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The Impact of the Pharmaceutical Ecosystem in Achieving Universal Health Coverage in Sub-Saharan Africa

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ABSTRACT

Background: The purpose of universal health coverage (UHC) is to provide equitable access to health services to people without financial hardship. Nevertheless, despite the diverse measures in place to accomplish this goal, there are still obstacles including access to affordable essential medicines. Specifically, low and middle-income regions like Sub-Saharan Africa and South Asian countries are the most affected due to regional disparities in achieving UHC. Citizens in financially vulnerable positions in these nations rely on their governments to provide essential medicines at little or no cost. However, government health systems are plagued with the unavailability of necessary medicines and services, forcing citizens to resort to more expensive private options and placing them at greater financial risk. The pharmaceutical ecosystem is responsible for the research, development, manufacturing, distribution, regulation, and safe use of these medicines. This study reviewed the impact of the pharmaceutical ecosystem in achieving universal health coverage in Sub-Saharan Africa.

Method: A narrative review of published peer-reviewed articles and grey literature was executed to examine how the pharmaceutical ecosystems have impacted universal access to the use of medicines thus achieving universal health coverage.

Conclusion: The pharmaceutical ecosystem sector is complex and crucial in achieving Universal Health Coverage as it directly affects the accessibility of safe, effective, and affordable essential medicines. Pharmacists are the major drivers of this ecosystem and should build their capacity in this area for positive results to be achieved in improving access to medicines and reducing the global disease burden. In Sub-Saharan Africa, due to the lack of government structures and enforcement, sectors of this ecosystem operate sub-optimally, and players and actors have taken advantage of its weaknesses and disorganization. Therefore, further research is imperative to identify ways to progress and improve the pharmaceutical ecosystem.

1. Introduction

Health is a fundamental human right that is indispensable as affirmed by the United Nations. It is an indicator of the social, economic, and environmental climate of a region [1]. The awareness of its importance has led to the development of various state policies and programs such as the adoption of Sustainable Development Goal 3 by the United Nations "*Ensure healthy lives and promote well-being for all ages*". A critical component of this goal is achieving Universal Health Coverage and it includes financial risk protection, equitable access to quality essential healthcare services, and safe, affordable essential medicines and vaccines for all [2].

Universal Health Coverage is simply the equitable distribution of quality health services to all without financial hardship. Despite the steps taken by various countries in achieving Universal Health Coverage, this goal seems elusive, especially for those living in poverty as

various gaps have been identified such as inequitable access to health services. About 400 million people cannot access essential health services, medicines, and vaccines [3]. There is an evident correlation between health coverage and the income of regions. With Low and middle-income (LMIC) regions, Sub-Saharan Africa, and Southern Asian countries suffer a lack of health coverage putting them at risk of financial ruin, having up to 67% of their total expenditure on pharmaceuticals of which 50 to 90% are out of pocket [4].

Essential medicines are an essential component of health care, WHO defines *essential medicines as medicines that satisfy the priority health care needs of the population*. They can save lives, reduce suffering, and improve health. They are selected based on disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness [5]. Ensuring its access is necessary for achieving UHC. Currently, about one-third of the world population lacks access to these medicines and there is also a growing need as there is an increasing burden of diseases. This puts a spotlight on the sector largely involved with these medicines- the pharmaceutical ecosystem.

The pharmaceutical ecosystem refers to the complex and diverse network of various stakeholders involved in developing, manufacturing, regulating, distributing, and consuming pharmaceutical products. It encompasses pharmaceutical companies, research organizations, regulatory authorities, healthcare providers, patients, and other relevant entities. A functional well-regulated pharmaceutical ecosystem is necessary for achieving UHC; they are an indispensable element for the delivery of services and are also a requirement for high-quality care.

The pharmaceutical ecosystem in Sub-Saharan Africa faces a lot of challenges, from the lack of local production of pharmaceuticals, low capacity for pharmaceutical research and development, inefficient logistics and supply chain, ineffective policies, inefficient regulation authorities, presence of counterfeit and adulterated drugs, high human poverty index to the unstable social, economic and political climate in most regions allowing for inaccessibility of drugs in locations needed and brain drain of healthcare workers.

With all these obstacles in mind, the impact of the pharmaceutical ecosystem must be reviewed as it is paramount in the production and access to essential medicines.

The objective of our study was to assemble available evidence on the impact of the pharmaceutical ecosystem in achieving Universal Health Coverage. This paper presents our findings and recommendations.

2. Method

The methodological approach utilized in this narrative review is similar to what was used in some previous studies [6]. We conducted a narrative review with the inclusion of published articles and grey literature written up to 2023 and in the English Language. The data reported in this study were obtained from articles about Universal Health Coverage, access to medicine, the pharmaceutical industry, and the pharmaceutical ecosystem. Our data sources included journal articles from different e-bibliographic databases, including Scispace, Springer, PubMed Central, PubMed, and Google Scholar. The search terms used include 'Access to Medicines', 'Medicine Access', 'Africa', 'Issues', 'Challenges', 'Efforts', 'Pharmaceutical Industry', Supply Chain', 'Research and Development', and 'Policy'.

The extracted data were discussed narratively, with themes identified, to explore the aim of the study.

3.1. The Pharmaceutical Industry's Role

The pharmaceutical industry generally encompasses the discovery, development, manufacture, and distribution of medicines.

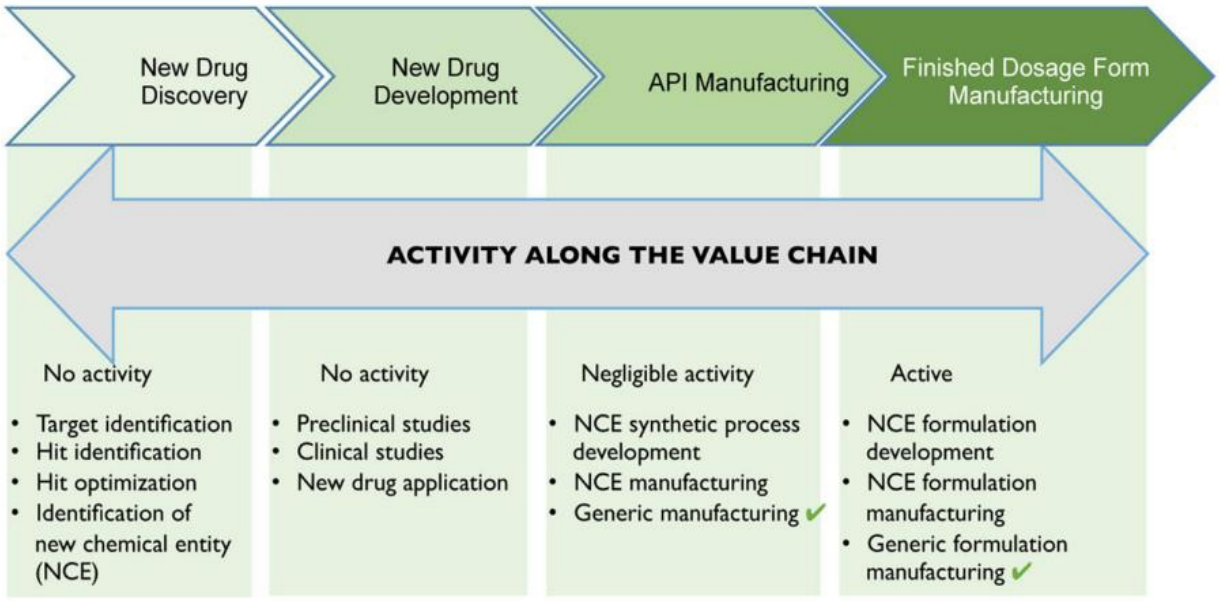

Figure 1: The activities within the pharmaceutical industry value chain. API active pharmaceutical ingredient, NCE new chemical entity. Culled from: *Pharmaceutical Sector Development in Africa: Progress to Date. Pharmaceutical Medicine, 32(1), 1–11* [7].

3.1.1 Research and Development

Research and development are the drivers to increasing the industry's growth by developing new medicines and improving existing medicines in advancing health. While it is recognized that the pharmaceutical industry in Africa is increasing rapidly i.e. $4.7 billion in 2003 to $20.8 billion in 2013 [8], there is little research and development capacity growth; with only 10% of global funding allocated for 90% of the burden of diseases affecting the continent and other LMIC countries [9]. There are various obstacles leading to poor research and development capacity growth which include: the inability to develop a sustainable research capacity even with a few investments and aid from developed countries [10], lack of research infrastructure and technological capability, lack of funding for research and development, power relations of developed countries on LMIC in relation to research capacity building [11] e.t.c. Despite these challenges, Some organizations and countries have risen to the task of addressing some of these gaps such as the African Development Bank that established the African Pharmaceutical Technology Foundation. The foundation's mandate is to facilitate Africa's access to the technologies needed for the manufacturing of medicines, vaccines, and other pharmaceutical products by acting as a transparent intermediator advancing and brokering the interests of the African pharmaceutical sector with global and other Southern pharmaceutical companies to share IP-protected technologies, know-how, and patented processes focusing primarily on diseases that are widely prevalent in Africa. It will also build human and professional skills, the research and development ecosystem, and support the upgrading of manufacturing plant capacities and regulatory quality to meet World Health Organization standards [12]. The inclusion of African health centers into clinical trials is necessary for the development of safe and effective medicines. Initiatives such as The African Consortium for Cancer Clinical Trials AC3T, the Association for Good Clinical Practice in Nigeria AGCPN, and The Prostate Cancer Transatlantic Consortium CaPTC are building clinical trial capacity in Africa, while also creating continent-wide clinical trial networks. AGCPN is building an environment in Nigeria that encourages rigorous clinical assessments of traditional medicines. CaPTC's Oncology Clinical Trials Appconnect OnCTAC is helping connect African patients with cancer and health care providers with open clinical trials via the use of a smartphone application [13]. National Institutes for Research such as the Nigerian Institute of Pharmaceutical Research and Drug Development (NIPRD) and National Institute of Medical Research (NIMR) are exploring indigenous pharmacopeia and extracting active principles from herbs that have been suspected to possess medicinal properties based on indigenous traditions [14]. Non-government organizations such as the Bill and Melinda

Gates Foundation are partnering with government agencies and organizations to fund initiatives to increase the research capacity of infectious diseases and innovative technologies [15].

While Research and Development ensures the creation of safe and effective novel therapies and the improvement of existing ones, manufacturing ensures the availability of these medicines.

3.1.2 The Local Production of Pharmaceutical Products

The Pharmaceutical Market in Africa is growing tremendously due to expansion in health insurance schemes and enhanced investments, an improved business climate, a maturing regulatory environment, and increased confidence in generic products [16].

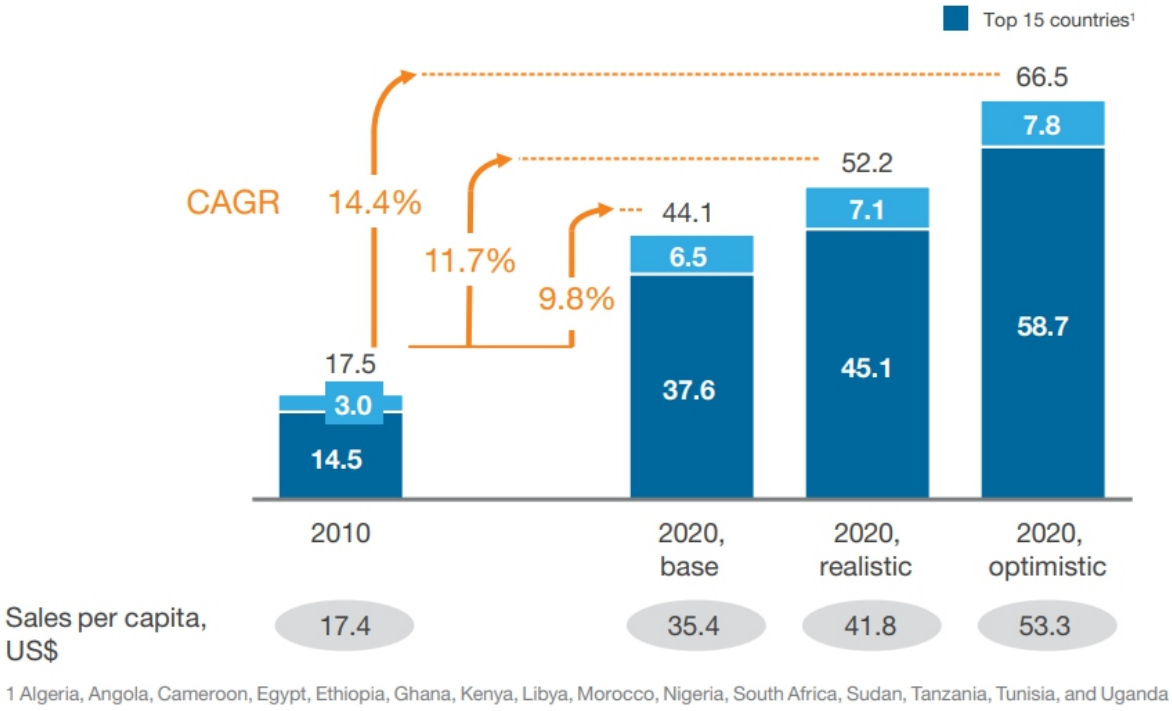

Figure 2: A clear correlation between a company's digital quotient and its financial performance. Source: WHO; World Bank; IMF; African Development Bank; BMI Research; McKinsey analysis [8]

Thus, the local production of generic medicines is increased from imported active pharmaceutical ingredients and excipients. Despite being the fastest growing sector in the Pharmaceutical Industry, pharmaceutical manufacturing in Africa is still faced with a lot of constraints which include a lack of Good Manufacturing Practices Compliance, lack of technology, limited access to markets, lack of partnerships, etc. Currently, Africa accounts for only 3% of global pharmaceutical manufacturing with about 70 – 80% of the medicines being used in Sub-Saharan Africa imported from other countries [17]

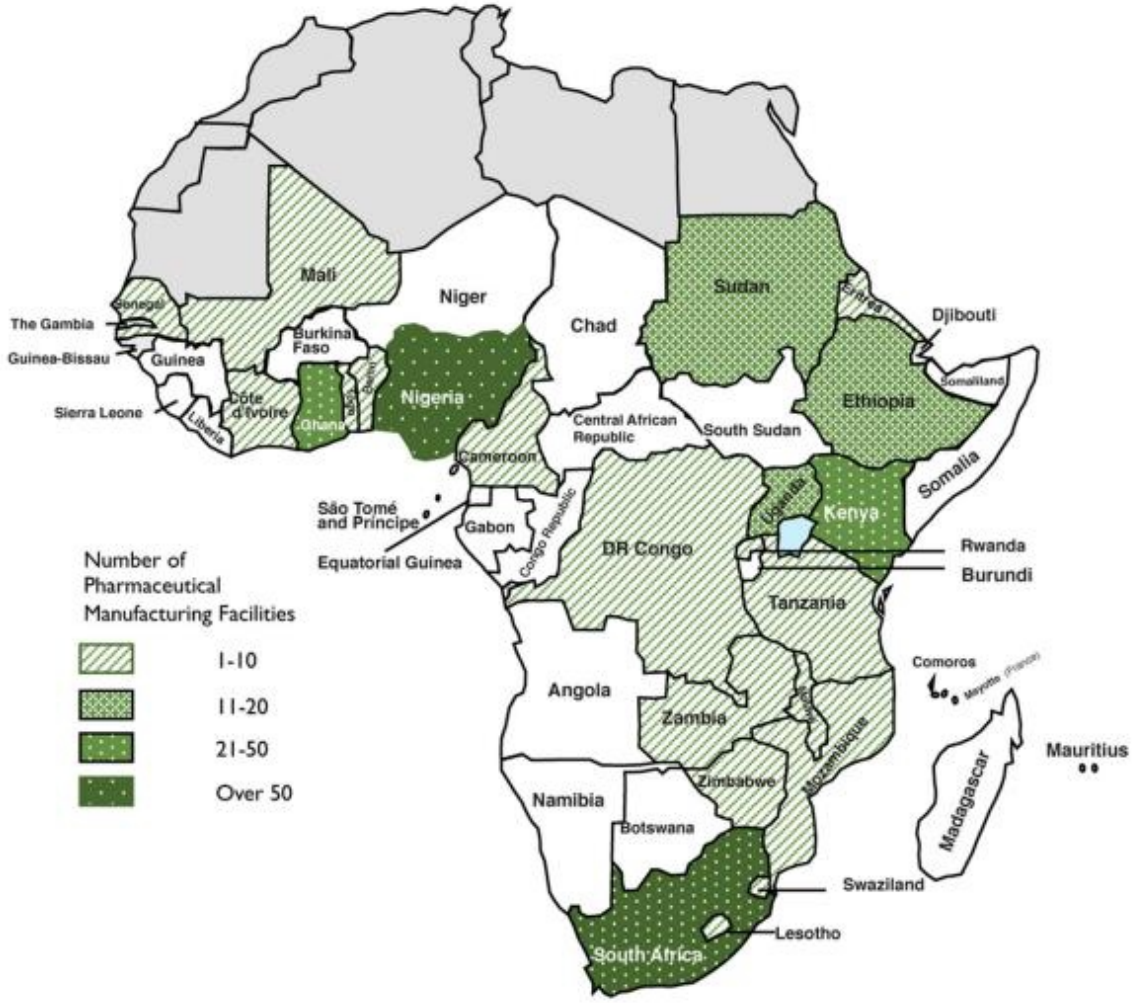

Figure 3: Distribution of pharmaceutical manufacturing capacity in Sub-Saharan Africa. Source: United Nations Industrial Development Organization 2011.

The significance of local production of pharmaceuticals cannot be overemphasized, as it increases the availability, affordability, and access to the medicines being produced and strengthens health systems [18]. The recognition of the potential growth in this sector has led to some advances such as; the formation of initiatives such as the development of regional and national pharmaceutical plans by the Pharmaceutical Manufacturing Plan for Africa (PMPA) to increase the manufacturing capacity and supply of essential medicines of the African states [19], the adoption of novel technologies by pharmaceutical companies to improve and increase manufacturing capacity making it more efficient, and cost-effective e.g the first construction of the mRNA vaccine manufacturing facility in Africa by Pfizer BioNtech which has the potential to produce not only malaria and covid 19 vaccines but also vaccines for other neglected tropical diseases [20]. The development of the technology transfer hub by Afrigen to build capacity by transferring technology and information to local producers in low- and middle-income countries to produce mRNA vaccines [21]. Provision of funds by organizations such as the International Finance Corporation IFC, and World Bank Group to research institutes to proffer strategies to boost Africa's Pharmaceutical production capacity [22]. The partnership of NGOs with local manufacturers such as the API for Africa (APIFA) with EMZOR® and India's Mangalam Drugs & Organics Limited via an API Manufacturing Technology Transfer and Licensing Agreement in the production of four APIs artemether, lumefantrine, sulfadoxine, and pyrimethamine locally in

the treatment and prevention of malaria [23].

3.1.3 Supply chain

One of the targets of SDG 3 is access to quality and affordable essential medicines and the logistics involved in the flow of materials and finished products from the manufacturer to the warehouse, distribution centers, pharmacies, and hospitals i.e. the pharmaceutical supply chain. The pharmaceutical supply chain is a critical component of the pharmaceutical ecosystem. It is the backbone of quality health care services as it plays a crucial role in the distribution of quality essential medicines to the end consumer and it assures consistent availability of high-quality medicines, vaccines, and health products at health service delivery points in the most cost-effective and timely manner[24]. While there is general knowledge of the importance of the pharmaceutical supply chain, access to quality affordable essential medicines continues to be a challenge in Sub-Saharan Africa. This is due to various factors such as lack of infrastructure such as cold storage, transportation for vaccines, lack of skilled personnel e.g Pharmacists play an essential role in several aspects of the pharmaceutical supply chain such as forecasting, procurement, and inventory but they face challenges such as insecurity, low remuneration, lack of support from the government ultimately leading to brain drain of these skilled workers to developed countries[25], lack of funds, poor policy and poor implementation of standard operating procedures, poor data management of medicines and vaccines e.t.c.[24,26]. Some steps have been taken by the government of these countries to salvage the situation such as the creation of a regulatory body e.g the National Agency for Food and Drug Administration and Control NAFDAC with the responsibility of creating registration guidelines for drugs and ensuring drug administration and control, introduction of Mega Drug Distribution Centers (MDDC) in a bid to stop open drug marketing and ensure the distribution of quality drugs and also the adoption of policies such as the New Drug Distribution Guideline in Nigeria restricting pharmacists as the only drug distributor and employing, NAFDAC and the Pharmacy Council of Nigeria PCN as the enforcers [27], healthcare tech startups such as DrugStoc®, Lifestores Healthcare®, mPharma®, Field Intelligence®, Remedial Health® are digitizing the pharmaceutical supply chain connecting manufacturers with pharmacies and hospitals while managing inventory all online addressing the challenge of stock-outs of essential commodities which causes limited access to healthcare [28,29]. The use of technologies such as Radio Frequency Identification Technology (RFID) for inventory management, packaging, and logistics gives real-time data and ensures authenticity and traceability [30].

3.2 Regulation bodies

Medicines regulation is an important but neglected component of the pharmaceutical ecosystem. It is needed to ensure that all pharmaceutical products being produced, imported, distributed, sold, and consumed are safe, effective, and consistently meet approved quality standards in achieving universal health coverage. Sound and effective regulatory systems are needed to ensure the quality, safety, and efficacy of medical products and for the promotion of trade and socioeconomic advancement [31]. Medical products are highly regulated due to the critical role they play in society and the complexities, and sometimes controversies, associated with assessing their safety, quality, efficacy, and effectiveness[31]. All countries, therefore, need to have effective and efficient National Medicines Regulatory Agencies (NMRAs). NMRAs are responsible for ensuring the quality, safety, and efficacy of medical products throughout their lifecycle, including clinical trials, marketing authorization, inspections, testing, and post-marketing surveillance. Globally, WHO estimates that at least 30% of NMRAs have limited capacity to perform core regulatory functions[32]. According to WHO, there are 54 NMRAs in Africa, but their capacity is variable with most of them incapable of performing the core functions expected of NMRAs [32]. The WHO report shows that only 7% of African countries have moderately developed capacity with more than 90% having minimal or no capacity [33]. This leaves little incentive for local manufacturers to attain GMP Compliance. The absence of functional NMRAs in any country (i) exposes the population to potentially unsafe medical products of variable quality and effectiveness; (ii) facilitates the proliferation of substandard, spurious, falsely labeled, falsified, and counterfeit (SSFFC) medical products; and (iii) prevents rational use of medical products, all of which are detrimental to public health and patient safety [34,35].

For evaluation and marketing authorization of imported drugs in LMIC such as countries in Sub-Saharan Africa, authorization is given to the drug manufacturer or importer either by an internationally recognized regulatory entity or upon inclusion in the WHO pre-qualification list, and the receiving country must verify the identity of the drug. To assess these generic products, the regulatory bodies of said countries must possess the requisite capacity. A major determinant shown to influence the quality of essential

medicines is the existing country's policy on pharmaceutical regulation. Policies such as the African Medicines Regulatory Harmonization (AMRH) initiative were established by the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) and funded by the Bill Melinda Gates Foundation and other bodies to strengthen the regulatory capacity of these countries and promote socio-economic development by contributing to standardization and simplification of medicines registration procedures to meet internationally accepted standards and providing regulatory training programs for African medicines regulators [31]. The WHO pre-qualification program ensures key health products are safe, effective, and meet internationally stringent standards by partnering with NMRAs to assess product dossiers, inspect manufacturing and testing sites, organize quality control tests of vaccines and medicines, validate the performance of diagnostics, and verify that the products are suitable for use in the destination countries. It also provides a competitive market to products on its list especially antiretrovirals and antimalarials making them safe and affordable. In 2006, the programme included medicines and commodities for reproductive health responding to the growing need for family planning and sexual health in these countries [36]. The WHO Global Bench marketing tool helps strengthen regulatory systems for medical products by setting norms and standards, providing technical assistance, and evaluating oversight for vaccines, medicines, blood products, and medical devices [37]. These steps might be sabotaged due to the ever-growing presence of fake and substandard (FS) drugs imported into these countries; southeastern Asia is the main source of FS medicines according to a study by the United Nations Office of Drugs and Crime Trafficking in 2009. More than 40% of anti-infectives used in West Africa were determined to be counterfeit and the value of fake antimalarial drugs trafficked in the region was estimated at US$438 million causing a major public health problem - Microbial resistance [38]. Efforts have been made to prevent the distribution of FS drugs. These include the introduction of the United Nations Impact program which supports criminal justice systems and strengthens international and regional cooperation against FS drugs smuggling and other organized crimes [39], the use of cutting-edge technologies by NMRAs e.g. NAFDAC use mobile authentication services, Truscan® to detect FS drugs, tech startups in Sub-Saharan Africa using Blockchain, Artificial Intelligence such as mPedigree®, Chekkit®, Rx Scanner®, etc. to detect FS drugs in circulation [40].

3.3. Health Systems Strengthening and Governance

A health system refers to the organized network of institutions, resources, and people that provide healthcare services to a population. It encompasses various components, including healthcare facilities, healthcare professionals, health policies and regulations, financing mechanisms (such as insurance), and information systems for managing patient data and healthcare processes. While health systems may vary in form, irrespective of the form of the health system, pharmaceuticals play a critical role in improving health outcomes, preventing diseases, and treating various medical conditions. It is important to understand the organization of each country's pharmaceutical sector to ensure consistent access to pharmaceuticals [41]. The Technical efficiency of the pharmaceutical subsystem within national health systems implies achieving the best pharmaceutical-related health outcomes at the lowest cost which is in line with the Universal Health Coverage goal. In LMIC countries, this is not the case, as they spend most of their total health costs on pharmaceuticals relative to their GDP using out-of-pocket (OOP) monies; the reverse is the case for high-income countries where health insurance and other financings might be in place 41. Major health financing mechanisms in these countries include a government budget using general tax revenue; direct out-of-pocket payments; a social insurance scheme such as the National Health Insurance Scheme (NHIS) in Nigeria; and donor funding. These financing schemes are performing at suboptimal levels. In Nigeria Abuja Declaration target of 15% allocation to the health sector from the national budget was not achieved, The reported expenditure on health in Nigeria is less than US$8 per capita, compared with US$34 recommended by the Commission of Microeconomics and Health [42]. Resources are not allocated equitably or used efficiently to minimize wastage. The quality of services is perceived to be substandard, and individuals and households are not protected from catastrophic health expenditures. There are needed changes that must occur to improve health financing and ensure that Nigeria is on the right trajectory to achieving UHC. Key stakeholders in health financing and decision-makers that drive policy formulation and implementation need to make these changes in collaboration with non-health sectors [43]. Another major challenge is the lack of effective leadership and governance-stewardship which has contributed to the failure of health systems [44]. This role is solely the government's responsibility. Reports have indicated that the leadership competencies to manage health systems

effectively are essentially lacking among those charged with the responsibility – i.e., ministries of health in LMICs [45]. Models such as the Systems for Improved Access to Pharmaceuticals and Services (SIAPs) framework focus on interventions that can be used to strengthen the pharmaceutical system emphasizing the weaknesses of the pharmaceutical governance of these countries and framing interventions around it e.g. policies and legislation, governance structures, transparent, ethical, and accountable systems, and human resource management systems [46]. Organizations like the WHO through the National Health Workforce, Leadership, and Stewardship Capacity initiative, support member states to strengthen their leadership capacity in the process of developing, implementing, monitoring, and evaluating human resources for health policies, plans, norms, and standards. The introduction of digital health programs to strengthen the capacities of health systems such as the Be Healthy®, Be Mobile (BHBM) initiative which was set up by the WHO and the International Telecommunication Union (ITU) in 2012 to partner with governments to scale up targeted client communication messaging services for non-communicable diseases and their risk factors [47], mDiabetes® of Senegal and mCervical® Cancer of Zambia [48]. Health systems strengthening is necessary to ensure steady progress toward universal health coverage and global health security [49]. To achieve these goals, it is necessary to establish competent leadership and governance structure and collaborations between the African governments and global health funding organizations.

3.4. Healthcare workers

Healthcare workers play a vital role in the pharmaceutical ecosystem in achieving universal healthcare coverage. Human Resources for Health (HRH) have been described as the cornerstone and drivers of health systems and must be adequate if the health millennium development goals are to be achieved [50]. The WHO has noted that overall, there is a strong positive correlation between health workforce density, service coverage, health systems performance, and health outcomes [51]. Access to quality medicines and competent healthcare professionals are fundamental aspects of any healthcare system. Pharmaceutical human resources ensure the uninterrupted supply of quality medicines, their management, and responsible use. Although higher than in other Sub-Saharan countries, the human resources for health in Nigeria, pharmacist-population, physician-population, and nurse-population ratios of 9.3 per 100,000, 37 per 100,000, and 91 per 100,000, respectively did not reach the WHO-recommended standard of healthcare workers to population ratio. In general, the distribution of the health workforce is skewed to the urban areas, the southern geopolitical zone, and tertiary care center [52]. Pharmacists play a chief role in the development, manufacture, regulation, distribution, and ensuring safe consumption of these medicines and thus can be dubbed as the major drivers of the pharmaceutical ecosystem. They play a crucial role in achieving UHC by expanding their practice roles and providing primary health care (PHC) services. They contribute to the successful implementation of UHC by offering underutilized services, such as health education, preventive care, and medication management e.g. community pharmacists are generally the first point of call for patients seeking medical advice [53, 54]. Pharmacists globally including in LMIC countries are transitioning from product-oriented to patient-centered roles relieving the workload on other healthcare facilities and improving accessibility to quality health services [54]. Pharmacists are also highly involved in the research and development of these medicines, including research institutes e.g. National Institute of Pharmaceutical Research and Development (NIPRD) and Schools of Pharmacy. In the manufacturing sector, they implement quality assurance protocols and ensure compliance with regulatory requirements during the production of these drugs. Pharmacists are also involved in the regulation to combat substandard and falsified drug manufacture and distribution, inventory management, and distribution of these drugs. However, pharmacists and other healthcare workers in Nigeria are facing various challenges such as low reimbursement structure, insecurity, lack of support from the government, increased workload due to brain drain and migration of their colleagues, lack of involvement in public health policies, lack of funding of pharmacy education; all these lead to low motivation to perform and carry out their duties accordingly and migration to developed countries for greener pastures. The progression of pharmacy education and practice in Nigeria is confronted with several challenging factors, including deficiencies in academic manpower, disparity within the pharmacy profession, inadequacy in the remuneration of professionals in public service, limited availability of faculties of pharmacy, insufficient numbers of pharmacy technicians to assist pharmacists in dispensing functions, the enforcement of areas of specialization for pharmacists in hospital and community practice and the persistent opposition of most physicians to patient-oriented

pharmaceutical services. These impediments have resulted in major setbacks for the practice of hospital and community pharmacies in the country, including poor staffing, inadequate infrastructure, inefficient coordination of activities, and the reluctance of hospital and community pharmacists to embrace new changes. A significant challenge in the pharmacy profession in Nigeria is the inadequacy of human resources. The distribution of pharmacists and registered pharmaceutical premises is scarce in comparison to Nigeria's vast population and land mass. According to available data from 2008, the number of registered pharmacists per 100,000 population varies from less than 1 to 40 in different states of the country with the WHO Recommended standard being 1 in 2000 [52,55,56]. Moreover, most pharmacists and pharmaceutical premises are concentrated in urban areas, while they are practically absent in rural areas and smaller hospitals/clinics. Addressing this challenge calls for the expansion of the pharmacists' labor force to effectively match the country's healthcare system and expected demand and provision of appropriate reimbursement structures and comprehensive service package guidelines.

4. Conclusion

The pharmaceutical ecosystem sector is complex and crucial in achieving Universal Health Coverage as it directly affects the accessibility of safe, effective, and affordable essential medicines and pharmacists are the major drivers of this ecosystem. For developing countries like Nigeria, pharmacists must enhance their capacity in this area to yield positive outcomes in terms of improving access to medicines and curbing the global disease burden. The inadequacy of structured policies, leadership, and government structure has created vulnerabilities and disorganization, which various players and actors have exploited, leading to a chaotic drug distribution system, professional complacency and conservatism, extrinsic system failure, and inadequate human resources. To address these issues, it is imperative to intensify drug regulatory activities, be proactive in responding to current global trends in pharmacy education, practice, and research, and develop structures to tackle problems of poor governance and administrative failures related to medicine supply management in Nigeria. Moreover, major collaborations between the government and global funding programs and health initiatives in the pharmaceutical sector are needed to ensure the effectiveness, efficiency, and compliance of standards in the system, with prioritization in addressing emerging health needs such as non-communicable diseases and antimicrobial resistance. The development of Policy instruments that contribute to the effectiveness of the concept of essential medicines, including National Essential Medicines Lists, formularies, standard treatment guidelines, and measures to ensure access to affordable quality-assured medicines, is also necessary. Therefore, it is imperative to conduct more research to identify ways forward to improve the impact of the pharmaceutical ecosystem in achieving universal health coverage.

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