Article

The Role of the Biotechnology Industry in Addressing Health Inequities in Africa: Strengthening the Entire Health Care Value Chain

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ABSTRACT

There are many misconceptions surrounding health care in Africa, a continent of 54 sovereign countries and a population exceeding 1.2 billion souls which is growing at the fastest rate in the world. Enormous diversity has direct impact on the notion, practices, and availability of health care on the continent. There are no satisfactory generalizations about the state of health and the strength of health care systems for the continent as a whole. Indeed, differences between neighboring countries are enormous, as well as among population groups within countries. There is a significant mix of public, private, and faith-based health care providers. In most African countries, 60 percent of health providers fall into the latter two categories (IFC, 2008). Moreover, movements towards national and private risk pooling for payment of health care are underway in only a few countries, but virtually all modern African constitutions declare health care as a human right and aspire to some form of Universal Health Coverage (UHC). Despite these principles, Africans endure a dual burden of communicable and non-communicable disease. In the face of these challenges, Africans are confronted with out-of-pocket payment for health services – when it is available at all – and challenging logistics for accessing and maintaining consistency of care. The patient journey for Africans is a winding path, often exacerbated by an additional reliance on the importation of talent, pharmaceuticals and vaccines, medical and diagnostic tools, and digital support of the health systems. The health care value chain in Africa is incomplete. Each of Providers, Payers and Producers need further development. When any of these is weak or missing, there cannot be a sustainable health system. The issue, therefore, is not scientific or clinical competence; it is capacity and the necessity to promote a comprehensive and integrated health care ecosystem – including the Producer segment. To address the Producer link, more direct engagement by the global biopharmaceutical industry in assisting and investing in the advancement of indigenous laboratory and clinical development, product production and distribution, and the advancement of human capital necessary to achieve health care sovereignty for the continent is necessary. There is all the more reason to do so as humanity enters the age of genomic and precision medicine. There is a pathway for African health care to leapfrog as it has done in telecommunications.

Journal of Commercial Biotechnology (2021) 26(4), 50–69. doi: 10.5912/jcb1008

I. INTRODUCTION

A. Highs and lows of health care in Africa

What are the relevant factors in African health care? According to the WHO average life expectancy at birth in the African region is low but increasing, albeit slowly, driven by declines in adult and child mortality. During the period 2010 – 2015, the average life expectancy at birth in the African region (both sexes) increased by 5.1 percent, from 57 years in 2010 to 60 years in 2015. The average life expectancy for

females is about four years higher compared to males. By 2015, the female life expectancy was estimated to be 61.8 years compared to 58.3 for males. During the same period, the average life expectancy at birth for females increased by 5.7 percent from 58.4 years in 2010 to 61.8 years in 2015 (average annual increase of 0.7 years), and for males increased from 55.6 years in 2010 to 58.3 years in 2015 (average annual increase of 0.6 years). There are substantial country differences in the average life expectancy at birth. (WHO, 2018 a).

Compared to other WHO regions, the average life expectancy at birth in the African Region is much lower: people in the Eastern Mediterranean and South-East Asia live at least 9 years longer, and those in the Americas, Europe and Western Pacific live at least 17 years longer than those in the African region. When the healthy life expectancy at birth is considered, that is, the number of years a person lives in a healthy state, the life expectancy at birth in the African region drops by about 14 percent. Compared to the other WHO regions, the African region had the lowest healthy life expectancy at birth in 2015 (52.3 years), which is about 8 years lower than Eastern Mediterranean and Southeast Asia, and about 16 years lower than the healthy life expectancy in the Americas, Europe, and Western Pacific regions. (WHO, 2018 a).

How should we interpret this picture? There is room for optimism in that the overall trend is up – not for the continent as a whole – but there are signs that interventions, particularly for communicable diseases are having a positive effect. Of course, when the dust settles from COVID-19 the picture will likely reverse, at least temporarily. Before thinking further, causes of death should be considered.

The picture may be different from what the reader is expecting. Ischemic heart disease and strokes are the world's biggest killers, accounting for a combined 15 million deaths in 2015. While this is not yet the case in the African region the numbers are closing fast. Health systems strengthening throughout the continent is required to control noncommunicable diseases (NCDs) and their risk factors. In the year 2000, stroke and ischemic heart disease were ranked 8th and 9th leading causes of death, respectively, but in 2015, they were in the 4th and 5th position, after lower respiratory tract infections, HIV/AIDS, and diarrheal diseases. When both stroke and ischemic heart disease are combined, they rank second among the leading causes of death in the Region. (Musau, 2017; Fymat, 2019).

Malaria has dropped quite substantially in position, from being the 4th leading cause of death in 2000 to the 7th, which is largely due to the good performance of the malaria control programme in the Region rather than the emergence of other diseases. HIV remains the second leading cause of death, but if the current improvements in HIV control programmes are sustained, it will not be long before the effect of HIV/AIDS on mortality is diminished relative to the group of leading killers in the Region. (WHO, 2018 a).

Proportional mortality from lower respiratory tract infections and diarrheal diseases have remained largely unchanged in 15 years (2000 – 2015); special efforts are therefore required, including research that helps to understand the specific organisms responsible for the cause of death from lower respiratory tract infections and diarrheal diseases, as well as research on practices related to seeking health care. Death from road traffic injuries is on the rise. In year 2000, road traffic injuries accounted for 1.2 percent of the deaths, but in 2015, it accounted for 2.9 percent. Road traffic injuries have moved up the ladder of the leading killers, from the 13th position in the year 2000 to the 10th position in 2015. Tragically, younger people are disproportionately killed in road accidents (WHO, 2018 a).

The principal concern going forward is that by 2030, the incidence of neoplastic diseases in low- and middle-income countries may reach catastrophic proportions with perhaps 75 percent of all cancer deaths occurring in poorer countries. Extrapolation of data from the Institute for Health Metrics and Evaluation (IHME, 2021), and articles by Naghavi, et al. (2015) and Fitzmaurice et al. (2017) strongly imply that sub-Saharan Africa will be a locus of a disease burden greatly compounded by cancers of all types, thus highlighting the importance of prevention, screening and early intervention.

B. The Health Care Value Chain: Strategies for achieving health equity through stronger health systems

This section establishes a case for the development and integration of an entire health care value chain in the African continent. The health care value chain model was posited by Burns (2002) and constitutes a fundamental lens through which to observe health systems. Put simply, there are three key components necessary for patient care: Providers (the institutions and health care professional human resources). The Payers, be they individual or more desirably managed risk pools – either public or private (but hopefully universal) for health care costs. Finally, Producers, the product innovators, manufacturers, and others that bring the needed medicinals, diagnostics, devices, information technologies and the like to the care setting.

Throughout this article, "local," "indigenous," and "African" manufacturing refer to manufacture physically located in sub-Saharan Africa, regardless of ownership. The extent to which the current industry is under African

ownership is striking. Unlike the industry in other settings which seek to serve global markets, however, the output in Africa is produced for local or regional use. At the same time, African players fall into a competitive global environment in pharmacy. For example, Kenya, Tanzania, Ethiopia, and Mozambique have histories of production. In Kenya, there has been a palpable evolution of capabilities from bench to plant. In Tanzania, the incumbents have managed to sustain a relatively shallow sector. Ethiopia has experienced a turnaround using linkages to joint ventures. Mozambique, a Lusophone country, is developing a nascent industry with support from Brazil.

In a health system, when there are missing links in the value chain – these are usually domestic payer systems or producer functions – the health system will compensate or find a substitute. Sooner or later, the consequence of a weak link affects the functioning of the entire system. In Africa – appropriately – the aid efforts have been directed at the Provider function seeking to drive patient care to the highest level of attainable quality and desirable outcome. The Payer function has recently received greater attention. Of course, in order to achieve UHC, countries must have the administrative, judicial, and civic finance infrastructure to implement a national health care risk pool. The Producer function is another matter. Producers emerge when there is a mechanism to be paid for goods and services that functions well enough to justify investment. Investment relies on congenial laws and regulations, property rights, access to skilled labor, attentive capital markets, and the ability to fairly adjudicate disputes. The particular risks of an absent Producer sector are over-reliance on importation and the associated price concerns, logistical challenges, inefficiencies, limited control over quality, and lost employment opportunities for domestic workers.

The prescription for improvement of health systems in Africa, according to the WHO, the World Bank, USAID, the International Monetary Fund (IMF), and many other international organizations and foundations, such as the Bill and Melinda Gates Foundation, will have to include: a more balanced, horizontal approach to disease; focus on prevention, education, and awareness of the mode of transmission or exposure to both infectious and chronic diseases; an integrated approach to health, involving whole sectors of government, such as the ministries of health and the ministries of education; transportation and infrastructure; law enforcement; water and sanitation; food security and housing; the sharing of information while stressing the same general health goals and appropriate strategies; self-efficacy in the management of disease; a scaled down reliance on expensive medical equipment that only serves the rich and the families that can afford it, who often "overstretch the workforce"; more attention paid to the real needs of the people through proper retooling of the health personnel; accurate diagnosis of disease, as Botswana has done in monitoring and screening for HIV (here, screening increased from less than 10 percent of the population in 2000 to 90 percent in 2014); and systematic increase of children's immunization against diphtheria, measles, and hepatitis. (Azevedo, 2019).

Martyn Sama and Vinh-Kim Nguyen (2008) hold the view that all societies have had health systems "*of some sort*" as long as people have tried to protect themselves against diseases. Systems, they say, can be defined as those traditional practices, "often integrated with spiritual counseling and providing both preventive and curative care," which have "existed for thousands of years and often co-exist today with modern medicine," often undergoing consistent changes (Sama and Nguyen, 2008). Their thesis is the more relevant as they refer to African stewardship and the crisis the health system is experiencing virtually everywhere on the continent. They point out that effective stewardship is the government's key role in oversight and trusteeship, which involves formulating health policy, defining the strategic vision clearly, and articulating the direction the leadership wishes to see the health system follow. This is strengthened by exerting influence and vocalizing in word and action the approaches to regulations guiding the health system and collecting and using intelligence (data and information) effectively. In sum, stewardship implies vision, "overall system design and policy formulation; setting priorities, and "performance and impact assessment for outcomes, promotion of health and advocacy; and establishment of norms, standards, and ethical framework." In their assessment, the two authors note that African systems are among the "most bureaucratic and least effective managed institutions in the public sector. The ministries are fragmented with vertical programs, or ritual chiefdoms, dependent on certain donor funding." (Sama and Nguyen, 2008).

While Sama and Nguyen's theses may be troubling to some and interpreted to challenge the donor and philanthropic *modus operandi* since the second World War, and further emphasized over the last two decades, there is a basis for examining the tension between focused vertical programs, i.e., disease-oriented initiatives, versus horizontal approaches across systems. Some observers have advocated a "diagonal" approach. The diagonal approach overcomes the barriers between vertical (disease-specific) and horizontal (systemic) approaches by making full use of potential synergies between disease programs and health functions and prioritizing programs that respond to multiple diseases. (Knaul et al., 2015) Suffice it to say, there is renewed attention to health systems strengthening – the horizontal – but that focus is on the Provider link in the health care value chain. It

is only recently that more attention has been directed to the Payer function – the advocacy for UHC. And concurrently, the observation that the supply chain for products is essential. Recognition of this last point has been revealed through the consequences of COVID-19. Supply chains are, indeed, essential but are only a fragment of the Producer function. Producers must have an indigenous face across the continent.

In short, health systems are an ecosystem of functional sectors. Any ecology must have all components in place to function sustainably. Health system strengthening, therefore, is social strengthening. National and international efforts must be directed accordingly. To put an even finer edge on this razor, can health equity be achieved in a system with an incomplete value chain or dysfunctional sectors?

II. CHARACTERIZING THE HEALTH CARE VALUE CHAIN IN AFRICA

A. The Patient Journey in Africa: Implications for the Producer Segment

A way to approach an assessment of health equity is to explore differences in the patient journey through the system from a state of health to the personal experience and determination of illness. From illness through medical or surgical intervention to recovery or palliation. From recovery or palliation to a sense of well-being or acceptance. The efforts along this path translate into addressing and assessing four steps in the patient journey, whether through a public system or private system (*italics* designate points of the journey dependent on producers):

1. Wellness, prevention, and *screening* (management of the social determinants of disease);
2. Presentation and *diagnosis* (physical examinations, *laboratory*, or *imaging* validation), financial qualification as under social contract, or private payment;
3. Intervention for an acute or chronic condition, either *medica*l or *surgical* treatment (in- or outpatient) support during recovery by provider or family;
4. Aftercare with or without needed maintenance *medication*, access to *devices* (such as oxygen), rehabilitation services, counseling towards a sense of well-being or acceptance, nutritional support, financial restoration.

These steps are presented without regard to the quality of each component or the ultimate outcome at the end of the journey. The steps summarize the patient journey only in general terms but touch on most elements. Particular experiences vary significantly by patient, their circumstances, their geography and local access to care, the sophistication and resources of the providers, the maturity and viability of the payment system, and the functioning of the producers and their supply relationship to the providers and patients.

Everyone has experienced variability throughout their life at each interaction with the health system – there is limited predictability even in high income countries. In low- and middle-income countries (LMICs), the variability is greater. The best that one system has to offer is seldom equivalent to what another system has to offer. Equivalence, however, is not necessarily based on absolute access to resources. There can be an acceptable patient journey even in the most austere setting when a health system has a complete value chain, and each link is optimized for the local setting and culture.

African institutions are slowly closing structural and resource gaps in the continent's Provider segment. The efforts in meeting goals most intensively focus on quantity and quality of health care professionals, development of professional management, serviceable physical plants, navigating relationships with health ministries, regulatory conformance, designing and managing supply chains, and constantly struggling with continuity of care and improving the patient journey. Aspirations are high in many countries and confidence is growing, but few Providers have arrived at the best managed journey imaginable. Beyond controlling what they can control, there are still the Payer and Producer segments outside their control.

B. The Providers: Foundations for Incorporating Biopharmaceutical Assets

There is a primary care conundrum that is universal to all health systems. Primary care, especially when preventive services are included, is the cornerstone to the integrity of a health system. Ironically, from a resource perspective, it is the least valued or compensated dimension of care at the Provider level, but for the Payers and Producers as well.

From the Providers' point of view, primary care is a gateway function to higher orders of care. In itself, primary care is least compensatory as a profit center. There are no procedures. Perhaps free vaccines are dispensed. There is likely basic but low margin lab testing prescribed. If the consultation results in a prescription, it is typically filled by a pharmacy with no direct connection

to the Provider entity. Even such prescriptions are likely filled with an Essential Medicine in generic form.

Applying crass marketing terminology to primary care defines it as a loss leader function. It is necessary for referral into advanced care services but has small or negative margins. The investment in primary care, as a result, is usually a public function. Alternatively, people will consult with their local pharmacist for primary care. The pharmacist may be prepared to advise the person correctly and refer them to a specialist, but as the vendor for a medicine that might be prescribed, the pharmacist is inherently conflicted. That said, there is throughout Africa, a heavy reliance on pharmacies as the first port of care.

The primary care challenge in Africa is exacerbated by a chronic shortage of physicians and nurses, despite heavy national and philanthropic investment into the creation of medical and nursing schools. Furthermore, primary health care facilities in sub-Saharan African countries are facing a rising pressure from growing populations and the emergence of infectious diseases such as the recent outbreaks of Ebola and COVID-19. Uneven distribution of health care accessibility, in addition to limited public health financial resources and other fiscal constraints, calls for better planning for the next generation of health care facilities. (Falchetta et al., 2020).

The primary care gap in Africa is important as an issue of human equity and as a precursor to poverty reduction and human development. Africa has 24 percent of the world's burden of disease, but only 3 percent of the world's health workforce. The Joint Learning Initiative and the 2006 *World Health Report* called attention to the particularly severe shortages of human resources for health in Africa. Early responses to the recognition of these shortages included calls for increased production of community health workers and non-physician clinicians, and task shifting to make effective use of available cadres. Attention has now focused on education and retention of medical doctors in Africa, not because doctors will solve the vast unmet health needs of the continent, but in the belief that no health system can function well without an adequate number of doctors to participate in clinical and public health work, management, education, and policy making. (Ighobor, 2017). Sub-Saharan Africa has an estimated 145,000 physicians (5 percent of the 2.9 million practicing physicians in Europe) to serve a population of 821 million (more than the population in Europe). Overall, sub-Saharan Africa has a physician-to-population ratio of 18 per 100,000, compared with countries such as India (60 per 100,000), Brazil (170 per 100,000), and France (370 per 100,000). Africa's poorest countries have even greater physician shortages. The very low physician-to-population ratios in countries in sub-Saharan Africa result from several factors, including a modest output of students by a small number of medical schools, and emigration of many graduates to other countries or continents. Any effort intended to improve health-system functioning in these countries should consider options to increase both the productivity of medical schools and the retention of their graduates within their countries. (Mullan et al., 2011).

C. The Payers: Creating the Capacity to Achieve Health Equity

Achieving universal health care access is a key development priority and a target of Sustainable Development Goal number 3. The COVID-19 pandemic has only reinforced this urge. A rapid expansion of public, affordable health care infrastructure is particularly crucial in sub-Saharan Africa (SSA): communicable diseases are the first cause of death, infant mortality rates are above 5 percent, and lengthy journeys to health care facilities undermine the accessibility to basic health care for millions. (Falchetta et al., 2020).

Universal Health Coverage (UHC) is directed at financial risk protection (FRP) which aims at reducing the financial barriers communities face in accessing essential services by ensuring that the financial costs of using essential services are minimized for households and individuals. Out of pocket payments are recognized as one of the major barriers to accessing essential services, as utilization is influenced by a person having the funds required to use needed services. Financial protection is measured by monitoring the proportion of the population with large household expenditures on health as a share of total household expenditure. (WHO, 2018 – B).

In the realm of public funding of health care, it is convenient to think of these categories:

1. General Government Health Expenditure
2. Out of Pocket Expenditure
3. Social Security Funds

Many countries have not introduced social insurance mechanisms for health due to the perceived high costs governments would have to incur, subsidizing those with low ability to pay and covering at least the start-up management costs. However, for elective movement towards financial risk protection in a manner that will lead towards UHC, it is important for countries to critically look at how they can increase the focus of their funding towards social security. Inequities are also seen based on the overall health expenditures. The countries with the highest health expenditures also have the

highest financial risk protection Index – more than double that for the countries with the lowest health expenditures. *This suggests health expenditures are increasingly spent in areas that provide better financial risk protection.* Additionally, the smaller the country population, the higher the financial risk protection – though this pattern is reversed for social security funding, with higher population countries having higher spending on social security. This may be a result of a preference for government funded and managed services in smaller countries, where social security mechanisms may not provide the economies of scale needed to run them. (WHO, 2018 – B).

Health security is a key measure of UHC in the African Region, given the devastating effects of disease epidemics and health emergencies on health and wellbeing. as shown by the devastating Ebola epidemic in West Africa. The region is particularly vulnerable to outbreak events, with an average of over 40 events being monitored at any given time [pre-COVID-19 data]. This high vulnerability calls for a need to focus on identifying and monitoring populations vulnerable to events and to respond to their needs. Health security is assured if a country can build core capacities to prevent, detect and respond effectively to outbreak and disaster events that influence health. (WHO, 2018 – B).

Although 44 percent of current health expenditures in Africa was financed through domestic government funds in 2016, more than 37 percent of all of Africa's health spending comes from out-of-pocket payments. This burden has significant implications at the household level. For example, at least 11 percent of Africans experience catastrophic spending for health care every year, while as many as 38 percent delay or forgo health care due to high costs. If the ambitious United Nations Sustainable Development Goals of 2015 (SDGs) are to be reached in Africa, significant efforts must be made to change the current spending environment. (Ogbuoji, 2019).

The Addis Ababa Action Agenda highlighted the need for the mobilization of private-sector finance and domestic public resources. Yet it is not clear how much of the financing gap can actually be closed by mobilizing domestic resources alone. Another source of financing for the health SDGs is a higher share for health care in domestic budgets, which will encourage large allocations of investment from the private sector when governments are seen as partners. But most countries are moving far too slowly. In 2001, African Union countries pledged to spend at least 15 percent of their annual national budgets on health. Ten years later, an analysis by the WHO found that only Tanzania achieved that target and 11 countries had actually *cut* the share of government expenditures going to health. To address financing shortfalls, leader met on the sidelines of the recent African Union Summit in February 2019 to "launch a new initiative aimed at increasing commitments for health, improving the impact of spending and ensuring the achievement of universal health coverage." (Ogbuoji, 2019).

Ogbuoji (2019) of the Brookings Institution has proposed the following actions:

1. *Keep moving towards pooled financing of health care***.** Since out-of-pocket payments account for 31 percent of health care financing, pooling these resources could allow strategic purchasing of health services. Universal health coverage (UHC) initiatives provide opportunities to pool, and it is encouraging to see that several countries are pursuing UHC goals. Here again, progress needs to intensify in order to assure the populations and the private sector that there is political will at work.
2. *Encourage donors to be more innovative and strategic*. Funding models that allow governments to reallocate money away from health care should be discouraged while models that encourage domestic resource mobilization and prioritization of health should be encouraged.

Donors should also be persuaded to be more flexible with their graduation/exit criteria. Most poor people in the world now reside in middle-income economies, not low-income countries. Ironically, middle-income countries face imminent loss of donor funds because of their recent history of economic growth. Economic growth, however, does not necessarily equate with heath system strengthening or growth – a matter of inadequate government resolve. If donors cut funding and middle-income countries are unable to close the gap in financing, then the SDG pledge to "Leave No One Behind" would sound hollow.

3. *Adopt systems that foster innovation and continuous learning in financing and delivery.* Potential opportunities include using technology to create alternative and more efficient care delivery models, fostering learning across countries through collaborative learning systems and the adoption of homegrown solutions for health care delivery problems.
4. *Get serious about addressing waste and leakages.* The 2010 World Health Report suggest that 20 to 40 percent of all health care resources are lost to inefficiencies in the system. Areas with potential for results include: 1) medicines and health technologies,

where increased use of generics and reductions in counterfeits can help a lot, 2) human resources for health, where tackling absenteeism and promoting task-shifting have been shown to work, and 3) corruption and fraud, where policies to improve transparency and regulation could help." (Ogbuoji, 2019).

The Payer gap will remain resistant to improvement in most countries. Those with expanding GDPs are in a position to plan the implementation of UHC as family incomes and the taxation base improve. There is, however, a need for the data upon which actuarial models can be built, as well as defining a scope of services based on epidemiologic indicators and assessment of costs of treating and managing particular diseases in both public and private Providers. While this paper's central thesis is that the Producer segment must increase presence and investment in Africa – ideally towards assisting in the establishment of indigenous capacity – the ability for the payment of goods and services is a persistent challenge. The payer needs to be a partner in building the supply chain. An improved supply chain will also expand the economy and bring in jobs. This, however, contributes to the argument that indigenous Producer capacity also expands the economy as a whole and makes the health ecosystem more viable and sustainable.

D. The Producers: rethinking presence and investment in products

Generic pharmaceuticals in Africa. Perhaps generic and essential medicines are not top of mind for the innovation companies in the biopharmaceutical industry, but the landscape of pharmaceutical need is essential to the thesis of this paper. According to Pheage (2017) about 80 percent of Africans, mostly those in the middle-income bracket and below, rely on public health facilities, reported the World Bank in 2013. With public health facilities suffering chronic shortages of critical drugs, many patients die of easily curable diseases. Several factors inhibit access to medicines, but the major ones, according to the WHO, are the shortage of resources and the lack of skilled personnel. "Low-income countries experience poor availability of essential medicines in health facilities, substandard-quality treatments, frequent stock-outs and suboptimal prescription and use of medicines." The WHO updates biannually the "Essential Medicines List," an extensive collection of approximately 350 pharmaceuticals spanning the spectrum of disease management. Most of the medicines on the list are off-patent and available in generic formulations, yet there is a scarcity of these same medications in Africa. (Robertson, 2016).

Africa's inefficient and bureaucratic public sector supply system, Pheage (2017) adds, is often plagued by poor procurement practices that make drugs very costly or unavailable. Added to these are the poor transportation system, a lack of storage facilities for pharmaceutical products and a weak manufacturing capacity. Africa's capacity for pharmaceutical research and development (R&D) and local drug production are lagging. Only 37 out of 54 African states have some level of pharmaceutical production. Except South Africa, which boasts some active local pharmaceutical ingredients, most countries rely on imported ingredients. The result is that Africa imports 70 percent of its pharmaceutical products, with India alone accounting for nearly 18 percent of imports as of 2011. Pharmaceutical imports in Africa include up to 80 percent of the antiretroviral drugs (ARVs) used to treat HIV/AIDS, according to trade data. Pheage (2017).

To produce medicines, a country must abide by Current Good Manufacturing Practices (CGMP), which are enforced by the United States and other governments to ensure the quality of manufacturing processes and facilities. Many African countries do not have the technical, financial, or human resources required for high-scale drug production. Egypt, Morocco, South Africa, and Tunisia have made progress in local pharmaceutical productions. Morocco is Africa's second-largest pharmaceutical producer (after South Africa), and has 40 pharmaceutical manufacturing companies that supply 70 percent of products for local consumption and also exports to neighboring countries. Countries such as Ghana, Kenya, Nigeria, and Tanzania are currently developing production capacity.

E. Closing the pharmaceutical gap

The need for indigenous production: vaccines and more. According to Anyakora (2017) pharmaceutical companies in Africa need to invest in both facilities and quality management systems to achieve good manufacturing practice (GMP) compliance. Compliance with international GMP standards is important to the attainment of World Health Organization (WHO) prequalification. However, most of the local pharmaceutical manufacturing companies may be deterred from investing in quality because of many reasons, ranging from financial constraints to technical capacity. Investment in quality improvement intervention is cost-beneficial for local manufacturing companies. Governments and regulators in African countries should support pharmaceutical companies striving to invest in quality. Collaboration

of local manufacturing companies with global companies will further improve quality. Local pharmaceutical companies should be encouraged to seek development opportunities with offshore innovator pharmaceutical companies under equitable terms.

Government can play a role in increasing the capacity of local pharmaceutical companies to manufacture quality medicines. Companies that have already invested or are investing in improving quality in their pharmaceutical manufacturing would need support from regulators. Local manufacturing companies may be deterred by the cost required to reach and operate at an international quality standard, such as the standard required for WHO prequalification. Capital needed for manufacturers in Africa runs into the millions of dollars and may require long-term financing. Most pharmaceutical companies in Africa are limited in their ability to upgrade because of a lack of access to financing. Governments of developing countries can make available grants, soft loans, and subsidies and improve financing of health services such that they are able to patronize local manufacturers, facilitate joint ventures, and encourage international cooperation. (Anyakora, 2017).

Local manufacturing companies in Nigeria currently satisfy only 25 percent of local demand. This speaks to the need to increase the capacity of local pharmaceutical companies to manufacture quality medicines. Although local pharmaceutical production strengthening would take time, certain interventions would help fast track results. One such intervention is the inclusion of industrial training in the module for pharmaceutical schools in Nigeria and West Africa at large. To achieve that goal, industrial training should be done in GMP-compliant companies. Such trainings would improve the sustainability of the processes and quality of new pharmaceutical industries.

Local manufacturing companies considered to be operating at a good or stable GMP level should begin to explore working with global companies either by joint venture or licensing agreement to further improve their quality. Local pharmaceutical industries are also encouraged to key into development opportunities available for pharmaceutical companies in Africa. For instance, the African Development Bank has plans in place to support pharmaceutical industries. These plans include capacity building, learning events such as visitation of policy makers and industrialists to India, and setting up dialogues between public and private sector to discuss opportunities and challenges. Capacity building also is made available by other organizations such as the USAID-funded Promoting the Quality of Medicines (PQM) program, implemented by the U.S. Pharmacopeial Convention and WHO. The activities of the WHO prequalification team include, among others, capacity building of regulators and provision of guidance to manufacturers. (Anyakora, 2017).

Research on the African continent. The subject of research capacity in Africa can be opened with a mournful refrain from Christoffels (2018): "Africa still lags behind the rest of the world in generating new scientific knowledge. As figures collated by the World Bank (2014) show, the continent—home to around 16 percent of the world's population—produces less than 1 percent of the world's research output. These are painful admissions to make, but there are several projects and initiatives that offer hope amid all the bad news. One is a major funding and agenda setting platform, the Alliance for Accelerating Excellence in Science in Africa based in Nairobi, Kenya, which was established by the African Academy of Sciences in partnership with NEPAD. It will award research grants to African universities, advise on financial best practice, and develop a science strategy for Africa. It also offers an opportunity for African scientists to speak with one voice when it comes to aligning a research and development agenda for African countries. Africa has only 198 researchers per million people compared to 4500 per million in the UK and the US or global average of 1150. Another initiative is the US's National Institute of Health and Wellcome Trust's commitment to invest nearly $200 million into Africa-led genomics projects, biobanks, and training of bioinformatics personnel. This investment targets diseases that affect the African continent and gives African scientists the opportunity to set priorities with regard to health interventions and skills development." Christoffels (2018).

By way of illustration, McCall (2014) reflects on 25 years of progress by the KEMRI-Wellcome Trust in Kenya: research priorities are shaped by the needs identified by the Kenyan health services. Marsh points out that they aim to engage with the Kenyan Ministry of Health at an early stage, opening an effective channel for research uptake by policy makers, and ultimately changing practice. "Often researchers address policy makers too late, but policy is complicated, and it pays to engage from an early stage." Gilbert Kokwaro, former director of the Consortium for National Health Research Director, Nairobi [now the director of the Strathmore University Institute for Health Care Management] was one of the Programme's first research fellows. Working with colleagues, Kokwaro focused on refining the dosages and routes of administration of drugs used for associated disorders in children with severe malaria. Kokwaro also highlights that, "no other group, within or outside Africa, has contributed more to understanding of the underlying complications associated with severe malaria in children, and also to the improvement of treatment and management of this condition." KEMRI-WT also

develops research leadership and capacity across Kenya and east Africa. McCall (2014).

A further illustration of progress for pharmaceutical research readiness is provided by Gumba (2019) who reports that the implementation of Good Clinical Laboratory Practice (GCLP) at the KEMRI-WT. Implementing a quality system ensures that the research data are accurate, valid, and reliable. GCLP implementation requires proper documented procedures and safety precautions to achieve this objective. The laboratory managed to implement GCLP elements that could be applied to a basic research laboratory, such as standard operating procedures, equipment management, laboratory analytical plans, organization, and personnel. The laboratory achieved GCLP accreditation in October 2015. The methodology, suggestions, and comments that arose from the KEMRI-WT experience in implementing GCLP guidelines can be used by other laboratories to develop a quality system using GCLP guidelines to support medical research conducted to ensure the research data are reliable and can be easily reconstructed in other research settings. Gumba (2019).

Okeke et al. (2017) provide the important observation that "many of Africa's challenges have scientific solutions, but there are fewer individuals engaged in scientific activity per capita on this continent than on any other. Only a handful of African scientists use their skills to capacity or are leaders in their disciplines. Underrepresentation of Africans in scientific practice, discourse, and decision making reduces the richness of intellectual contributions toward hard problems worldwide. Their essay outlines challenges faced by teacher-scholars from sub-Saharan Africa as they build scientific expertise. Access to tertiary-level science is difficult and uneven across Africa, and the quality of training available varies from top-range to inadequate. Access to science higher education needs to increase, particularly for female students, first-generation literates, and rural populations. They make suggestions for collaborative initiatives involving stakeholders outside Africa and/or outside academia that could extend educational opportunities available to African students and increase the chance that Africa-based expertise is globally available." Okeke et al. (2017) Thus, furthering the partnering thesis of this paper.

Implications, prospects and promises of genomics in Africa. One critically important development in African life science research is offered by Nordling (2018) who reports that African scientists call for more control of their continent's genomic data. This is a sign that African life-scientists are reaching a place of independence and pride. "As the genomics revolution finally turns its attention to Africa and northern researchers flock there to collect data, scientists from the continent are demanding a larger role in projects. On 18 April, a group of Africa-based researchers issued guidelines for the ethical handling of samples for genomic studies. The voluntary rules are an effort to combat 'helicopter' research [sometimes referred to as "Hoovering," as in the vacuum cleaner], in which foreign scientists take samples and data from communities and then return to their home institutions. The guidelines also aim to ensure that African citizens enjoy health benefits from research." Nordling (2018).

[NOTE: The editors of the *Journal for Commercial Biotechnology* are planning a dedicated issue on precision medicine in the coming months. Among the topics to be treated is African genomics. The insights from the paragraph immediately above will be treated in great detail.]

III. PARTNERING STRATEGIES FOR ACCELERATED DEVELOPMENT AND HEALTH EQUITY

A. African economic zones

The prospect of direct entry to a continent with 54 sovereign countries which are a mix of Middle Income and Low income casually appears as a daunting and thankless effort. Efforts by the African Union in concert with the Chinese government to rationalize the African continent have had positive structural results which are still being refined. The goal was to establish Free Trade Areas, or regions encompassing a trade bloc whose member countries have signed a Free Trade Agreement (FTA). Such agreements involve cooperation between at least two countries to reduce trade barriers, import quotas and tariffs, and to increase trade of goods and services with each other. If natural persons are also free to move between the countries, in addition to a free-trade agreement, it would also be considered an open border.

Essentially, to establish operations across the continent, a health care Producer could strategically focus on building relationships with a targeted country in each of the following Regional Economic Communities (REC) whose member countries have entered into an FTA. Membership is often overlapping. The RECs are:

Community of Sahel-Saharan States (CEN-SAD)
Common Market for Eastern and Southern Africa (COMESA)
East African Community (EAC)
Economic Community of Central African States (ECCAS/CEEAC)
Economic Community of West African States (ECOWAS)

Intergovernmental Authority on Development (IGAD)
Sothern African Developmental Community
Arab Maghreb Union (UMA)

Theoretically, a biopharmaceutical or device company can establish a subsidiary or facility in a country associated with one of the RECs, and service customers within that Community without trade barrier restrictions, quotas, or tariffs. Although the road systems are still evolving, transportation and shipping between countries in a REC is near-seamless.

B. Regulation and Intellectual Property

Other factors that can rationalize operations in Africa and encourage the development of products for the population on a proprietary basis, and enable their manufacture and distribution are a unified system of intellectual property, ideally consistent with WTO provisions and effective across borders or within an REC, and a unified approach to drug evaluation, approval, and regulation. The former is still a conceptual aim but conceivable. The latter is in underway, albeit in a long process.

Moreover, although a work in progress, there is a movement in Africa towards establishment of an African Medicines Agency. Ncube et al. (2021) comment that insufficient access to quality, safe, efficacious, and affordable medical products in Africa have posed a significant challenge to public health for decades. In part, this is attributed to weak or absent policies and regulatory systems, a lack of competent regulatory professionals in National Medicines Regulatory Authorities (NMRAs) and ineffective regional collaborations among NMRAs. In response to national regulatory challenges in Africa, a number of regional harmonization efforts were introduced through the African Medicines Regulatory Harmonization (AMRH) initiative to, among others, expedite market authorization of medical products and to facilitate the alignment of national legislative frameworks with the AU Model Law on Medical Products Regulation. The goals of the model law include increasing collaboration across countries and to facilitate the overall regional harmonization process. The AMRH initiative is proposed to serve as the foundation for the establishment of the African Medicines Agency (AMA). The AMA will, as one of its mandates, coordinate the regional harmonization systems that are enabled by AU Model Law domestication and implementation.

In their paper, Ncube et al. review the key entities involved in regional and continental harmonization of medicines regulation, the milestones achieved in establishing the AMA as well as the implementation targets and anticipated challenges related to the AU Model Law domestication and the AMA's establishment. This review shows that implementation targets for the AU Model Law have not been fully met, and the AMA treaty has not been ratified by the minimum required number of countries for its establishment. In spite of the challenges, the AU Model Law and the AMA hold promise to address gaps and inconsistencies in national regulatory legislation as well as to ensure effective medicines regulation by galvanizing technical support, regulatory expertise, and resources at a continental level.

Ndwandwe, D., et al. (2020) have contributed an important article to the literature with a narrative survey of vaccine clinical trials in Africa which offers an encouraging insight into the systems and practices in place. They note that Africa has a high burden of infectious diseases such as malaria, tuberculosis, HIV/AIDS, and Ebola virus disease. In their article they provide a database surveillance study of vaccine-related clinical trials conducted in Africa. Their objectives include addressing and profiling vaccine clinical trials conducted in Africa from the WHO International Clinical Trials Registry Platform on 22 July 2018 and updated on 05 September 2019. They found that 61 percent of the 377 clinical trials were registered prospectively and 35 percent registered retrospectively. About 72 percent of the trials were single-country studies and within the country, most trials (86 percent) were single-center studies. The proportion of trials involving multiple African countries was 11 percent and that of trials involving countries outside of Africa was 16 percent. The biggest funder of the vaccine trials (34 percent) was industry, followed by governments (25 percent) and universities (21 percent). The most studied diseases were malaria (20 percent), HIV/AIDS (15 percent), tuberculosis (7 percent), and Ebola virus disease (6 percent). Most of the vaccine trials were conducted in adults (42 percent). The trials ranged from phase I to phase IV, with most of the trials being in phase I (18 percent) and phase III (18 percent). The conduct of vaccine clinical trials in Africa seeks to address the disease epidemics faced by the continent. There is a need, they observe, for more investments from governmental bodies toward vaccine research in Africa.

Further, African country collaborations are needed in efforts to find African solutions to the current infectious disease threats faced by the continent. Their analysis of data and reporting of activity supports the notion that drug trials generally and vaccine trials in particular can be conducted within the established infrastructure. Ndwandwe, D., et al. (2020).

With respect to Covid-19 vaccine clinical trials, despite Africa's strong performance in its own battle against COVID-19, its capacities have been drastically underused in the race toward a vaccine. The first

COVID-19 vaccine trial in Africa began last June when the Oxford-AstraZeneca trial launched in South Africa, where additional trials have since followed. But in spite of their highly developed trial capabilities, countries such as Cameroon, Nigeria, and Tanzania have yet to host vaccine trials. Of the 33 vaccine candidates under clinical evaluation at the end of August, only two were being tested in Africa—little progress against the status quo of only two percent of all clinical vaccine trials globally taking place in Africa. (Boms et al., 2021).

Somewhat less encouraging are the views on intellectual property. Motari et al. (2021) offer an important study on the prevailing data and infer the attitude about the role of IP and access to medicines. They write that it is now 25 years since the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the same concerns raised during its negotiations such as high prices of medicines, market exclusivity and delayed market entry for generics remain relevant as highlighted recently by the Ebola and COVID-19 pandemics. The World Health Organization's (WHO) mandate to work on the interface between intellectual property, innovation and access to medicine has been continually reinforced and extended to include providing support to countries on the implementation of TRIPS flexibilities in collaboration with stakeholders. Their study analyzed the role of intellectual property on access to medicines in the African Region using patent data from the African Regional Intellectual Property Organization (ARIPO) and *Organisation Africaine de la Propriété Intellectuelle* (OAPI) to provide a situational analysis of patenting activity and trends. They also reviewed legislation to assess how TRIPS flexibilities are implemented in countries. They found, unsurprisingly, that patenting activity was low for African countries. Only South Africa and Cameroon appeared in the list of top ten originator countries for ARIPO and OAPI respectively. Main diseases covered by African patents were HIV/AIDS, cardiovascular diseases, cancers, and tumors. The majority of countries have legislation allowing for compulsory licensing and parallel importation of medicines, while the least legislated flexibilities were explicit exemption of pharmaceutical products from patentable subject matter, new or second use of patented pharmaceutical products, imposition of limits to patent term extension and test data protection. Thirty-nine countries have applied TRIPS flexibilities, with the most common being compulsory licensing and least developed country transition provisions. They conclude and recommend that opportunities exist for WHO to work with ARIPO and OAPI to support countries in reviewing their legislation to be more responsive to public health needs. Motari et al. (2021).

That said, while advocating that more countries strengthen their knowledge and use of the flexibilities of TRIPS, they add: The low levels of patenting activity by African Region countries calls for the need to develop and strengthen health innovation systems in the Region. This can be done through policies that support health research systems and a local incentive structure that focuses research on local health challenges. Other aspects of developing health innovation systems would include developing local scientific and biomedical research capacities and local manufacturing capabilities. In the interpretation of this author, this is one of the most balanced views of the relationship of IP as a potential obstacle to medicinal access but also as an incentive to driving research, development, and manufacturing to meet needs. Stronger, equitably managed IP may be a key to the development to neglected diseases that affect Africa. This will seem paradoxical to most public health advocates but is a balance that must be achieved. The RECs might be a key to rationalizing IP in an administratively efficient manner but there is a chasm in advancing this point of view. Advocacy and flexibility by the private sector can accelerate progress.

C. Innovative pharmaceuticals: research, development, and production in Africa through partnering.

A foundational study on the role of the private sector in Sub-Saharan African health care was conducted by McKinsey & Company for the International Finance Corporation (IFC) with support from the Bill & Melinda Gates Foundation. (IFC, 2008). The report noted that the continent already has a private sector that plays a major role in delivering positive health outcomes. Though its importance varies from country to country, the report observes, in many areas it is an indispensable part of the health care system, complementing and, in some cases, directly supporting the public sector.

Market solutions alone, the report cautions, are no panacea for Sub-Saharan Africa's health challenges. The challenges are that the private sector is diverse and fragmented, and therefore, quality can be variable and oversight difficult. An appropriately managed and regulated private sector, the report notes, can increase quality standards and efficiencies and take some of the financial burden off the public sector. The authors also observe that harnessing market forces to address the region's health challenges will require increased engagement and stewardship from the public sector and other stakeholders. The implication being that the private sector cannot operate independently from the public sector and must

observe priorities and plans that are the product of sound public health research.

To the benefit of the continent, the report observes, investments in the private health sector can lead to long-term, sustainable increases in funding and health infrastructure. The authors ask how best to leverage the capacity and resources of the private sector through investment, partnerships, and public sector oversight. The IFC (2008) report seeks to begin the process of developing those new approaches and has two primary objectives:

> To highlight the importance of the private health sector in Sub-Saharan Africa, suggesting ways in which key policy makers, donors, and other stakeholders can engage and develop it as a complement to over-stretched public sector health care systems; and to identify opportunities for investors to participate in the expected growth in health care spending in Sub-Saharan Africa over the next decade. While not seeking to detract from the role of national governments in delivering health care, this report aims to demonstrate that the health of the region's inhabitants would be improved through a more formalized, integrated, regulated, and better capitalized private sector.

This landmark report delivered high principles for action and behavior. Nearly 15 years after its publication, its observations still ring-true but have been barely enacted. For example, the report observed that the future growth of Sub-Saharan Africa generics manufacturing, inclusive of South Africa, is projected from three factors: (1) the same GDP per capita/Total Health Expenditure (THE) per capita relationship as drove the growth of the overall health care market; (2) substitution of generics and lowered use of patented products in South Africa; and (3) scenario-based projected changes in Sub-Saharan African manufacturers' share of the future generics market.

The prescriptions for action in the 2008 report were sound but more specific advice was needed and rendered as to the role of partnering and appeared in IFC (2011). The premise of the second report is that:

> collaboration between the government and the private health sector is nothing new in Africa. Private providers, especially faith-based organizations (FBOs), have been serving African communities for decades. But engagement between governments and self-financing or for-profit providers occurs far less often, even though the clear majority of private providers are self-financing. For this Report, a new framework was developed to assess the level of engagement between The public health authorities and private sector providers . . . As stewards of the health care system, governments should be seeking ways to leverage available resources, thereby improving quality and access. Our research starts with three observations: Africa's health systems need to be improved; the private health sector is too large to ignore; engagement can improve the use and effectiveness of existing resources.

The emphasis of the report was on the Provider sector but many of the insights are foundational to the Producer sector, as well. The recommendations as related to the private sector generally are: 1. Form a representative body to participate in the engagement process. While there is some evidence of private health sector organization across the region, it is insufficient in most countries. 2. Seek meaningful dialogue as a first step in improving public-private engagement. The private sector initiative has driven the engagement process in some countries. The private sector should express interest early and often. 3. Collaborate with the government to address the issue of quality of care – whether patient services or product quality. Provider networks, capacity building in clinical practice, and business management training are all ways that private groups can help improve the care offered by their members. For example, Strathmore University in Nairobi has been aggressive in offering academic and executive programs in management and leadership across the health care industry. They and other institutions would welcome the opportunity to collaborate with the Producer sector. 4. Offer credible solutions to shift some oversight responsibility from the government to the representative body. While the government remains the steward of the health system, effective self-regulation can improve the sector overall and ease the capacity constraints of the government. The Producer sector has accumulated meaningful experience across civic relationships and often has a better grasp of the issues that government staff. There is a great opportunity to work proactively. 5. Strengthen internal quality control and business management processes at private facilities and in the case of production facilities, have Standard Operating Procedures and quality controls at the ready to address any concerns. Especially in terms of business management practices, most government employees have a lot to catch up to. Associations of private providers have a role to play in providing guidance and support for improvements at individual facilities and government overseers.

IV. A RESEARCH AGENDA FOR THE STUDY OF AFRICAN BIOTECHNOLOGY

A. Health systems strengthening vis-à-vis product availability

Oleribe, et al. (2019) engaged in extensive research that reinforced that healthcare systems in Africa suffer from neglect and underfunding, leading to severe challenges across the six World Health Organization (WHO) pillars of healthcare delivery. These pillars or "building blocks" are: i) service delivery; ii) healthcare workforce; iii) healthcare information systems; iv) medicines and technologies; v) financing; and vi) leadership/governance. Oleribe, et al. (2019) conducted their study to identify the principal challenges in the health sector in Africa and their solutions for evidence-based decisions, policy development and program prioritization. The first three challenges identified were inadequate human resources (34.29 percent), inadequate budgetary allocation to health (30 percent) and poor leadership and management (8.45 percent). The leading solutions suggested included training and capacity building for health workers (29.69 percent), increase budgetary allocation to health (20.31 percent) and advocacy for political support and commitment (12.31 percent). Their conclusion is telling: The underdeveloped healthcare systems in Africa need radical solutions with innovative thought to break the current impasse in service delivery. *For example, public – private initiatives should be sought, where multinational companies extracting resources from Africa might be encouraged to plough some of the profits back into healthcare for the communities providing the workforce for their commercial activities*. Most problems and their solutions, they emphasize, lie within human resources, budget allocation and management. These should be accorded the highest priority for better health outcomes. Oleribe, et al. (2019).

B. Building a continental biopharma ecosystem

McKinsey & Company (2015) developed these principles further and extended them into completing the African health care ecosystem by promoting the advancement of a pharmaceutical industry in Africa. They observe that in a world of slowing and stagnating markets, Africa represents perhaps the last geographic frontier where genuinely high growth is still achievable. Early movers can take these four steps to pursue competitive advantage:

1. Focus on pockets of growth. Africa is not one unified market, but 54 distinct ones, with wide gaps between countries in terms of their market size, growth trajectory, macroeconomic landscape, legal structure, and political complexities. Over the past decade [as of 2015], ten countries have delivered more than two-thirds of Africa's GDP and cumulative growth. However, much of the opportunity lies not at country level, but in cities. In fact, our analysis shows that 37 percent of African consumers are concentrated in 30 cities, which will have more consuming households than Australia and the Netherlands combined by 2025.
2. Build strong local teams. Real talent is key and requires investment in big, effective local marketing and sales teams. That means hiring more pharmacy representatives, building teams' technical skills, and selecting and developing strong local managers to lead them. Sales teams also should be set up in a flexible way that enables them to be responsive to the needs of local markets.
3. Forge partnerships. Global pharmaceutical companies need local business partners — manufacturers, packaging companies, and distributors –to help them navigate the continent's many markets, with their widely varying consumer preferences, price points, manufacturing, and distribution infrastructures. In the absence of a pan-African pharma regulatory body, they also need to invest in local partnerships to understand varying regulatory environments. Partnerships with governments are equally important, whether they involve working with medical opinion leaders to guide research priorities and secure funding, or collaborating with health ministries and nongovernmental organizations to provide public-awareness campaigns, health screening, treatment, equipment, and training for hospitals and clinics. Johnson & Johnson, for example, has partnered with the South African government to introduce an education program for maternal, newborn, and child health that operates via mobile-phone messaging.
4. Address supply and distribution challenges. In parts of Africa, supply and distribution mechanisms still pose challenges: regulations are evolving, transport and logistics infrastructures are patchy, and lead times can be long. The ability to innovate the distribution

> channel and set up effective operations against this challenging backdrop are critical to capturing growth opportunities. Helpful strategies include locating fixed assets in countries with well-established political and business structures, outsourcing supply chains to third-party operators, and partnering with local logistics providers to identify efficient transport routes. In the key area of customs and border control, companies should work with the most reliable agents to minimize shipping delays, use only bonded distribution centers, and ensure all customs paperwork is airtight. Those countries are Algeria, Egypt, Ivory Coast, Kenya, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia.

In summary, McKinsey & Company (2015) posit that "in a world of slowing and stagnating markets, Africa represents the last geographic frontier where high growth is still achievable. As ever, the key to success lies in understanding individual markets in granular detail. Early movers with the right approach should be able to capture competitive advantage. Africa will continue to grow for the foreseeable future. Now is the time for drug companies to decide whether they want to be part of that growth and, more important, play an active role in improving public health."

Jimenez, J. (2015) offers the perspective of Novartis after their years of building a presence and contributing to the state of health in Africa. Writing as the CEO, Jimenez offers:

> We've learned a few important lessons on how to deal with infrastructure challenges in Africa and have identified where sustainable investments can make a long-term difference. We need to focus on three areas: leveraging digital technologies, improving knowledge, skills, and resources, and creating collaboration and consensus among key stakeholders.

These lessons fall into three categories:

1. *Digital technologies.* Mobile phones have been particularly beneficial where infrastructure is limited in Africa. Mobile devices are a profound source in delivering better healthcare. For example, previously, patients would travel to far-off health clinics only to find that the medicines they needed were no longer in stock. Today, around 27,000 government health workers in Uganda use a mobile health system called mTRAC to report on medicine stocks across the country.
2. Skill set development. Through training the next generation of scientific leaders. Jimenez observes what was reported above: the Kombewa Clinical Research Center and the CDC-KEMRI Center in Kenya demonstrate that sub-Saharan Africa is making strides in building up its own R&D capabilities. While Kombewa is remote, it is impressive that Phase II and III research is being conducted at the Kombewa Clinical Research Center on various drugs, vaccines and diagnostic tests. He also saw increased commitment to training local scientists and encouraging research through programmes such as Human Health and Heredity in Africa (H3Africa), which was recently established by the NIH and Wellcome Trust. This initiative funds African scientists and local institutions to conduct basic research on the genomic and environmental bases of health issues prevalent on the continent. Novartis is supporting scientific exchange through a partnership with H3-D, the first drug discovery and development center in Africa. The goal of H3-D is to train local scientists from Ghana, Kenya, South Africa, Sudan, and Zimbabwe to develop treatments that address widespread conditions in Africa, such as tuberculosis, malaria, and cardiovascular disease.
3. *Public-private partnerships for health.* Public-private partnerships, according to Jimenez, can really make a difference. For example, USAID and Orange, the global telecommunications operator, just announced a new collaboration to find innovative ways to use mobile phones to accelerate access to health information and services in Africa. Novartis is reaching across sectors through building the Foundation for Chronic Disease Management (FCDM), in collaboration with IBM and Vodacom in South Africa. The FCDM links public sector community health workers and private physicians to bring high-quality, cost-effective care to people's homes with mobile technologies. This grass-roots approach can make a big difference, as the cost of a patient spending one day in a hospital could fund two health workers for a month.

Jimenez closes, "We need to commit ourselves to working together with all other healthcare players to move away from simply donating aid, to building sustainable infrastructure that can ensure needed therapies are

available in even the most remote areas. Everyone should have access to good health, no matter where they live."

To conclude this section on building the pharmaceutical sector in Africa, there is a cautionary note. On the matter of advancing an indigenous pharmaceutical industry on the African continent, the African Union (2012) produced after long-deliberation a visionary document for *A Manufacturing Plan for Africa*. The detail is thorough, immense in fact, but at that time, the concept of partnering applied to multi-lateral organizations and NGOs. There was little attention on partnering with the Producer sector or even private Providers. Nearly a decade has passed since that publication and as groups like the African Development Bank and the International Finance Corporation address implementation of the vision, there is focused attention on engaging the Producer industries, as well as private equity and venture capital funds in the process of driving towards pharmaceutical sovereignty for the continent. Progress has been made but the Producer segment must be sensitive that there are constituencies that continue to have reservations about the role of the private sector in any aspect of health care. Humility and careful attention are the stylistic imperatives in building dialog.

Integrating biopharma availability with patient care. McKinsey & Company (2019) explored feasibility and sustainability of building an industry in any country influenced by both private- and public-sector factors. They posit that "on the private side, the inherent market dynamics, and the attractiveness of available investments, will determine whether there is a strong business case for putting money into the pharmaceutical sector. These include, for example, whether there's enough unmet demand to make a sizeable plant competitive and the practicalities of exporting excess production."

They further elaborate that "on the public side, governments have several potential levers to encourage local production. These include local production incentives in national tenders, subsidies and tax breaks, investment in special economic zones, and talent- and skill-building programs. The availability of these levers varies across countries, and individual governments' attitudes toward the pharmaceutical industry influence their willingness to employ these levers.

The research convinced the authors that:

> increased local drug production is feasible in about a half dozen sub-Saharan African countries at current and projected demand levels. While only South Africa is currently as attractive to private-sector pharmaceutical investors as Brazil and India, other countries are rapidly improving their investment climate. Each has its own strengths and weaknesses relative to Brazil, China, and India. Some are stronger in areas like logistics, business climate, and tax policies. Others might do well in some areas, such as tax policy, logistics, and technology, but show weaknesses in government and business climate. Still others could quickly become attractive to international investors with continued improvement.

In those countries where increased local production of pharmaceuticals would be both feasible and have a positive impact, the question is how to do it. There are five principles: focus on quality, production capacity (or scale), regional hubs, drug-product formulation, and value-chain effects.

"*Focus on quality.* Regulatory standards and enforcement across sub-Saharan Africa typically lag behind global standards. There are only six companies operating in the region that have achieved WHO prequalification. The fight against counterfeit, expired, and substandard drugs is improving, but it is still common in some countries in the region. As sub-Saharan Africa develops its local pharmaceutical industry, it is imperative that countries continuously upgrade their quality standards and enforcement."

"*Build plants with sufficient production capacity.* Any theoretical production-cost advantages that countries in sub-Saharan Africa might enjoy could be outweighed by their lower production capacity and utilization relative to India. Most production in the region today is in small plants with low capacity—plants need to be big enough and have enough capacity to get the benefits of scale economics. And utilization is affected by unreliable infrastructure, frequent power interruptions, and high logistics costs. At what point would manufacturing plants there become competitive with imports? According to the McKinsey analysis, production volume—that is, the plant's capacity times utilization—affects economics and affordability disproportionately more than other commonly cited concerns, such as labor productivity and electricity costs.

"*Create regional hubs that include smaller countries.* Given the minimum production requirements and the fact that there are only a few countries where pharmaceutical manufacturing is feasible, sub-Saharan African countries could work together to encourage a handful of globally competitive industry clusters. These clusters have a better chance of producing affordable, high-quality drugs than if efforts were dissipated across a larger number of subscale investment attempts throughout the continent. With proper regulatory harmonization, smaller countries could experience faster lead times and more responsive supply chains because they could be served by local, and not overseas, suppliers.

"What's next for pharma in emerging markets? As previously discussed, there is already a broader movement to create freer trade across Africa. Yet these efforts are not enough to enable the creation of regional hubs for pharmaceuticals, since drugs are such a highly specialized product. The African Medicines Regulatory Harmonization effort has yielded noteworthy results, with the East Africa Community countries at the stage of conducting joint assessments and inspections. However, it is still not possible for companies to file a single registration that is recognized by neighboring countries anywhere in sub-Saharan Africa today. Until that happens, no at-scale company can realistically serve multiple countries.

"Focus on drug-product formulation but keep an eye on new technology. Focusing on the right part of the value chain will be critical to the success of a pharma sector in sub-Saharan Africa. Active Pharmaceutical Ingredients (APIs) today are very scale sensitive and hard to manufacture. Most countries in the region lack the requisite chemicals sector for API production, which our modeling suggests would already be 10 to 15 percent costlier than imports from India. That makes drug-product formulation the better bet, while continuing to import APIs—for now, at least.

"Upgrade the value chain. Though the focus may be on drug-product manufacturing, countries might also consider upgrading the value chain beyond just manufacturers. Many countries in sub-Saharan Africa have a highly fragmented landscape of distributors, wholesalers, and retailers, who all add their individual markups to the product. In some countries, for example, it's not unheard of for a drug to be marked up by nearly double the manufacturer's price by the time it reaches the end consumer. In addition to raising the price of drugs, this system also has the effect of compromising quality assurance, since each additional step creates the potential for improper storage, tampering, or delay, even as drugs near their expiration dates.

"There are some who have questioned the ability of the countries in sub-Saharan African to build a local pharmaceuticals industry, and others who question the wisdom of doing so. To those skeptics, the analyses presented here should provide comfort that the potential for building a robust local industry could be real in some countries under the right conditions. It is now for public- and private-sector leaders in the region to decide whether to try."

McKinsey & Company (2020) addresses "Acting now to strengthen Africa's health systems: five big ideas to safeguard lives in the COVID-19 crisis – and prepare the future."

The fourth idea in the report is the most relevant to this discussion. It stresses reliable access to high-quality medical commodities and equipment. Repeating what has been stated herein, "Africa faces a severe shortage of medical commodities and equipment due to constrained domestic capacity and supply. The COVID-19 pandemic has shown that the continent is highly dependent on global manufacturing and supply chains, and many African countries found themselves unable to procure PPEs and other essential medical commodities."

As stated previously, a comprehensive analysis of pharmaceutical manufacturing showed that increased local drug production is feasible in about a half dozen sub-Saharan African countries for some product groups. "Ethiopia was the first African country to develop a strategy and plan of action for pharmaceutical sector development, establishing pharma as one of the priority sectors under its Growth and Transformation Plan II (GTP II). It aims to substitute imported essential medicines with locally produced ones as well as producing for export markets, with a target to increase foreign exchange earnings from $3 million to $111 million."

Again, McKinsey emphasizes partnerships at the local, regional, and global level will be crucial in the effort to advance manufacturing. "Governments could seek to leverage global partners to build up the capabilities of local manufacturers and engage private sector partnerships to boost technical capabilities and innovation and improve quality standards. Countries may need to upskill their workforces, including through technical and vocational education and training. They could also explore regional trade partnerships and harmonized trade policies that exploit the competitive advantages in different countries. And they could introduce important enablers such as standardized cross-border regulations for rapid custom clearance and regionally pooled procurement mechanisms to benefit from economies of scale."

The COVID-19 pandemic, McKinsey (2020) shares, also highlights the benefits of a more sustainable supply chain strategy across the continent, and several African countries are already formulating action plans to address the gap in essential commodity supplies. "Expanding the scope with a more systematic approach can help build resilient and reformed healthcare systems in the long term. Governments can start this journey by determining their commodity and equipment needs, identifying sourcing opportunities, and developing plans for importation or local production based on a cost/benefit analysis. Strong collaboration at the national and regional level, as well as advanced logistics across the entire value chain, including digital tools like Logistics Management and Information Systems (LMIS), and close collaboration with the private sector can be critical. Creating a national supply chain nerve center with decision-making power could help drive implementation."

As policy recommendations, the report opines "to realize the full potential of local manufacturing and supply chains, governments may also consider providing financial and nonfinancial incentives to support their strategies, including tax incentives and greater support for private investments. Some countries have potential to build a robust local industry, under the right conditions. It is for public- and private-sector leaders in the region to decide whether to pursue this avenue through sustained and careful effort."

V. CONCLUSION

A. Health equity and sovereignty vis-à-vis technology and products

Health equity is a normative concept that posits that most inequalities in health among people of differing social locations such as class, gender, race, geography, immigrant, and disability status, among others, are preventable, avoidable, and unnecessary, therefore making their presence immoral, unfair, and unjust. (Braverman & Gruskin, 2003; Kawachi, Subramanian & Almeida-Filho, 2002). Unlike the concept of health inequalities which can be limited to simply describing health differences, the concept of health equity implies a moral imperative to act upon the sources of health inequalities, thereby reducing them. Raphael and Komakech (2019).

Raphael and Komakech (2019) observe that research on promoting health equity by reducing health inequalities in Africa presents an emerging research frontier. They frame the issues with concepts from the political economy of the health literature as having relevance to Africa, namely decommodification (strength of social entitlements and citizens' degree of immunization from market dependency), stratification (relative social position of persons within a social group, category, geographic region, or social unit), class mobility and the relative responsibility ascribed to the state, the marketplace, and the family in defining the quality and distribution of the social determinants of health.

Generally, the thought processes and analyses surrounding health equity compartmentalize market forces away from a central role. While an emphasis on the state as mediator and ultimate guarantor of health equity is practical, it is not complete. The market plays a special role that cannot be managed per se but must be considered. Mackintosh et al. (2016) also take a political economy framework when exploring the role of making medicines in Africa. The central argument of their book is that industrial development in pharmaceuticals and the capabilities it generates are necessary elements in African initiatives to tackle acute health care needs.

To put a finer point on their reasoning:

> A successful pharmaceutical industry is no guarantor of good health care: India indeed has managed to grow a highly successful industry while leaving many of its people without access to competent care. However, without the technological, industrial, intellectual, organizational and research-related capabilities associated with competent pharmaceutical production, the African subcontinent cannot generate the resources to tackle the needs and demands of its population. Mackintosh et al. (2016)

This paper has argued that a critical but overlooked dimension of achieving health equity in Africa is the development of a fully integrated health care value chain. In order to arrive at full integration, Providers must continue their drive towards accessibility, quality care and affordability. Their partner in this quest are the schools, regulators and policy makers, offshore providers, NGOs, and donors – the latter two until the Providers reach a stage of self-sustainability. The Payers which must achieve financial viability built on risk pooling that is based on sound actuarial analysis of health data, outcomes, and restored ability. The partner in their quest is governments that levy equitable taxation to fund the common risk pool and other managers of risk pools, such as employers or other social groups. Finally, the Producers which in Africa must move from the role of importation and distribution to comprehensive capabilities of research, development, manufacture, marketing, and medical affairs to monitor the clinical success of their goods. The partners in their quest are the global pharmaceutical, biotechnology, device, diagnostic and IT companies seeking a presence in Africa that goes beyond mere distribution and sales to an ambition of building full scale capability with Africans towards the goal of completing the health care ecosystem. How can this be achieved?

B. What then must we do?

As Mtui (2011) points out, investments in, and development of biopharma – technological research capacity in Africa would best be accomplished in phases.

The first phase is conventional biotechnologies such as health status and genomic profiling of the population to set the stage for population specific drug discovery and development. This critical first step can occur

through intense recruitment and training of African scientists, and later equipping them with the relationships, material, instrumentation, and networks to continue their work in collaboration with offshore universities and innovation-oriented companies. The prerequisite here is greater investment in education and professional training funded by governments and donors but supplemented by corporations with a long-range view. Africans can further advance their participation in the production of scientific and medical literature, thus informing the world of better approaches to disease.

The second phase is positioning the population for clinical trials under deliberate design and carefully administered regulations. This is a process that has begun on the continent but must be accelerated. The world generally seeks greater diversity in clinical trials for the purpose of equity, but there are inevitable population health benefits and scientific insights that will result. The foundation of clinical trials is a strong, integrated Provider sector. The components of a trial are dependent on a system that can diagnose, process, and provide after-care for patients. Trials contribute to strengths and expose weaknesses of Providers and health systems. As a consequence, the allocation of resources can be more targeted.

The third phase is the development of capacity for generic production of medicines and vaccines, with accompanying sophistication in supply chains, distributions, and pricing of goods. Building capacity beyond the existing generics base will secure more robust economics and sustainability for African health care as a whole. Increase in indigenous supply alone will not guarantee access to medicines, but it will increase to possibility and provide greater financial resources to the health care ecosystem as a whole. Generic capability and capacity are the precursors to the production of APIs on the one hand, and pharmaceutical innovation on the other. At the generics stage, IP is a manageable factor and will not serve as an obstruction to growth. As companies approach a point in their growth where innovation is a driver, the industry and countries will gradually accede to an IP regime – ideally a pan-African approach. At that point, the playing field is closer to being level.

To abet the third phase, African operators and offshore operators must seek alliances to accelerate and fund the needed capacity and capability. There are tested and viable models that address financing, knowledge transfer and production, such as the Gilead Access Program. The presumption of these relationships should not be one of charity but of collaboration and investment. This will set the stage for the fourth phase.

The fourth phase is the innovation of new pharmaceuticals and biologicals that address specific needs of the African population as well as exportation for offshore needs. At this juncture, African Producers are participating as peers and are full signatories to international standards and regulations. Here again, the incumbent industrial participants in the pharmaceutical innovation world should seek proactive relationships that advance the African enterprise but at the same time protect the interests of African companies and Africans who need access to medicines. To the greatest extent possible, staffing of laboratories and factories should be with local populations, and the economic benefits of the industry should be patriated to the hosting societies.

The fifth and final phase is full integration of the Producer function with the Provider function. There must be a full exchange of information and human and financial resources. Information systems should be seamless, and care supplemented with technology for delivery to remote parts of the continent.

Thus is the path towards health care and medicinal sovereignty. It may require a leap of faith, but at every phase, responsible business and investment decisions are possible with acceptable returns of resources and profound impact. Finally, Africa does not have to mimic the history of health systems development experienced by others. There will be opportunities where the lessons learned in the evolution of care and industry can be applied to allow Africa to leapfrog into more rapid development. All of this will require acceptance of risk but for a greater moral good. We all benefit.

VI. ACKNOWLEDGEMENT

The author acknowledges Dr. Samantha L. Vogt of the Johns Hopkins School of Medicine for her expert review and recommendations for this article. Her expertise and experience acquired from running a long-term oncology project in South Arica were most insightful and helpful.

CONFLICTS OF INTEREST

None to Declare

GRANTS OR CONTRACTS

None to Declare

VII. REFERENCES

1. African Union. (2012). Pharmaceutical Manufacturing Plan for Africa. AUC-UNIDO. https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa.

2. Anyakora, C., et al. (2017). Cost benefit investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer. *BMC Health Services Research*. **17**:1, 665. https://doi.org/10.1186/s12913-017-2610-8

3. Azevedo, M. J. (2019). *Historical Perspectives on the State of Health and Health Systems in Africa, Volume II*. Palgrave Macmillan. https://doi.org/10.1007/978-3-319-32564-4_1

4. Boms, O., Korte, M. & Fawzi, W. (2021). A case for more (and more ethical) COVID-19 vaccine trials in Africa. *Health Affairs Blog*. https://www.healthaffairs.org/do/10.1377/hblog20210112.870609/full/

5. Braverman, P. & Gruskin, S. (2003). Defining equity in health. *Journal of Epidemiology and Community Health*. **57**: 254 – 258.

6. Burns, L. R. (2002). *The Health Care Value Chain*. Jossey-Bass.

7. Christoffels, A. (2018). Africa needs another million PhD scientists to develop homegrown solutions. Quartz Africa. https://qz.com/africa/1290710/africa-needs-one-million-more-scientists/

8. Falchetta, G., Hammad, A. & Shayegh, S. (2020). Planning universal accessibility to public healthcare in sub-Saharan Africa. *PNAS*. **117**:50, 31760 – 31769.

9. Fitzmaurice, C., and Members of the Global Burden of Disease Cancer Collaboration (2017). Global, regional, and national cancer incidence, mortality, years of life lost, years live with disability, and disability- adjusted life-years for 32 cancer groups, 1990 to 2015: a systematic analysis for the global burden of disease study. *JAMA Oncol*. **3**:4, 524-548. https://doi.org/10.1001/jamaoncol.2016.5688

10. Fymat, A. (2019). Are neurological disorders the next concern in sub-Saharan Africa's future health landscape? *In* Kapalanga, J., Raphael, D., & Mutesa, L., eds. *Science and Biotechnology in Africa: Proceedings of a Conference on Scientific Advancement*. Cambridge Scholars Publishing. 140 – 156.

11. Gumba, H., et al. (2019). Implementation of good clinical laboratory practice in an immunology basic research laboratory: the KEMRI-Wellcome Trust Research Laboratories Experience. *American Journal of Clinical Pathology*. **151**: 270 – 274.

12. Ighobor, K. (2017). Diagnosing Africa's medical brain drain. *Africa Renewal*. 30:3, 8 – 9.

13. Institute for Health Metrics and Evaluation (IHME). 2021. http://www.healthdata.org/ This website is valuable for global data and visualizations.

14. International Finance Corporation. (2008). *The Business of Health in Africa: Partnering with the Private Sector to Improve People's Lives*. World Bank Group/McKinsey. https://www.unido.org/sites/default/files/2016-01/IFC_HealthinAfrica_Final_0.pdf

15. International Finance Corporation. (2011). Healthy Partnerships: How Governments can Engage the Private Sector to Improve Health in Africa. World Bank Group/McKinsey. https://openknowledge.worldbank.org/handle/10986/2304

16. Jimenez, J. (2015). Three ways to improve healthcare in Africa. World Economic Forum. https://www.weforum.org/agenda/2015/01/3-ways-to-improve-healthcare-in-africa/

17. Kawachi, I., Subramanian, S. & Almeida-Filho, N. (2002). A glossary for health inequalities. Journal of Epidemiology and Community Health. **56**:9, 647 – 652.

18. Knaul, F., Bhadelia, A., Atun, R. & Frenk, J. Achieving effective universal health coverage and diagonal approaches to care for chronic illnesses. *Health Affairs*. **34**:9, 1514– 1522. https://doi.org/10.1377/hlthaff.2015.0514

19. Mackintosh, M., Banda, G., et al., eds. (2016). *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*. Palgrave-Macmillan.

20. McCall, B. (2014). KEMRI-Wellcome Trust Programme celebrates 25 years. *Lancet*. **383**: 1796.

21. McKinsey & Company (2015). Africa: A Continent of Opportunity for pharma and patients. McKinsey & Company. https://www.mckinsey.com/~/media/McKinsey/Industries/Pharmaceuticals%20and%20Medical%20Products/Our%20Insights/Africa%20A%20continent%20of%20opportunity%20for%20pharma%20and%20patients/Africa_a_continent_of_opportunity_for_pharma_and_patients.pdf

22. McKinsey & Company. (2019). Should sub-Saharan Africa make its own drugs? McKinsey & Company. https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs

23. McKinsey & Company. (2020). Acting now to strengthen Africa's health systems: five big ideas to safeguard lives in the COVID-19 crisis – and prepare the future. https://www.mckinsey.com/featured-insights/middle-east-and-africa/acting-now-to-strengthen-africas-health-systems

24. Motari, M., Nikiema, J. B., et al. (2021). The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. *BMC Public Health*. 21; 490. https://doi.org/10.1186/s12889-021-10374-y

25. Musau, Z. (2017). Lifestyle diseases pose new burden for Africa. *Africa Renewal*. 30:3, 10 – 11.

26. Mtui, G. (2011). Status of biotechnology in Eastern and Central Africa. *Biotechnology and Molecular Biology Review*. **6**:9,183 – 198.

27. Mullan, F., et al. (2011). Medical schools in sub-Saharan Africa. *Lancet.* **377**: 1113 – 1121.

28. Naghavi, M. and Members of the Global Burden of Disease Cancer Collaboration (2015). Global burden of cancer 2013. *JAMA Oncology.* 1: 4, 505 – 527. https://doi.org/10.1001/jamaoncol.2015.0735

29. Ncube, B., Dube, A. & Ward, K. (2021). Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. *Journal of Pharmaceutical Policy and Practice.* **14**:29.

30. Ndwandwe, D., et al. (2020). Description of vaccine clinical trials in Africa: a narrative review. *Human Vaccines & Immunotherapeutics.* **16**:4, 972 – 980.

31. Nordling, L. (2018). African scientists call for more control of their continents genomic data. *Nature* News. https://www.nature.com/articles/d41586-018-04685-1

32. Ogbuoji, O., et al. (2019). Closing Africa's Health Financing gap. *Brookings Institution*. https://www.brookings.edu/blog/future-development/2019/03/01/closing-africas-health-financing-gap/

33. Okeke, I., Babalola, C., et al. (2017). Broadening participation in the sciences within and from Africa: purposes, challenges and prospects. CBE-Life Sciences Education. 16:es2, 1 – 9. https://www.lifescied.org/doi/10.1187/cbe.15-12-0265

34. Oleribe, O., et al. (2019). Identifying key challenges facing healthcare systems in Africa and potential solutions. *International Journal of General Medicine*. **12**:396 – 403.

35. Pheage, T. (2017). Dying from lack of medicines. *Africa Renewal*. 30:3, 24 – 25.

36. Raphael, D. & Komakech, M. (2019). Rwanda: Opportunities for research in health equity through a political economy of health framework. *In* Kapalanga, J., Raphael, D., & Mutesa, L., eds. *Science and Biotechnology in Africa: Proceedings of a Conference on Scientific Advancement.* Cambridge Scholars Publishing. 186–208.

37. Robertson J, et al. (2016). Essential medicines for cancer: WHO recommendations and national priorities *Bulletin of the World Health Organization*. **94**:735–742. doi: http://dx.doi.org/10.2471/BLT.15.163998Research735

38. Sama, Martyn & Nguyen, Vinh-Kim (eds.). (2008). G*overning Health Systems.* Dakar, Senegal: CODERSRIA.

39. WHO. (2018 a). *Atlas of African Health Statistics 2018: universal health coverage and the Sustainable Development Goals in the WHO African Region*. https://creativecommons.org/licenses/by-nc-sa/3.0/igo

40. WHO. (2018 b). *The state of health in the WHO African Region: an analysis of the status of health, health services and health systems in the context of the Sustainable Development Goals.* https://reliefweb.int/sites/reliefweb.int/files/resources/State%20of%20health%20in%20the%20African%20Region.pdf

41. World Bank Group. (2016). *A Decade of Development in Sub-Saharan African Science, technology, Engineering & Mathematics Research.* Elsevier. https://documents1.worldbank.org/curated/en/237371468204551128/pdf/910160WP0P126900disclose09026020140.pdf