drugs and rising antimicrobial resistance, ensuring timely availability of essential health products, and driving local innovation. As AMA continues the implementation of continental framework that anchors pharmaceutical reliance across Regional Economic Communities (RECs) and NRAs, aiming at reducing duplication of effort, accelerate access to quality medical products, and provide adaptable models for national implementation (Drury et al., 2019; Rubin Thompson et al., 2023; Fleck-Vidal et al., 2025).

Such combined digital and genomics efforts enhance production yields, improve healthcare delivery quality and outcome.Vaccine and drug production, such as novel medicines like RNA vaccines and cell-based therapies to potential prevent and cure diseases. But also, reducing reliance on fossil fuels and minimizing environmental pollution, and swift to renewable energy sources in supporting a more sustainable green energy and circular economic development across Africa. Increasing biomanufacturing innovations into commercial applications investment in research and development leadership and commitment of government and stakeholders to support the enabling policy and regulatory environment. African government biomanufacturing and reliance harmonization policies and regulations play a crucial role in fostering a supportive and collaborative environment for biomanufacturing development and economic growth.For example, AU pharmaceutical and biotechnologies infrastructures and facilities policies has opened the doors for inventors and entrepreneurs using legislating incentives, registering new ideas, localize the new stars-ups inventions, monitoring needs and market based initiatives.

Promoting innovation, and ensuring responsible development.in addition to traditional capital investment, the biomanufacturing field needs investment in human capital. Besides keeping up with the latest biology and engineering, the technicians and leadership in biomanufacturing need to understand and use new advances in automation and data science (Fonjungo et al., 2012). Hence, National Strategy for Advanced Manufacturing Readiness Levels (BRLs) focuses on strengthening domestic manufacturing capabilities, including biomanufacturing products clinical trails and licensure pathways and addressing supply chain vulnerabilities (Mahoney et al., 2023).

Recognizing maturity framework and harmonized reliance of biomanufacturing technologies and processes is essential in guiding medical products and targeted vaccines development and deployment. Scaling up and modernization of vaccine manufacturing will have spillover effects, while much-needed future innovations and investments in CGT and ETO manufacturing will provide surge and advanced manufacturing capacity for vaccines. BioMRLs framework (Biomanufacturing Readiness Levels) provides a shared language for assessing the maturity of technologies and facilitating their transition from research to commercial medical products scale. This framework helps organizations prioritize R&D efforts, mitigate risks, and collaborate effectively in bringing promising technologies to market landscape (Narsai et al., 2025).

While vaccines are in development for infectious diseases like COVID-19, the primary targets cancer, blood disorders, liver diseases, and numerous rare disorders (Josephson et al., 2021). “Regulatory agencies also recommend extended monitoring of vaccinated individuals over months to years. For example, In Nigeria, where the pharmaceutical industry is among the most developed of the continent, manufacturing of drugs for noncommunicable diseases is also a key focus area for investment and producing 70 percent of the medical supplies it needs within five years. Nigeria population demand for

medicines is expected to increase as Nigeria adopts universal health insurance coverage for its 227.9 million people. Nigeria's life sciences sector, currently valued at $46 billion, has the potential to more than double by 2030. The development of Nigeria's health sector could generate almost $1.6 billion in new investment and create up to 44,000 jobs.

With an integrated data infrastructure across pharmaceutical manufacturing sector and clinical outcomes, data science and AI concepts could provide new insights into how to improve processes, as formulation differences and dosing could be correlated to patient outcomes in electronic health records and long-term follow-up studies. be controlled and monitored during manufacturing to yield consistent, high-quality products.Compared to communicable diseases, the conditions addressed by CGT are less cyclical or episodic, resulting in a more linear, plateauing, and predictable demand for CGT" (Mahoney et al., 2023; Narsai et al., 2025). As the need for worldwide, immediate supply of a particular vaccine wanes, a common, integrated manufacturing infrastructure and framework could be used for both advanced therapies and emerging vaccines control and characterization of the manufacturing process and integration smart downstream consumable with the AI-driven and digital architecture of pharmaceutical facilities, production and supply chain management.

2.4 Advancing Data-Driven Diversification and Programmatic Biomanufacturing vaccines and Medical Products Development and Uptake impact

Findings showed that developing and implementation of quality data collection ans sharing/exchange standards, including AI-assisted mapping tools and distribute learning architectures, *f*acilitate seamless data exchange and collaboration among supply chain partners. Africa-wide issues around regulatory strengthening and harmonization, sustainable and well-capitalized pooled procurement, to incentivize local manufacturing. In pooled procurement, multiple countries or organizations combine their purchasing power to procure medicines and other health supplies collectively. Offering such scale allows governments to negotiate prices and create distribution centers, both of which are critical to a successful pharmaceutical sector

Data-Driven diversification and programmatic biomanufacturing effective policy and financial innovation is fundamentally reshaping the lifecycle of vaccines and medical products, transitioning from experimental pilots to core operational necessities, by moving away from single-source manufacturing toward resilient, multi-regional ecosystems. Integrating digitalization, Artificial Intelligence (AI) and Machine Learning (ML) helps identify hidden correlations in complex bioprocesses, optimizing upstream yields and predictive control. Shifting toward highly adaptable platforms like mRNA, viral vectors, and virus-like particles (VLPs) that can be rapidly pivoted to target new diseases and Using sensors and big data analytics for constant process monitoring ensures consistent product purity and quality while reducing costs and import dependence as Africa CDC aims to produce 60% of the continent's required vaccines locally by 2040.

Diversification and resilience is important and crucial by reducing reliance on single and external sources for critical materials and components. This involves identifying alternative suppliers, local and regional outsourcing and establishing redundancy in the vaccine and drugs expedients procurement and supply chain resilience.This can promote faster, cheaper, and higher-quality data transfer, enabling more efficient operations and faster product development. Enhanced data integration and analytics capabilities is crucial in accessing and utilizing data to track production and inventory, predictive and modelling vaccines and medicine demand and supply decision-making, as well as optimizing programmatic logistics planning and supply chain market visibility and return of investment. For example, Nigeria government has embarked on a holistic health sector reform program to move Nigeria toward universal health insurance coverage and is leveraging partnerships with the private sector. As part of these African manufacturers efforts and to attract new investment to foster, to stimulate, to lower the cost of manufactured products by enacting policy reforms in health systeme strengthening profound benefits and to break the vaccine and medicine import dependency.

Leveraging locally data-driven biomanufacturing technology and automation is necessary in advancing manufacturing technologies including software developers to create tools for computer-aided biology, bioprocess design, and consistent data analysis. Automation in research services,

such as automated laboratory operations, streamlines workflows and facilitates high-throughput screening (Ndomondo-Sigonda et al., 2021).

Adopting data sharing across sectors for continuous manufacturing, digital twins, and automation can improve efficiency, reduce costs, and enhance supply chain responsiveness. Real-time visibility and tracking dashboard integrated Manufacturing systems with firm resource planning systems provides biomanufacturers with enhanced products availability, supplier performance, and scale production processes. This enables proactive vaccines and vaccination stocks management of inventory, identification of potential supply and coverage bottlenecks, and fostering data-driven decisions for in and/or external API products sourcing and procurement (Ndomondo-Sigonda et al., 2021; Rubin Thompson et al., 2023).

Increasing the use of AI, robotics and digital methods and application platforms is associated with higher effective availability, cost-effective utilization and coverage of new tools. Scaling up uptake and adherence strategies could be increased by improving underserved and vulnerable populations including targeted frontline health professionals digital literacy, especially elder population streamlining ease of use.

2.5 Building Biomanufacturing Skilled Workforce Development and Capacity Building

Findings showed that promoting domestic investment in strategic logistics and supply chain capabilities, technology transfer, workforce training, and establishing a regulatory process including domestic and international partnerships and alliances manufacturing capacity building and training in enhancing Africa public health sovereignty and security. Strengthening the Regional Capability and Capacity Networks (RCCNs) are being established to address the critical shortage of skilled professionals in biomanufacturing, R&D, and regulatory affairs is paramount in co-design, co-production and shard benefits. Thus, bolstering the number of qualified personnel and aligning policies and regulations to support the growth of the biomanufacturing sector, potential of digital tools to enhance coverage of social support, safety and protection programmes. Improving public awareness and educational outreach programs of patients/end-users and most vulnerable populations is critical in building public confidence and trust of medical products safety, efficacy and quality supported by the Partnership for African Vaccine Manufacturing (PAVM), coordinate government and international efforts to ensure sustainable demand and market health and African Medicines Agency (AMA) (Rubin Thompson et al., 2023). We reported a lack of information about the existence of pharmaceutical manufacturingand supply chain management programmes and accessibility to yield the most tangible decisions all stakeholders. Ensuring that more use of culturally-targeted communication strategies either telephone lines, mobile text messages, social media platforms, or community boards and youth voices and influenzers in engagement and dessimination is capital for locally-led initiatives and sustainability.

Strengthening pharmaceutical manufacturing workforce has now been pressure tested, as they have kept operations up and running despite lockdowns and social distancing requirements during the COVID-19 pandemic. For example, many biomanufacturing and biotechnologies organizations established routines and protocols to keep biopharmaceutical manufacturing facilities operating in the event of another pandemic-related lockdown. The professional development should be nurtured and preserved within the workforce" (Tagbo et al., 2025). In addition to a national stockpile of biomanufactured vaccines or therapeutics, a "national guard" for biomanufacturing could be just as important to increase our preparedness. Such a workforce needs to come not just from four-year colleges and universities and post-graduate trainees. Importantly, from the nation's two-year technical and community which are the primary supplier of manufacturing technicians across all industries.

Investing in targeted skilled workforce for biotechnology, pharmaceuticals, and agriculture research, development, and production training programs and educational initiatives is essential to ensure a sufficient supply of qualified personnel to operate and manage advanced biomanufacturing facilities can boost job creation in various sector and ensure sufficient capacity to propel economic growth across Africa.

2.6 Fostering Business Biomanufacturing Risk Mitigation for Social Impact

Establishing a robust supply risk management program is crucial for identifying and mitigating

potential disruptions. This includes diversifying the supplier base, establishing safety stock, and forming long-term agreements with contract manufacturers. Harnessing new pharmaceutical discoveries is critical as Africans' health concerns shift. African rates of noncommunicable diseases are expected to become the leading cause of mortality and morbidity by 2030. Chronic conditions like heart disease, cardiovascular disease, and diabetes especially point out the need for relevant, accessible treatments as change in epidemiological burden and outbreaks public health emergencies underscores the potential for investments in local drug manufacturing and distribution, especially for generics formulation.

Furthermore, biopharmecutical and related business continuity and management plans, including multi-site scale production manufacturing and avaibility and affordability can help minimize downtime and ensure a reliable supply of medical products and vaccines stockpiling as strategic investment for greater local and regional preparedness and emergency response against future health emergencies crises including antimicrobial resistance (AMR). As the demand for vaccines and therapeutics increases, a concomitant strengthening of biomanufacturing infrastructure requires new cross-cutting integration across the vaccines and CGT fields to meet today's needs, and in due course, the post-pandemic world.Address logistical challenges and simplify application procedures. While these barriers were less frequently reported when compared to lack of information, they are likely to become more prominent as awareness increases. Investing in vaccination risk mitigation and supply chain for social impact programmes with higher effective coverage, such as disability support, are already demonstrating the prevalence of these.

Adopting circular and sustainable supply chain-based economy impact such as recycling, reuse, and resource efficiency, is becoming increasingly important (Drury et al., 2019; Tagbo et al., 2025). Reducing waste, utilizing renewable energy, and investing in sustainable packaging are key aspects of building a more environmentally friendly biomanufacturing supply chain. Implementing sustainable practices throughout the pharmaceutical manufacturing supply chain, from sourcing raw materials to waste management, is increasingly important (Elhassan et al., 2024). Implementing these strategies, biomanufacturers can build resilient, efficient, and sustainable supply chains that support the continued growth and innovation of the industry.

2.7 Addressing Barriers and Challenges in Pharmaceutucal Manufacturing Implementation Across Africa

Boosting Intra-African trade and free commerce zones implementation policies that facilitate the free movement of people, goods, and services (like the African Continental Free Trade Area) to foster economic interdependence. Also investing in scale Pharmaceuticals and biotechnologies infrastructure, digital, energy, transport) connectivity through public-private partnerships (PPPs) is essential as well as investing in human workforce training and skills development in Good Manufacturing practice, regulatory and reliance harmonization and monitoring and evaluation needs for Africans in governance, finance, and technology to build local expertise is paramount to addressing the reported gaps and challenges.

Ultimately, fostering regional financial sovereignty is a deliberate process of building institutions and aligning policies to create an environment where cooperation is mutually beneficial and sustainable, greater self-reliance on internal resources and markets lessens reliance on external powers, fostering true sovereignty and independence.

Finding reported that key challenges including shortage of skilled labor, complex and inconsistent regulatory environments, inadequate and unreliable infrastructure like power increasing increasing operational costs and limits production. In addition, fragmented markets, transportation inefficient roads and ports, drives up freight costs and causes significant supply chain bottlenecks,and a lack of access to finance and funding gaps to secure the financing needed for modernization and expansion, disruptions in supply chains, and stiff competition from imports and counterfeit goods. Corruption, policy uncertainty, and political instability deter long-term investment in the sector, with fragile banking sectors and risk-averse lending practices restrict access to affordable financing for expansion and equipment upgrades. despite abundant natural resources, a significant portion of raw materials are exported with little value-addition occurring locally. However, weak regulatory frameworks, Prioritizing the production of high-quality, affordable generics and essential

Table 2. Barriers and challenges in Biomanufacturing implementation in Africa

Types	Detailed barriers and challenges implications
Policy ethics and regulatory	Lack comprehensive biosafety laws or have frameworks that are not harmonized across the continent, creating regulatory bottlenecks Significant gap in the technical expertise needed to conduct risk assessments and effectively manage biosafety regulatory uncertainty and risk capacity data privacy and mistrust and cybercrimes, deepfakes and data theft and espionage, discrimination and stigma to broad consent Insufficient government leadership and local investment support hinder the development of biomanufacturing and pharmaceutical sectors
Structural and organisational	Weak regulatory frameworks, inadequate infrastructure such as unreliable power supply Inefficient waste management practices are an operational inefficiency Dependence on imported inputs and a lack of local scientific capacity for full-scale production
Workforce	Lack of a sufficiently trained and skilled workforce or lack of skilled personnel, Spread of misinformation and disinformation creates public skepticism, slows adoption of new technologies, and erodes public trust in science Lack of awareness or understanding of the technologies being developed Deficiencies in research and innovation as well as translation
Funding and economic	Insufficient research funding and a lack of investment make it difficult for local industries to expand High cost of raw materials and imported technological inputs is high, increasing financial burdens and limited funding, Over reliance and dependency of external partners Complex and costly purification steps in downstream processing and affordability
Digital and cloud	Lack the necessary high-speed internet, reliable power supply, and data centers required for AI and digital systems Weak or limited clear policies on data ownership, privacy, and security to build trust and ensure responsible use of data Data often fragmented, incomplete, or siloed AI systems meet the stringent regulatory requirements for pharmaceutical production is a major hurdles deter commitment without clear near-term returns Competitiveness and free trade zones commercialization Disparities in digital access between urban and rural areas, hindering widespread implementation Transparency and accountability issues, which is problematic in a highly regulated industry like biomanufacturing

medicines through adequate infrastructure such as unreliable power supply, efficient waste management practices are an operational efficiency, less dependency on imported inputs and local community and scientific capacity for full-scale production have assets. In addition, reported workforce and financial deficiencies in research and development funding and encouragement to weak standardization pharmaceutical and medical laws and streamline approvals to and quality norms investment across governments hinder innovation and the creation of new products. as the roll out of the AfCFTA has been slow due to complex negotiations and weak implementation due to lack of capacity among public officials to effectively implement industrial policies, strategies, and trade regulations is a persistent problem, slow submission of tariff schedules, and non-tariff barriers like customs delays and innovation, Consistent pharmaceutical reliance and regulatory regional biomanufacturing value chains is capital in scaling and diversifying their products. As now, Africa still trades more with the rest of the world than it does internally. African firms. Prioritizing the local production of high-quality, affordable generics and essential medicines and improved managerial capabilities for fast adoption of automation, smart manufacturing, and other industry 4.0 technologies can scale productivity and competitiveness of African manufacturers (Tagbo et al., 2025).

While the continent has high potential due to its large and youthful population, manufacturing remains underdeveloped, with only 2% of global manufactured goods originating from Africa.Inadequate and unreliable infrastructure is one of the most critical barriers to manufacturing growth and implementation (Table 2).

We reported that local manufacturers face intense competition from cheaper imports, which can reduce market share and profitability and in most African countries the prevalence of counterfeit products threatens the reputation and viability of legitimate African-made goods as African Continental Free Trade Area (AfCFTA), regional integration and trade barriers remain a significant challenge (Elhassan et al., 2024; Arney et al., 2014). Also There is a need to increase the adoption of modern technology and Industry 4.0 solutions to boost efficiency and competitiveness. Addressing existing public vaccines and vaccination stigma, fear and countermeasures social medial disinformation and misinformation concerns by scaling up public awareness, educational outreach programs in promoting understanding of biomanufacturing technologies is crucial for building trust and acceptance from lab-scale experiments to large-scale industrial production remains a significant challenge, requiring investment in infrastructure and process optimization.

Ensuring that biomanufactured products are cost-competitive is crucial to build a more resilient and competitive manufacturing sector, with traditional products is essential for widespread adoption of clear and supportive regulatory frameworks are needed to facilitate the development and commercialization of biomanufactured health commodities and others products (Kana et al., 2023; Mynhardt et al., 2023).

3. Conclusion and Recommendations

The article emphasizes on strategic partnership and mutual collaboration for widespread adoption and implementation biopharmaceutical manufacturing and biotechnologies programs and strategies through data-driven and market-informed effective and practical regulatory frameworks and standards guidelines to promote and facilitate patient/public acceptance, trust and uptake of medically biomanufactured products (e.g.: safe and efficacious vaccines and medicines and diagnostics) against emerging and persisting public health emergencies crises. Moving towards a new global pharmaceutical and health governance system ensuring equity, sustainability, and African leadership requires Achieving pharmaceutical reliance and financing sovereignty is critical for health equity and long-term sustainable transparent and shared governance, including two annual ministerial meetings and the involvement of civil society impact, particularly in Low- and Middle-Income Countries (LMICs) aiming to reduce dependence on external suppliers in Africa. This emphasizes the urgent need to reduce dependence on external aid by promoting local and regional solutions to achieve Universal Health Coverage (UHC) and ensure the continent’s health security.There is need for tailored industrial policies that leverage Africa's unique resources capitalizing on biomanufacturing opportunities that can play a vital role in driving sustainable economic growth and creating a more resilient and prosperous future of Africa. Also, ensuring continuous enabling environment with biomanufacturing regulatory and policy

frameworks for scale productivity, and sustainability strategies for overcoming the implementation challenges and issues hindering partnership and supply chain vulnerabilities in most African countries.

Investing in promoting understanding of biomanufacturing technologies is crucial from lab-scale experiments to large-scale industrial production to human clinical trail building public trust and acceptance. Moreover, strategies focus on fostering regional manufacturing and health central can play in local vaccines and medicines development and a driver of global innovation, implementing sustainable financing models, and strengthening regulatory systems to ensure access to essential medicines diversification for Moving manufacturing closer to demand centers near-shoring or partnering with regional hubs helps secure supply chains.

The urgently of sustainable investment and financial mobilization mechanisms in prioritized manufacturing infrastructure, regulatory reliance and policy harmonization, and scale workforce skills development to capitalize on Africa's immense human and resource potential for structural, social and economic transformation. Also, fostering AfCFTA's and AMA framework for sustainability and social economic impact of biomanufacturing and biotechnologies sector diversification and productivity for Africa shared prosperity. Once Biopharmaceutical ecosystems fully realized, is expected to enhance specific investments, trade and supply dynamics and efficiency in facilitating industrial cooperation and boosting Africa market and economy, Tackling biomanufacturing infrastructure and market gaps as seen in Nigeria's power sector privatization and Ethiopia's industrial parks development are user-case experiences.

Accelerating joint African countries pharmaceutical and biotechnologies programs co-financing and leadership is crucial in prioritizing and advnacing adoption and implementation of AU Agenda 2063 industrialization road-map and financial soverigneity across Africa countries. This is a key driver of sustainable development initiatives and upholding 'The Africa We Want'. While leveraging on advanced digital technologies and tools for scale industrial production, productivity and competitiveness across Africa and globally. Moreover, Africa pharmaceutical transformation landscape shapes by the dynamic global and public health ecosystem that integrates the public and private sectors across the entire value chain-from research and development to manufacturing, distribution, and healthcare delivery impact. By enabling the seamless movement of health goods, services, and expertise across borders, unlocking economies of scale, and spurring investment in local industries in shaping both the health of its people and the well-being of the world.

Disclaimer (Artificial Intelligence)

Author(s) hereby declare manuscript is authentic and no generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of this manuscript.

Competing Interests

Author has declared that no competing interests exist.

References

Adebisi, Y. A., Nwogu, I. B., Alaran, A. J., Badmos, A. O., Bamgboye, A. O., Rufai, B. O., Okonji, O. C., Malik, M. O., Teibo, J. O., Abdalla, S. F., Lucero-Prisno, D. E. III, Samai, M., & Akande-Sholabi, W. (2022). Revisiting the issue of access to medicines in Africa: Challenges and recommendations. *Public Health Challenges*, *1*(2), e9.

Aguilar, A., Twardowski, T., & Wohlgemuth, R. (2019). Bioeconomy for sustainable development. *Biotechnology Journal*, *14*(8), 1800638.

Akegbe, H., Onyeaka, H., Michael Mazi, I., Alex Olowolafe, O., Dolapo Omotosho, A., Olatunji Oladunjoye, I., Amuda Tajudeen, Y., & Seun Ofeh, A. (2023). The need for Africa to develop capacity for vaccinology as a means of curbing antimicrobial resistance. *Vaccine X*, *14*, 100320.

Ali, A., Usman, M., Jayamani, E., Soon, K., & bin Ab Wahab, M. K. (2024). Sustainable biomanufacturing. In *Biomedical Implants* (pp. 195–217). CRC Press.

Arney, L., Yadav, P., Miller, R., & Wilkerson, T. (2014). Strategic contracting practices to improve procurement of health commodities. *Global Health: Science and Practice, 2*(3), 295–306.

Carter, E. (2025). Sustainable biomanufacturing: Leveraging circular economy principles for

competitive advantage. *Journal of Commercial Biotechnology*, *30*(1), 1–10.

Clomburg, J. M., Crumbley, A. M., & Gonzalez, R. (2017). Industrial biomanufacturing: The future of chemical production. *Science*, *355*(6320), aag0804.

Drury, G., Jolliffe, S., & Mukhopadhyay, T. K. (2019). Process mapping of vaccines: Understanding the limitations in current response to emerging epidemic threats. *Vaccine*, *37*(17), 2415–2421.

Duga, A., Dereje, N., Fallah, M. P., Angasa, T., Bayih, A. G., Agbenu, E., Ngongo, N., Tajudeen, R., & Kaseya, J. (2025). Strengthening national regulatory authorities in Africa: A critical step towards enhancing local manufacturing of vaccines and health products. *Vaccines (Basel)*, *13*(6), 646.

Elhassan Taha, M. M., Abdelwahab, S. I., Moni, S. S., Farasani, A., Aljahdali, I. A., Oraibi, B., Alfaifi, H. A., Alzahrani, A. H., & Ali Jerah, A. (2024). Nano-enhanced immunity: A bibliometric analysis of nanoparticles in vaccine adjuvant research. *Human Vaccines & Immunotherapeutics*, *20*(1), 2427464.

Fleck-Vidal, C., Le Moal, A., Mogeni, O. D., Shaffer, D., Canouet, V., Ndembi, N., Wartel, T. A., Plant, L., & Kim, J. H. (2025). A landscape analysis of the vaccine ecosystem in Africa: Research and development funding, clinical trials, regulation, and manufacturing readiness. *Lancet Global Health*, *13*(11), e1983–e1990.

Fonjungo, P. N., Kebede, Y., Messele, T., Ayana, G., Tibesso, G., Abebe, A., Nkengasong, J. N., & Kenyon, T. (2012). Laboratory equipment maintenance: A critical bottleneck for strengthening health systems in sub-Saharan Africa? *Journal of Public Health Policy*, *33*(1), 34–45.

Josephson, A., Kilic, T., & Michler, J. D. (2021). Socioeconomic impacts of COVID-19 in low-income countries. *Nature Human Behaviour*, *5*, 557–565.

Kana, B. D., Arbuthnot, P., Botwe, B. K., Choonara, Y. E., Hassan, F., Louzir, H., Matsoso, P., Moore, P. L., Muhairwe, A., Naidoo, K., Ndomondo-Sigonda, M., & Madhi, S. A. (2023). Opportunities and challenges of leveraging COVID-19 vaccine innovation and technologies for developing sustainable vaccine manufacturing capabilities in Africa. *Lancet Infectious Diseases*, *23*(8), e288–e300.

Kristensen, L. (2025). Developing sustainable supply chain for biotechnological products. *Journal of Commercial Biotechnology*, *30*(1), 198–208.

Lokko, Y., Heijde, M., Schebesta, K., Scholtès, P., Van Montagu, M., & Giacca, M. (2018). Biotechnology and the bioeconomy—Towards inclusive and sustainable industrial development. *New Biotechnology*, *40*, 5–10.

Lopes, M. S. G. (2015). Engineering biological systems toward a sustainable bioeconomy. *Journal of Industrial Microbiology and Biotechnology*, *42*(6), 813–838.

Mahoney, R., Hotez, P. J., & Bottazzi, M. E. (2023). Global regulatory reforms to promote equitable vaccine access in the next pandemic. *PLOS Global Public Health*, *3*(10), e0002482.

Mynhardt, M., & Ndembi, N. (2023). The expansion of pharmaceutical manufacturing industries is critical to strengthen African health systems and decrease reliance on foreign imports. *Journal of Public Health in Africa*, *14*(8), 2826.

Mynhardt, M., Mwila, C., Habtemariam, M. K., Tshangela, A., Martinez, M., Ngongo, N., Kaseya, J., & Ndembi, N. (2023). Empowering Africa's healthcare future: The crucial role of human capital development in bio- and pharmaceutical manufacturing. *Journal of Public Health in Africa*, *14*(10), 2866.

Narsai, K., Leufkens, H. G. M., Brinkhuis, F., Mantel-Teeuwisse, A. K., & van den Ham, H. A. (2025). Transitioning to regulatory harmonisation for medicines: A comparison between Africa and Europe. *Drug Discovery Today*, *30*(8), 104416.

National Research Council, Division on Earth, Board on Life Sciences, Board on Chemical Sciences, Committee on Industrialization of Biology, & A Roadmap to Accelerate the Advanced Manufacturing of Chemicals. (2015). *Industrialization of biology: A roadmap to accelerate the advanced manufacturing of chemicals*. National Academies Press.

Ndomondo-Sigonda, M., Miot, J., Naidoo, S., Masota, N. E., Ng'andu, B., Ngum, N., & Kaale, E. (2021). Harmonization of medical products regulation: A key factor for improving regulatory capacity in the East African Community. *BMC Public Health*, *21*(1), 187.

Ogwu, M. C., Kosoe, E. A., & Osawaru, M. E. (2025). Raw materials for sustainable bioeconomy development in the Global South. In *Sustainable Bioeconomy Development in the Global South* (Vol. 1, pp. 37–63). Springer Nature Singapore.

Pandey, K., Pandey, M., Kumar, V., Aggarwal, U., & Singhal, B. (2024). Bioprocessing 4.0 in biomanufacturing: Paving the way for sustainable bioeconomy. *Systems Microbiology and Biomanufacturing*, *4*(2), 407–424.

Privor-Dumm, L., Excler, J. L., Gilbert, S., Abdool Karim, S. S., Hotez, P. J., Thompson, D., & Kim, J. H. (2023). Vaccine access, equity and justice: COVID-19 vaccines and vaccination. *BMJ Global Health*, *8*(6), e011881.

Ramin, E., Cardillo, A. G., Liebers, R., Schmölder, J., Von Lieres, E., Van Molle, W., & Gernaey, K. V. (2024). Accelerating vaccine manufacturing development through model-based approaches: Current advances and future opportunities. *Current Opinion in Chemical Engineering*, *43*, 100998.

Rasor, B. J., Vögeli, B., Landwehr, G. M., Bogart, J. W., Karim, A. S., & Jewett, M. C. (2021). Toward sustainable, cell-free biomanufacturing. *Current Opinion in Biotechnology*, *69*, 136–144.

Rubin Thompson, L. J., Grubo, M., Veller, M., Badenhorst, R. H., Nott, J., Debruyne, L., Makadzange, T., Nicolaou, S., Stanberry, L., Sall, A., & James, W. G. (2023). Building global vaccine manufacturing capacity: Spotlight on Africa. *Vaccine*, *41*(27), 4050–4056.

Saha, K., & Roy, K. (2021). Integrating United States biomanufacturing across vaccines and therapeutics. *NAM Perspectives*, 10–3147s8.

Shokoohi, M., & Attar, T. (2024). Biomanufacturing for a sustainable future: Unleashing the potential of biotechnology in pharmaceutical raw material production. *International Journal of New Findings in Health and Educational Sciences*, *2*(2), 142–153.

Sinumvayo, J. P., Munezero, P. C., Tope, A. T., Adeyemo, R. O., Bale, M. I., Nyandwi, J. B., Haakuria, V. M., Mutesa, L., & Adedeji, A. A. (2024). Advancing vaccinology capacity: Education and efforts in vaccine development and manufacturing across Africa. *Vaccines (Basel)*, *12*(7), 741.

Tagbo, B. N., Ejekam, C. S., Oppong-Amoako, W., Yameogo, T. M., Mitiku, A., Esangbedo, D. O., Khuzwayo, N., Mahlangu, G., Badar, S. M., Agbenu, E. A., Adechina, R. M., & Nyarko, K. A. (2025). Strengthening vaccine safety systems, research, and regional collaboration in Africa: A call to action. *Vaccines (Basel)*, *13*(6), 661.

Thomas, D. (2024). Measuring the US biomanufacturing economy. In *International Design Engineering Technical Conferences and Computers and Information in Engineering Conference* (Vol. 88353, p. V02BT02A024). American Society of Mechanical Engineers.

Timmis, K., De Lorenzo, V., Verstraete, W., Ramos, J. L., Danchin, A., Brüssow, H., … Timmis, J. K. (2017). The contribution of microbial biotechnology to economic growth and employment creation. *Microbial Biotechnology*, *10*(5), 1137.

Wagstaffe, H. R., Ascough, S., Openshaw, P. J. M., & HIC-Vac meeting contributors. (2025). Human challenge models for vaccine development—Strengths, limitations, and expansion into endemic settings: A HIC-Vac meeting report. *Immunotherapy Advances*, *5*(1), ltaf004.

Wohlgemuth, R. (2025). Biomanufacturing as key technology for a sustainable bioeconomy. *Chimia*, *79*(5), 352–358.

Peer-review history:
The peer review history for this paper can be accessed here:
https://pr.sdiarticle5.com/review-history/148194