**Research Article** 

## Unveiling the Absence of a Local Medical Device and Biomaterials Manufacturing Industry in Zimbabwe: A Literature Review

#### Mthabisi Talent George Moyo 1\*

<sup>1</sup>Department of Biomedical Engineering, Faculty of Engineering, Near East University, Nicosia, Cyprus

Received 2023 March 01; Accepted 2023 March 25.

#### Abstract

Medical devices and biomaterials play pivotal roles in the provision of healthcare and advancements in medicine. Zimbabwe, a low-income country in Southern Africa, faces resource constraints while combating both communicable and non-communicable diseases, which significantly contribute to the nation's disease burden. The lack of a medical device and biomaterials manufacturing industry in Zimbabwe is a critical issue with profound implications for the country's healthcare system and economic development. This literature review comprehensively examines the current state of medical device and biomaterials manufacturing in Zimbabwe, focusing on historical perspectives, health infrastructure, challenges, and the importance of establishing a local manufacturing industry. By analyzing barriers and constraints hindering industry growth and conducting international comparisons, successful strategies implemented by other countries are explored. Additionally, the review investigates ongoing research and development efforts, including collaborations between academic institutions and industries in the medical technology field. Furthermore, the impact of existing government policies and initiatives on the growth of the medical device and biomaterials manufacturing sector is evaluated. The review emphasizes the significance of a local manufacturing industry, as it enhances healthcare accessibility, reduces dependency on imports, and unlocks potential economic benefits. By identifying potential opportunities and providing recommendations for policymakers, investors, and stakeholders, this study advocates concerted efforts to address challenges and capitalize on growth opportunities in this critical sector. The call to action seeks to foster collaboration among relevant stakeholders to support the development of a thriving medical device and biomaterials manufacturingindustry in Zimbabwe, ultimately contributing to improved healthcare outcomes and overall national progress. Keywords: Medical Device; Manufacturing; Low-Income Countries

#### 1. Context

Medical devices and biomaterials are essential components of healthcare and medical advancements (1). However, Zimbabwe, a low-income and resource-limited country in Southern Africa, grapples with challenges in combating both communicable and non-communicable diseases, which impose a significant burden on the nation's health (2). The lack of a robust medical device and biomaterials manufacturing industry further compounds the situation, creating a heavy dependency on imports and hindering the country's ability to address its healthcare needs independently (3). As a result, there is a pressing need to explore solutions to establish a local manufacturing industry in Zimbabwe, which would not only enhance healthcare accessibility but also contribute to economic growth and self-sufficiency (4).

The country heavily relies on imports to meet its medical technology needs, which poses various implications

for the healthcare system and overall national development. Dependence on imports raises concerns about supply chain disruptions, increased costs, and potential delays in acquiring crucial medical equipment and materials (5). The limited local production of medical devices and biomaterials is primarily due to a lack of investment, technical expertise, and infrastructure, hindering the country's ability to address its healthcare needs independently (6). The absence of a robust domestic manufacturing industry exacerbates the challenges faced by the healthcare system, impacting patient care and health outcomes. Moreover, heavy reliance on imports strains the national economy, affecting the country's balance of payments and potentially missing out on economic opportunities. The existing regulatory framework and ongoing research and innovation efforts also play pivotal roles in shaping the current status of medical device and



<sup>\*</sup> Corresponding Author: Mthabisi Talent George Moyo: Department of Biomedical Engineering, Faculty of Engineering, Near East University, Nicosia, Cyprus. E-mail: mtgmoyo@gmail.com.

biomaterials manufacturing in Zimbabwe (7).

This literature review aims to explore the current state of medical technology in the country and the challenges hindering the establishment of a local manufacturing sector. The significance of this review lies in its potential to shed light on the importance of self-sufficiency in healthcare technology, the barriers preventing progress, and the opportunities that can be unlocked through the development of a domestic industry. By comprehending these factors, policymakers, investors, and stakeholders can collaboratively address the gaps and foster the growth of Zimbabwe's thriving medical device and biomaterials manufacturing sector. Ultimately, this endeavor seeks to improve the nation's healthcare capabilities and contribute to its economic development.

#### 2. Materials and Methods

This literature review explores the lack of a local medical device and biomaterials manufacturing industry in Zimbabwe. The search strategy employed data sources such as Google Scholar, Science Direct, Web of Sciences, Scopus, and PubMed, focusing on relevant studies published from 2016 onward. Through a systematic approach, the researcher collected, reviewed, and summarized emerging articles to obtain conclusive insights. This analysis aims to shed light on the challenges and potential policies that could stimulate the development of a thriving medical device industry in Zimbabwe.

The search strategy encompassed various reputable academic databases, including Google Scholar, Science Direct, Web of Sciences, Scopus, and PubMed. By utilizing these platforms, the researcher aimed to identify high-quality published studies related to medical device manufacturing in Zimbabwe.

The researcher employed a rigorous and independent approach in analyzing the collected articles. After the initial search, the focus was on the titles and abstracts of the identified studies to ascertain their relevance. Subsequently, relevant articles were thoroughly reviewed, and key findings were summarized to gain a comprehensive understanding of the subject matter. Through this systematic process, the researcher drew meaningful conclusions and insights from the pool of literature.

The literature review followed a three-step process to ensure the validity and relevance of the findings. The first step involved the collection of articles directly related to the absence of a medical device and biomaterials manufacturing industry in Zimbabwe. In the second step, the selected articles underwent a detailed review to extract essential information, insights, and potential solutions. Lastly, the researcher synthesized the information obtained to discuss and present a coherent understanding of the current state and prospects of the medical device industry in Zimbabwe.

#### 3. Results

The results of the literature survey offer a comprehensive historical overview of Zimbabwe's healthcare and medical technology development, shedding light on key milestones and advancements that have shaped the nation's healthcare landscape, thereby emphasizing the progress made in medical technology over time. The survey further delves into the existing health infrastructure, providing an evaluation of its strengths and weaknesses while addressing critical challenges faced by the healthcare system, including limited access to medical facilities, scarcity of medical professionals, and resource constraints.

A significant emphasis is placed on the importance of establishing a domestic medical device and biomaterials manufacturing industry in Zimbabwe. The findings highlight potential benefits, such as economic growth, job creation, and improved availability of healthcare products. Moreover, the literature review explores the advantages associated with local production, including cost reduction, enhanced quality control, and decreased reliance on imports. However, the study identifies key factors, including insufficient funding, infrastructure limitations, and regulatory challenges, which act as obstacles to industry growth. Additionally, the survey focuses on international comparisons in life sciences and healthcare, elucidating the challenges encountered by Zimbabwe's healthcare and life sciences sectors. The review also identifies potential opportunities for improvement through collaboration and knowledge sharing with other countries.

The importance of research and development in advancing Zimbabwe's healthcare system is underscored in the findings. The study emphasizes the need for increased investment in research to drive innovation and effectively address healthcare challenges. Furthermore, the impact of government policies and initiatives on the advancement of healthcare and medical technology in Zimbabwe is assessed, exploring how supportive policies can foster growth in the healthcare sector.

Finally, the results provide practical recommendations aimed at facilitating the development of a robust medical device and biomaterials manufacturing industry in Zimbabwe. The aforementioned recommendations encompass strategies to address the identified challenges and capitalize on opportunities to promote sustainable growth and advancement in the country's healthcare and medical technology domains.

#### 4. Discussion

4.1. Historical Overview of Healthcare and Medical Technology Development in Zimbabwe

A study by Nyazema highlights a historical overview of healthcare and medical technology development in Zimbabwe. The objective of this article was to explore the historical development of the challenges prevailing in Zimbabwe's health and education sectors after gaining independence. It was observed that both these areas, which initially showed positive progress following the independence in 1980, have suffered due to a lack of clear direction, unfavorable political conditions, and pervasive corruption. The article advocates a socialistic "investment for health strategy" instead of a purely economic "investment in health" approach, which primarily focuses on infrastructural development as previously recommended by the World Bank (8).

The historical context of healthcare and medical technology development in Zimbabwe provides essential insights into the challenges the country faces regarding the lack of a medical device and biomaterials manufacturing industry. Zimbabwe's colonial past left a legacy of unequal healthcare distribution, with limited resources primarily catering to the white minority population (9). After gaining independence in 1980, the newly formed government grappled with inherited disparities in healthcare infrastructure and services. Efforts were made to improve healthcare accessibility, including the establishment of rural health clinics and primary healthcare centers (10). However, Zimbabwe has faced numerous challenges in building a robust healthcare system (11).

Epidemics and health emergencies, such as cholera outbreaks and the human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) pandemic, put immense strain on the healthcare system and highlighted the need for improved medical infrastructure (12, 13). Economic hardships, including hyperinflation and external sanctions, hampered the country's ability to acquire modern medical technologies (14, 15). A significant brain drain of qualified medical professionals further strained the healthcare system, affecting the delivery of medical services (16).

Presently, Zimbabwe heavily relies on imports to meet its medical device and biomaterials requirements, contributing to healthcare challenges and economic implications (17). The limited local production of medical devices and biomaterials stems from a lack of investment, technical expertise, and infrastructure (18). This limitation hampers the country's ability to address healthcare needs independently and stimulate economic growth. Currently, medical device companies in Africa depend on European notified bodies, and this significantly increases their regulatory compliance costs (19, 20). Despite these challenges, Zimbabwe has recognized the importance of developing a domestic medical device and biomaterials manufacturing industry (21). The government and stakeholders are working toward creating an enabling environment to foster local production.

Past attempts or initiatives related to medical device and biomaterials manufacturing in Zimbabwe have been limited and faced various challenges. The lack of a wellestablished domestic industry has historically resulted in heavy reliance on imports to meet medical technology needs. Efforts to stimulate local production have been hindered by factors such as limited investment, technical expertise, and infrastructure. Despite facing challenges, some past initiatives might have aimed to promote medical device and biomaterials manufacturing in Zimbabwe (22). These initiatives might have included governmentled policies to encourage local production and attract investments in the medical technology sector.

### 4.2. Health Infrastructure and Challenges in Zimhahwe

An article by Truscott addressed health infrastructure and challenges in Zimbabwe. The author wrote that the health infrastructure in Zimbabwe is in a dire state, evident from the cholera epidemic that has resulted in thousands of deaths and infections. Once esteemed, public hospitals are now stripped of essential resources, with critical units closed due to a lack of supplies. Shortages of food, drugs, and medical equipment have forced the closure of the children's ward in a major hospital. Healthcare professionals have gone on strike frequently over low wages, leading to a significant exodus of doctors and nurses seeking better opportunities abroad. The country's healthcare system requires significant financial investment for reconstruction; nevertheless, local officials emphasize that more than money is needed to address the challenges and revive the crumbling health infrastructure (23).

The existing healthcare infrastructure in Zimbabwe has faced various challenges and limitations, particularly concerning medical device and biomaterials availability. The country's healthcare system has inherited disparities from its colonial past, leading to uneven healthcare resources and services distribution. Although efforts have been made to improve healthcare accessibility, especially in rural areas, the infrastructure remains insufficient to meet the growing demand for medical devices and biomaterials (24).

The healthcare infrastructure in Zimbabwe is facing significant challenges that have led to an inadequate and strained system. Limited access to healthcare, shortages of medical supplies and equipment, and a brain drain of skilled healthcare professionals are some of the critical issues contributing to the country's healthcare struggles. Economic challenges, lack of infrastructure development, and insufficient funding further compound the situation.

Additionally, a high burden of communicable and noncommunicable diseases puts immense pressure on the already strained healthcare system (25). Inconsistent healthcare policies and governance have also hindered progress. Addressing these issues requires substantial investments in infrastructure, healthcare personnel, research, and governance reforms to build a robust and effective healthcare system that meets the needs of the population and improves health outcomes in Zimbabwe (26). In Sub-Saharan Africa, including Zimbabwe, both communicable and non-communicable diseases pose significant challenges to public health. Communicable diseases, such as HIV/AIDS, malaria, and tuberculosis (TB), continue to afflict the population, alongside a growing burden of non-communicable diseases (NCDs), such as diabetes, hypertension, cardiovascular conditions, cancers, road traffic injuries, and mental health conditions (27). The coexistence of these disease burdens requires a multifaceted approach to healthcare and medical advancements.

The World Health Organization (WHO) projects that communicable diseases will only account for some 46.4% of all African deaths by 2030, compared to 70.7% in 2000 (28). On the other hand, deaths from NCDs are projected to rise considerably over the next few decades, with the number of mortalities related to cardiovascular diseases forecast to outnumber deaths from complications due to HIV/AIDS by 2030 (28).

The challenge that Sub-Saharan Africa has of dealing with multiple burdens of disease is characterized by high rates of communicable and non-communicable diseases (29). Communicable diseases, such as HIV/AIDS, malaria, and TB, alongside NCDs, such as diabetes, hypertension, cardiovascular conditions, cancers, road traffic injuries, and mental health conditions, continue to afflict the growing numbers of Zimbabweans (30, 31).

The WHO estimates that HIV/AIDS, TB, and malaria claim approximately 3 million lives in the Sub-Saharan Africa region each year (32). Parasitic diseases, such as hookworm (33) and schistosomiasis (34), are also prevalent, mostly among children, and cause hundreds of thousands of deaths and widespread suffering. Additionally, according to WHO's Noncommunicable Diseases Progress Monitor report, NCDs are increasingly becoming the main cause of mortality in Sub-Saharan Africa, where the diseases were responsible for 37% of deaths in 2019, rising from 24% in 2000, largely due to weaknesses in the implementation of critical control measures, including prevention, diagnosis, and treatment (35-37). The growing burden of communicable and noncommunicable diseases poses a grave threat to the health and lives of millions of individuals in Africa; over a third of deaths in the region are due to these illnesses (37).

To effectively address the healthcare challenges in Zimbabwe, it is crucial to invest in research and development, both in terms of medical technology and disease research. Moreover, strengthening the clinical research capacity and public health systems can leverage the effectiveness of healthcare interventions and improve disease management.

## 4.3. Significance of Establishing a Local Manufacturing Industry

A study by Dzingirai et al. assessed the health technology in Zimbabwe and established the baseline of health

and medical technology development in Zimbabwe. The study concluded that there is a need to institute a formal, systematic, and transparent process of determining the value of health technologies (38).

Having a domestic medical device and biomaterials manufacturing industry in Zimbabwe offers numerous significant advantages that can greatly benefit the country's healthcare system and overall socioeconomic development. Enhanced healthcare accessibility stands out as one of the key advantages, as local production reduces reliance on imports and makes essential medical technologies more readily available and affordable, particularly in rural and underserved areas. Additionally, the establishment of a local manufacturing industry brings supply chain stability, reducing dependence on international supply chains and ensuring a consistent and stable flow of medical devices and biomaterials, even during times of global market fluctuations and disruptions (39).

Furthermore, producing medical devices and biomaterials locally leads to cost savings in the long run by eliminating import costs, transportation expenses, and tariffs, enabling more efficient allocation of resources in the healthcare system. The customization of medical devices and biomaterials is another compelling advantage, as local manufacturers can tailor products to address specific healthcare needs in Zimbabwe, resulting in more effective and patient-centric healthcare solutions.

A domestic manufacturing industry also drives research and development efforts, leading to technological advancements in medical devices and biomaterials (40). This fosters innovation and keeps Zimbabwe at the forefront of medical technology, ultimately improving the quality of healthcare services provided to the population. Moreover, building a domestic medical device and biomaterials manufacturing industry generates employment opportunities and stimulates economic growth across various sectors, promoting entrepreneurship and attracting investments to create a vibrant and sustainable healthcare technology ecosystem (41).

Furthermore, establishing a domestic industry facilitates knowledge transfer and capacity building, promoting skill development and enhancing the capabilities of the local workforce (42). This collaboration between local manufacturers and international partners strengthens Zimbabwe's healthcare expertise. Additionally, a thriving domestic industry creates opportunities for exporting medical devices and biomaterials, contributing to foreign exchange earnings and enhancing Zimbabwe's reputation as a reliable and competitive healthcare technology hub (43).

A domestic medical device and biomaterials manufacturing industry in Zimbabwe can lead to a transformative shift in the healthcare landscape. With improved healthcare accessibility, cost savings, technological advancements, job creation, and national pride, the country can significantly enhance its healthcare capabilities

and position itself as a leader in healthcare technology within the region. By investing in local manufacturing capabilities and reinforcing regulatory oversight, Zimbabwe can strengthen its healthcare infrastructure and ensure better healthcare outcomes for its citizens.

## 4.4. Contrasting Local Production with Product Imports: Analyzing the Advantages

In a study conducted by Banda et al., the focus was on examining the comparison between locally produced medical manufacturing and imported products. The study shed light on the pressing need for restructuring the African pharmaceutical sector, transforming it into a responsive and innovative industry that not only enhances local health security but also aligns with the social, economic, political, and industrial goals outlined in the African Union's Agenda 2063 (19).

Comparing the benefits of local production of medical devices and biomaterials to importing these products in Zimbabwe reveals significant advantages for the country's healthcare system and economy. On the one hand, local production offers numerous benefits. First and foremost, it ensures a stable supply of medical devices and biomaterials, reducing dependency on international suppliers and mitigating supply chain disruptions (44). This enhanced accessibility to essential medical technologies proves especially beneficial for healthcare providers and patients in remote and underserved areas.

A report by the WHO, the United Nations Conference on Trade and Development (UNCTAD), the International Centre for Trade and Sustainable Development (ICTSD), and various stakeholders in the domains of public health was compiled to establish a comprehensive framework that could effectively guide policymakers and professionals from these relevant fields. The framework introduced herein offers a strategic approach to support local production of medicines, vaccines, and diagnostics, with the ultimate goal of enhancing access to these essential medical products and maximizing their potential to improve public health (45).

Moreover, manufacturing medical devices and biomaterials can locally lead to cost savings (46). By eliminating import costs, transportation expenses, and tariffs, resources can be allocated more efficiently within the healthcare system, ultimately benefiting patients and healthcare providers alike. Another advantage of local production lies in the ability to provide tailored solutions (47). Domestic manufacturers can customize medical devices and biomaterials to address specific healthcare needs in Zimbabwe. This level of personalization results in more effective patient care, improved treatment outcomes, and heightened patient satisfaction.

Furthermore, local production stimulates economic growth and job creation (48). By building a domestic medical device and biomaterials manufacturing industry, the country fosters entrepreneurship and attracts in-

vestments, contributing to a more robust and diversified healthcare technology ecosystem.

In addition to economic benefits, a domestic industry encourages research and development efforts, driving technological advancements and innovation in medical technology. Collaborations with academic institutions and international partners ensure that Zimbabwe remains at the forefront of medical innovation (40). In light of this issue, a mini-review by Glew encourages collaborations between life science scholars in the United States and Sub-Saharan Africa (49).

Simultaneously, importing medical devices and biomaterials offers its own set of advantages. Immediate access to advanced technologies stands out as a primary benefit. Importing allows Zimbabwe to have access to cuttingedge products that might not be locally available, enabling healthcare providers to offer state-of-the-art treatments and services to patients. Moreover, some medical devices and biomaterials require specialized expertise for operation and maintenance. Importing ensures access to trained professionals and technical support from international manufacturers, enhancing the overall functionality and reliability of the imported products (50).

Importing can also serve as a temporary solution during the development of a domestic manufacturing industry. Although local production capabilities are being established, importing provides a stopgap measure to meet immediate healthcare needs. Lastly, importing offers a diverse range of choices from the global market. Healthcare providers can select from a wide variety of products that align with their specific requirements and preferences (51).

Local production provides enhanced healthcare access, cost savings, tailored solutions, economic growth, and technological innovation. Importing, on the other hand, ensures immediate access to advanced technologies, specialized expertise, and a wide array of product choices. For Zimbabwe's healthcare sustainability and long-term economic development, fostering a robust domestic manufacturing industry remains crucial, complementing the benefits of importing and securing self-sufficiency in addressing specific healthcare needs. The strategic combination of local production and importing can lead to a thriving healthcare system and a stronger economy, benefiting the entire nation.

# 4.5. Obstacles and Limitations Impeding the Establishment and Advancement of a Medical Device and Biomaterials Manufacturing Industry in Zimbabwe

Several barriers hinder the establishment and growth of a medical device and biomaterials manufacturing sector in Zimbabwe. These challenges can be attributed to various factors that collectively impede progress and investment in the industry (52).

Firstly, limited investment and funding act as a significant barrier to developing a robust manufacturing sector. The lack of sufficient financial resources and limited investment opportunities make it difficult to establish manufacturing facilities and acquire advanced technologies in Sub-Saharan Africa for medical device and biomaterials production (53). Secondly, a shortage of technical expertise in the field of medical device and biomaterials manufacturing poses a critical challenge (54). Without a skilled workforce, Zimbabwe might struggle to develop and maintain sophisticated manufacturing processes, hindering the industry's growth. Moreover, inadequate infrastructure, including unreliable power supply, underdeveloped transportation networks, and limited access to industrial zones, further obstruct the establishment and efficiency of manufacturing facilities (55).

Additionally, concerns about intellectual property rights and their protection and enforcement might dissuade companies from sharing proprietary technology or investing in research and development in Zimbabwe (56, 57). The lack of access to reliable and cost-effective sources of raw materials required for medical device and biomaterials production adds to the challenges faced by local manufacturers (58).

Furthermore, Zimbabwe's relatively small market size and limited healthcare spending might deter potential investors who seek larger markets to justify their investments. The country might also face stiff competition from established medical device and biomaterials manufacturers in other countries, making it challenging to compete on a global scale (59). Economic and political instability within the country can deter investors from committing to long-term projects, including the establishment of manufacturing facilities. Moreover, the limited emphasis on research and development in the medical device and biomaterials sector hampers technological innovation and advancements needed for local manufacturing (60).

Unclear or restrictive regulations and policies related to healthcare technology and manufacturing create regulatory and policy constraints that can discourage potential investors and manufacturers from entering the market. The regulation of medical devices and pharmaceuticals across the world is very varied (61), ranging from comprehensive to none. The regulation of these devices has also evolved due to an increasing awareness of the need for a more consistent approach to regulatory documentation (62). The challenges include regulatory inefficiencies, policy incoherence across government ministries, the continent's well-documented infrastructure gap (63), and the lack of adequately skilled human capital in the country (64).

#### 4.5.1. Regulatory Inefficiencies

The regulatory oversight of the pharmaceutical and medical device manufacturing sector in different countries across Sub-Saharan Africa diverges greatly (65-68). Overall, however, the WHO estimates that the majority of regulatory agencies in Africa lack the basic functions in Sub-Saharan Africa to adequately protect public health (69).

Currently, the Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an act of parliament and is mandated to protect public health, ensuring that medicines and medical devices on the market are safe, effective, and of good quality (70). The MCAZ follows guidelines of the International Organization for Standardization (ISO) and WHO guidelines to ensure quality, safety, and efficiency (71). Pharmaceutical manufacturing in Zimbabwe is not a new phenomenon, and local pharmaceutical production is apparent with plants such as CAPS Pharmaceuticals (1952) and Datlabs (1954). However, it does not support the local manufacturing of medical devices (63).

The MCAZ uses a legal framework for the regulation of medical devices but in a more limited capacity. This legislation is restricted to the mention of medical devices and definitions of medical devices in legislative acts establishing national medicines regulatory authorities (72). It does not assign specific responsibilities or guidelines for regulation (72). Although regulations for imports and exports of medical equipment have been drafted by the MCAZ, they have not yet been implemented for the manufacturing of any products other than surgical gloves and male condoms.

A study concluded that Zimbabwe had a legal framework for regulating medical devices, conformity assessment, import and export, and post-market surveillance for condoms and gloves only (72). Due to the infectious disease burden, mainly HIV/AIDS, malaria, and TB, and clinician protection imperatives, the primary focus of the MCAZ medical device regulation since 1998 has been imported male condoms and latex gloves (73).

Similar to numerous other African countries, the regulation of medical devices is still rudimentary in Zimbabwe, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices (74).

#### 4.5.2. Policy Incoherence Across Government Ministries

Policy coherence and mutual reinforcement between policies are critical. This encompasses the deliberate crafting and deployment of policies and operational mechanisms that are not in conflict with each other (75). When different ministries have conflicting or divergent policies and priorities, it can create inefficiencies and hinder the development of a harmonized regulatory framework.

Incoherent policies can result in inconsistent standards, requirements, and procedures for medical device regulation. This inconsistency can lead to confusion and compliance challenges for manufacturers, importers, and healthcare providers. Disagreements or lack of alignment between ministries can cause delays in the development and implementation of regulations (76).

A comprehensive assessment by Rugera et al. was carried out to evaluate the regulatory framework governing medical diagnostics and medical devices within the Partner States of the East African Community (EAC). The data were gathered through a combination of desk-based document review and field research, which involved conducting face-to-face interviews using a structured questionnaire comprising both closed and open-ended questions. Medical device and in vitro diagnostics regulation has been overlooked in the EAC Partner States, leading to a notable weakness in regulatory frameworks across the region and significant policy incoherence (77).

Policy incoherence across government ministries has hindered, rather than promoted, the development of the life sciences industries and the further development of the pharmaceutical industries and the barely existent medical device manufacturing industry (28). A report by the WHO recommends an update on policies to achieve coherence across agencies (68).

#### 4.5.3. Continent's Well documented Infrastructure Gap

The continent's well-documented infrastructure gap hampers the development of the pharmaceutical industry (78). It is widely acknowledged that Africa faces infrastructure challenges in the life sciences sector. These infrastructure gaps can have significant implications for healthcare, medical research, and the development of the life sciences industry in the region. Numerous African countries lack adequate healthcare infrastructure, including hospitals, clinics, laboratories, and medical facilities (79). Insufficient infrastructure can limit access to healthcare services, diagnostics, and treatments, impacting the overall quality of healthcare delivery (80). Africa often faces a shortage of state-of-the-art laboratories, specialized equipment, and research institutions, limiting the capacity for high-quality research in some areas, such as pharmaceuticals, biotechnology, and medical devices (81). The lack of advanced manufacturing facilities for life sciences products, including pharmaceuticals and medical devices, hinders local production capabilities (82). A study by Yusuf et al. highlights the steps that need to be taken in establishing the Sub-Saharan Africa infrastructure and knowledge for teaching and research (83).

## 4.5.4. Lack of Adequately Skilled Human Capital in the Country

The general and poorly specified level of life sciencefocused education and skills continues to weigh down the countries' human capital (84). The lack of adequately skilled labor within the sector has hampered the development of certain sectors, such as sophisticated manufacturing and overall research and development (85, 86). An additional key element pertains to the development of human capital, considering the knowledge-intensiveness of the sector (87). Consequently, policy coherence across all these different industries and agencies is paramount to the development of a successful pharmaceutical. Zimbabwe has also faced economic instability and limited job opportunities in various sectors. High levels of unemployment and limited career prospects can lead skilled professionals to seek better opportunities abroad, where they can potentially earn higher salaries and have access to more resources. The availability of advanced training, professional development programs, and research opportunities might be limited in Zimbabwe. Skilled professionals, especially those in specialized fields, might seek opportunities in countries with more resources and better access to educational and career advancement options. According to the United Nations Educational, Scientific and Cultural Organization (UNESCO), more than 10% of individuals with graduate degrees in Sub-Saharan Africa choose to emigrate, and this percentage is even higher in the health workforce, particularly among skilled researchers (88). Various factors contribute to this trend, including limited local funding and training opportunities in comparison to high-income countries outside the region, which often provide more favorable research environments and working conditions. These issues are prevalent in regions that face challenges associated with a drain in research capacities (89).

## 5.Examination of International Comparisons in Life Sciences and Healthcare: Challenges and Opportunities

Life sciences encompass the study of living organisms, their life processes, and their interactions with the environment (90, 91). This diverse field includes disciplines such as medical biology, pharmacy, biotechnology, and biomedical engineering. Biomedical engineering combines technology and medicine to create innovative devices and equipment that enhance human health, with applications ranging from imaging equipment and micro-implants to prostheses and tissue regeneration (92). Medical devices play a crucial role in disease prevention, diagnosis, and treatment (93). In this context, biomaterials are integrated, and researchers focus on developing new biomaterials and manufacturing techniques to improve medical devices and pharmaceutical products (94, 95). Biomaterials serve various purposes in the medical sector, interacting with biological systems to provide support, promote healing, and enhance medical treatments (1). Biomaterials play a pivotal role in the medical sector, where their production occurs on an industrial and global scale to meet the increasing demand for innovative medical devices and treatments (96).

Statistically, the United States is currently both the largest producer and consumer of medical devices, with approximately 50% of the world market. It is followed by Japan, the European Union (EU), Canada, and Australia,

which boast of large and stable markets with medical devices (97). In most African countries, more than 90% of the medical devices in public hospitals are imported, with very limited local production (98). Less than 2% of drugs consumed in Africa are produced on the continent, meaning that many sick patients do not have access to locally produced drugs and might not be able to afford to buy the imported ones (98). At the heart of the poor state of health in Africa lies a failure to tackle extreme poverty. Today, about 40% of the population in Zimbabwe live on less than \$2.15 (£1.67; €1.93) a day, a greater proportion than 15 years ago (99). Numerous low- and middle-income countries are currently confronting a convergence of epidemics characterized by the simultaneous prevalence of chronic infectious and NCDs (100, 101). Therefore, without access to medicines, Zimbabweans are susceptible to these diseases (102, 103).

The African pharmaceutical industry is largely undeveloped, both from a manufacturing and innovation point of view. The supply of African pharmaceuticals remains highly dependent on foreign funding and imports, and around 70% of pharmaceutical products consumed in Africa are imported. Almost 80% of Sub-Saharan Africa's pharmaceutical imports during 2010 - 2013 were classified as medication (including antibiotics and vitamins) packed for retail use.

South Africa boasts the most sophisticated and productive research environment in Sub-Saharan Africa (103). The second-largest economy in Africa leads the continent in terms of the quality of scientific research institutions, although the country also produces highly-regarded research papers in numerous life science fields. However, South Africa still lags substantially behind the world leader, the United States. Kenya, East Africa's most sophisticated economy, records a strong performance in research publications in all the life science fields under analysis while also being considered to have the second highest quality scientific research institutions on the continent. Moving west, the Ivory Coast and Senegal boast Sub-Saharan Africa's third and fourth most highly regarded scientific research institutions, respectively, while also achieving an admirable performance in research publications (103). It is important to note that North Africa, particularly Egypt, Algeria, and Morocco, has a considerably more developed life sciences industry than its southern compatriots, except for South Africa (103).

Comparing the benefits of the local production of medical devices and biomaterials to importing these products in Zimbabwe reveals significant advantages for the country's healthcare system and economy. The local production of medical devices and biomaterials in Zimbabwe offers numerous advantages, ensuring a stable supply, reducing dependency on international suppliers, and enhancing access to crucial medical technologies, particularly in underserved regions (102). Cost savings from manufacturing locally can be reinvested in healthcare infrastructure, leading to improved patient care (103).

The customization of medical devices to address specific healthcare needs leads to better treatment outcomes and patient satisfaction (104).

## **6.** Advancing Research and Development in Life Sciences

Zimbabwe's healthcare sector, including medical device and biomaterials research, has faced challenges. Despite these obstacles, there might have been some ongoing research and development initiatives related to medical technology in the country. Research efforts in biomedical engineering could focus on designing and developing medical devices that cater to specific healthcare needs in Zimbabwe, particularly low-cost and appropriate technologies suitable for the local context. Studies related to biomaterials and tissue engineering might aim to develop biocompatible materials and tissue substitutes for medical applications, such as implants, wound healing, and regenerative medicine (105).

Research could be ongoing in developing point-of-care diagnostic devices that provide rapid and cost-effective diagnosis for infectious diseases and other medical conditions. The Medical Laboratory and Clinical Scientists Council of Zimbabwe (MLCScCZ) received authorization from the health minister to oversee the registration process for in vitro diagnostic devices during public national tendering procedures to streamline procurement. In response to the challenges posed by non-regulated HIV test kits in the context of the HIV pandemic, the minister of health directed the MLCScCZ to coordinate the evaluation of HIV test kits for national tendering and selection for the HIV testing algorithm (22). There might be research initiatives focused on health informatics, aiming to leverage technology to improve healthcare data management, patient records, and telemedicine services (22).

It is essential to note that collaborations between academia and industries are vital for driving research, innovation, and the growth of the healthcare technology sector. Such collaborations can lead to knowledge exchange, technology transfer, and the development of solutions that address real-world healthcare challenges.

Academic institutions in Zimbabwe might collaborate with local or international medical device companies on research projects related to medical technology. These projects could focus on developing new medical devices and biomaterials or improving existing technologies. Collaborative efforts might involve internship programs that allow students or researchers to gain practical experience and exposure to industry practices within medical device companies. This fosters a better understanding of industry needs and encourages innovation.

#### 7. Government Policies and Initiatives: Impact on Healthcare and Medical Technology Advancements

The government has implemented various policies and initiatives aimed at enhancing healthcare access, technology adoption, and overall health outcomes. Here is an analysis of some key government policies and initiatives related to the healthcare sector and medical technology in Zimbabwe:

#### 7.1. National Health Strategy

The government developed the National Health Strategy, which outlines the country's health priorities and strategic direction. The strategy aims to improve health service delivery, increase healthcare access, and enhance the quality of healthcare services across the country. The existence of an essential medicines and medical supplies list might have helped ensure the availability of Sub-Saharan Africa's medical devices and biomaterials, benefiting the healthcare sector and patients (106).

## 7.2. List of Essential Medicines and Medical Supplies

Zimbabwe maintains a list of essential medicines and medical supplies, ensuring that critical healthcare products are available and accessible to the population. This initiative is essential in addressing healthcare gaps and ensuring the availability of Sub-Saharan Africa medical technology (107).

#### 7.3. Health Financing Reforms

The government has been exploring health financing reforms to improve healthcare funding and sustainability. These reforms aim to increase public spending on healthcare, explore innovative financing mechanisms, and strengthen health insurance coverage (9).

#### 7.4. e-Health Initiatives

Zimbabwe has taken steps toward implementing ehealth initiatives to leverage technology for healthcare service delivery. This includes the use of electronic health records (EHRs) to improve patient data management, telemedicine services, and digital health platforms to enhance healthcare accessibility (26).

#### 7.5. Medical Equipment Procurement

The government has been engaged in efforts to procure medical equipment and technology to address gaps in the healthcare system. This includes the acquisition of essential medical devices and biomaterials to improve patient care and diagnostic capabilities (108).

#### 7.6. Skills Development and Training

The government has placed emphasis on skills development and training programs for healthcare professionals, including medical technologists, to enhance their capacity to utilize and maintain medical technology effectively. Emphasizing skills development and training for healthcare professionals might have contributed to enhancing their capacity to utilize and maintain medical technology effectively (109).

#### 7.7. Public-Private Partnerships

Zimbabwe has explored public-private partnerships to improve the healthcare infrastructure and enhance access to medical technology. Collaborations between the government and private sector entities can lead to more efficient resource allocation and technology adoption (110).

#### 7.8. National Pharmaceutical Company

The establishment of the National Pharmaceutical Company (NatPharm) aims to ensure the availability of essential medicines and medical supplies, including medical devices and biomaterials, to healthcare facilities across the country. The establishment of the NatPharm might have played a role in ensuring the availability of essential medical devices and biomaterials to healthcare facilities across the country (111).

It is important to acknowledge that Zimbabwe's healthcare policies and initiatives might encounter challenges due to broader economic and political constraints. The country has been facing hyperinflation, foreign currency shortages, and financial limitations, which could impede the successful implementation of healthcare-related policies.

Despite the government's efforts to improve healthcare access and technology adoption through various policies, the medical device and biomaterials manufacturing industry has faced several obstacles. The economic challenges, including hyperinflation and limited financial resources, might have hindered investments and the growth of the industry. Additionally, the healthcare technology sector's limited infrastructure and technical expertise might have affected the country's ability to establish a strong domestic manufacturing industry.

Policy implementation and regulatory enforcement challenges could also have an impact on the growth of the medical device and biomaterials manufacturing sector. Moreover, the relatively small market size and limited healthcare spending in Zimbabwe might have deterred potential investors from establishing significant manufacturing operations in the country.

Addressing these challenges and fostering a supportive environment for the healthcare technology sector are essential to drive sustainable growth in the medical device and biomaterials manufacturing industry. By overcoming these obstacles, Zimbabwe can create opportunities for economic development, improved healthcare access, and technological advancements in the healthcare sector.

Overall, although the government's healthcare policies and initiatives might have had some positive impacts on the medical device and biomaterials sector in Zimbabwe, significant challenges in the economic, infrastructural, and policy realms might have limited their full potential. To foster substantial growth in the domestic manufacturing industry, addressing these challenges, attracting investments, and fostering a supportive ecosystem for healthcare technology development is crucial. It is important to consider that the situation might have evolved since the last update, and for the most current evaluation, referring to recent reports and analyses from relevant sources is recommended.

## 8. Potential Opportunities and Recommendations

Zimbabwe, despite facing challenges, presents several potential opportunities for the growth and development of the medical device and biomaterials manufacturing sector. By capitalizing on these opportunities, the country can enhance its healthcare technology landscape and foster economic growth. Some potential opportunities are as follows:

#### 8.1. Favorable Regulatory Environment

Creating a supportive and clear regulatory framework specific to medical device and biomaterials manufacturing can attract investments and provide a conducive environment for growth. Streamlining approval processes and ensuring compliance with international standards can boost industry confidence (112).

#### 8.2. Research and Development Incentives

Offering incentives for research and development in the healthcare technology sector can drive innovation and indigenous product development. Tax breaks, grants, and other incentives can encourage local companies and researchers to invest in developing new medical technologies (113).

#### 8.3. Public-Private Partnerships

Collaborations between the government and private sector entities can leverage each other's strengths to drive industry growth. Public-private partnerships can facilitate technology transfer, infrastructure development, and resource sharing (114).

#### 8.4. Access to Raw Materials

Exploring local sources of raw materials required for medical device and biomaterials manufacturing can reduce costs and increase the competitiveness of local products (115).

#### 8.5. Export Opportunities

Establishing a domestic manufacturing industry can open opportunities for exporting medical devices and

biomaterials to regional and international markets. Focusing on quality and cost-effective manufacturing can make Zimbabwe a competitive player in the global market (116).

#### 8.6. Technology Transfer and Knowledge Exchange

Partnering with international manufacturers and institutions can facilitate technology transfer and knowledge exchange, enabling Zimbabwe to leverage external expertise and stay abreast of global advancements (117).

#### 8.7. Infrastructure Development

Investing in healthcare infrastructure, including manufacturing facilities and research laboratories, can enhance the country's manufacturing capabilities and attract further investments (118).

#### 8.8. Skilled Workforce

Strengthening technical education and training programs for healthcare technology can ensure the availability of a skilled workforce capable of operating and maintaining modern medical devices (11).

By capitalizing on these opportunities and addressing existing challenges, Zimbabwe can pave the way for sustainable growth and development of its medical device and biomaterials manufacturing sector. A robust domestic industry can lead to improved healthcare access, reduced import dependency, job creation, and economic development, ultimately benefiting the country's healthcare system and population.

#### 9. Conclusions

In conclusion, this literature review highlights the critical issue of the lack of a medical device and biomaterials manufacturing industry in Zimbabwe. The findings underscore the challenges faced by the healthcare system in having access to medical technologies due to heavy reliance on imports, limited local production, and infrastructural constraints. Establishing a domestic industry is crucial as it enhances healthcare accessibility, reduces dependency on imports, creates job opportunities, fosters economic growth, and enables export potential. Urgent action is called for from policymakers, investors, academia, and healthcare professionals to collaborate and address challenges. Policymakers should develop supportive policies, investors must recognize the industry's potential, and collaboration between academia and industries should be fostered. By doing so, Zimbabwe can overcome barriers and transform its healthcare technology landscape, contributing to better health outcomes and overall socioeconomic development.

Authors' Contribution:

The author solely contributed to the preparation of the final paper.

Conflict of Interests:

The author declares no conflict of interest. Funding/Support:

No funding/support was received for this study.

#### References

- Festas AJ, Ramos A, Davim JP. Medical devices biomaterials A review. Proc Inst Mech Eng L J Mater Des Appl. 2019;234(1):218-28. https://doi.org/10.1177/1464420719882458.
- Allen L, Williams J, Townsend N, Mikkelsen B, Roberts N, Foster C, et al. Socioeconomic status and non-communicable disease behavioural risk factors in low-income and lower-middle-income countries: a systematic review. *Lancet Glob Health*. 2017;5(3):e277-89. [PubMed ID:28193397]. [PubMed Central ID:5673683]. https:// doi.org/10.1016/S2214-109X(17)30058-X.
- Gwatidzo SD, Murambinda PK, Makoni Z. Medicines Counterfeiting in Africa: A View from Zimbabwe. Med Access Point Care. 2017;1:maapoc.0000017. https://doi.org/10.5301/ maapoc.0000017
- Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines Regulation in Africa: Current State and Opportunities. *Pharmaceut Med.* 2017;31(6):383-97. [PubMed ID:29200865]. [PubMed Central ID:5691122]. https://doi.org/10.1007/s40290-017-0210-x
- Ngoma G, Berke B. What determines import demand in Zimbabwe? Evidence from a gravity model. Cogent Econ Finance. 2020;8(1):1782129. https://doi.org/10.1080/23322039.2020.1782129.
- Simate GS, Ndlovu S, Iyuke SE, Walubita LF. Biotechnology and Nanotechnology: A Means for Sustainable Development in Africa. In: Gurib-Fakim A, Eloff J, editors. Chemistry for Sustainable Development in Africa. Berlin/Heidelberg: Springer: 2013. p. 159-91.
- Nyoni T. Exports and imports in Zimbabwe: recent insights from artificial neural networks. 2019. Available from: https://mpra. ub.uni-muenchen.de/96906/1/MPRA\_paper\_96906.pdf.
- Nyazema NZ. The Zimbabwe Crisis and the Provision of Social Services. J Dev Soc. 2010;26(2):233-61. https://doi. org/10.1177/0169796x1002600204.
- Mhazo AT, Maponga CC. The political economy of health financing reforms in Zimbabwe: a scoping review. *Int J Equity Health*. 2022;21(1):42. [PubMed ID:35346208]. [PubMed Central ID:8962130]. https://doi.org/10.1186/s12939-022-01646-z.
- Mashizha TM, Mapuva J. The colonial legislation, current state of rural areas in Zimbabwe and remedial measures taken to promote rural development. J Asian Afr Soc Sci Humanit. 2018;4(3):22-35.
- Kidia KK. The future of health in Zimbabwe. Glob Health Action. 2018;11(1):1496888. [PubMed ID:30058477]. [PubMed Central ID:6070968]. https://doi.org/10.1080/16549716.2018.1496888.
- Chigudu S. The political life of an epidemic: cholera, crisis and citizenship in Zimbabwe. Cambridge: Cambridge University Press; 2020.
- Chevo T, Bhatasara S. HIV and AIDS Programmes in Zimbabwe: Implications for the Health System. ISRN Immunol. 2012;2012:609128. https://doi.org/10.5402/2012/609128.
- Kanyenze G, Kondo T, Chitambara P, Martens J. Beyond the enclave: Towards a pro-poor and inclusive development strategy for Zimbabwe. Harare: Weaver Press; 2011.
- Chikukwa W. Democratising Africa, American sanctions on Zimbabwe [master's thesis]. Nairobi: University of Nairobi; 2017.
- Dzinamarira T, Musuka G. Brain drain: An ever-present; significant challenge to the Zimbabwean public health sector. *Public Health Pract (Oxf)*. 2021;2:100086. [PubMed ID:34494007]. [PubMed Central ID:8411806]. https://doi.org/10.1016/j.puhip.2021.100086.
- Tivatyi KS, Shou JM, N'Souvi K. Study on Import and Export-Led Economic Growth: Cases of Botswana, Namibia, South Africa, and Zimbabwe in Southern Africa. Open J Bus Manag. 2022;10(2):670-700. https://doi.org/10.4236/ojbm.2022.102038.
- World Health Organization. Medical devices and eHealth solutions: Compendium of innovative health technologies for lowresource settings 2011-2012. 2013. Available from: https://www. who.int/publications/i/item/9789241505918.
- 19. Banda G, Mugwagwa J, Mackintosh M, Mkwashi A. The Localisa-

- tion of Medical Manufacturing in Africa. 2022. Available from: https://oro.open.ac.uk/87114/.
- World Heallth Organization. Medicines Control Authority of Zimbabwe - Vaccine Safety. 2023. Available from: https://www. who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/vaccine-safety-net/vsn-members/medicines-control-authority-of-zimbabwe—vaccine-safety.
- 21. Price RA. Impacts of COVID-19 regulatory measures on small-scale and informal trade in Zimbabwe. 2020. Available from: https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/15323.
- Chiku C, Maruta T, Mbiba F, Manasa J. Regulation of Medical Devices in Zimbabwe: A qualitative study with key stakeholders. Preprint. medRxiv. Posted online June 12, 2023. https://doi.org/10.1101/2023.06.07.23291092.
- 23. Truscott R. Zimbabwe's health challenges. *BMJ*. 2009;**338**:b930. [PubMed ID:19289414]. https://doi.org/10.1136/bmj.b930.
- Claborn DM. A Narrative Review of the Role of Economic Crisis on Health and Healthcare Infrastructure in Three Disparate National Environments. Int J Environ Res Public Health. 2020;17(4). [PubMed ID:32075237]. [PubMed Central ID:7068242]. https://doi. org/10.3390/ijerph17041252.
- Nyabani P. Epidemiological transition and the dual burden of communicable and noncommunicable diseases in Zimbabwe. Int J Noncommun Dis. 2021;6(4):166. https://doi.org/10.4103/jncd. jncd\_69\_21.
- Furusa SS, Coleman A. Factors influencing e-health implementation by medical doctors in public hospitals in Zimbabwe. SA J Inf Manag. 2018;20(1):a928. https://doi.org/10.4102/sajim.v20i1.928.
- 27. Dalal S, Beunza JJ, Volmink J, Adebamowo C, Bajunirwe F, Njele-kela M, et al. Non-communicable diseases in sub-Saharan Africa: what we know now. *Int J Epidemiol.* 2011;**40**(4):885-901. [PubMed ID:21527446]. https://doi.org/10.1093/ije/dyr050.
- KPMG. Life Sciences in Africa with a focus on Sub-Saharan Africa.
  Available from: https://assets.kpmg.com/content/dam/kpmg/za/pdf/Global-Life-Sciences-sector-report-2015.pdf.
- Modjadji P. Communicable and non-communicable diseases coexisting in South Africa. Lancet Glob Health. 2021;9(7):e889-90. [PubMed ID:34143983]. https://doi.org/10.1016/S2214-109X(21)00271-0.
- de-Graft Aikins A, Unwin N, Agyemang C, Allotey P, Campbell C, Arhinful D. Tackling Africa's chronic disease burden: from the local to the global. *Global Health*. 2010;6:5. [PubMed ID:20403167]. [PubMed Central ID:2873934]. https://doi.org/10.1186/1744-8603-6-5.
- World Health Organization. WHO country cooperation strategy at a glance: Zimbabwe, At a glance. 2018. Available from: https:// www.who.int/publications/i/item/WHO-CCU-18.02-Zimbabwe.
- World Health Organization. Communicable Diseases. 2022. Available from: https://www.afro.who.int/health-topics/communicable-diseases.
- de Silva NR, Brooker S, Hotez PJ, Montresor A, Engels D, Savioli L. Soil-transmitted helminth infections: updating the global picture. *Trends Parasitol*. 2003;19(12):547-51. [PubMed ID:14642761]. https://doi.org/10.1016/j.pt.2003.10.002.
- 34. Kokaliaris C, Garba A, Matuska M, Bronzan RN, Colley DG, Dorkenoo AM, et al. Effect of preventive chemotherapy with praziquantel on schistosomiasis among school-aged children in sub-Saharan Africa: a spatiotemporal modelling study. Lancet Infect Dis. 2022;22(1):136-49. [PubMed ID:34863336]. [PubMed Central ID:8695385]. https://doi.org/10.1016/S1473-3099(21)00090-6.
- World Health Organization. Noncommunicable Diseases Progress Monitor 2022. 2022. Available from: https://www.who.int/publications/ii/item/9789240047761.
- World Health Organization. Medical device regulations: global overview and guiding principles. 2003. Available from: https:// apps.who.int/iris/handle/10665/42744.
- World Health Organization. Deaths from noncommunicable diseases on the rise in Africa. 2022. Available from: https://www.afro. who.int/news/deaths-noncommunicable-diseases-rise-africa.
- Dzingirai B, Matyanga C, Manyau P, Postma MJ, van Hulst M, Mafirakureva N. OP28 Health Technology Assessment: A Situation Analysis of Zimbabwe. Int J Technol Assess Health Care. 2022;38(S1):S11-2. https://doi.org/10.1017/s026646232200085x.

- 39. Livingston AN, Mattingly II TJ. Drug and medical device product failures and the stability of the pharmaceutical supply chain. J Am Pharm Assoc (2003). 2021;61(1):e119-22. [PubMed ID:32753251]. [PubMed Central ID:7395820]. https://doi.org/10.1016/j.japh.2020.07.005.
- von Zedtwitz M, Gassmann O. Market versus technology drive in R&D internationalization: four different patterns of managing research and development. Res Policy. 2002;31(4):569-88. https:// doi.org/10.1016/s0048-7333(01)00125-1.
- Harris JJ, Lu S, Gabriele P. Commercial challenges in developing biomaterials for medical device development. *Polym Int.* 2018:67(8):969-74. https://doi.org/10.1002/pi.5590.
- Wei S. Facilitating Industrialization in Africa: China's Aid and African Industrial Capacity Building. China Q Int Strateg Stud. 2019;5(4):577-99. https://doi.org/10.1142/s2377740019500301.
- Kaplan W, Laing R. Local production of pharmaceuticals: industrial policy and access to medicines, an overview of key concepts, issues and opportunities for future research. 2005. Available from: http://hdl.handle.net/10986/13723.
- Chakravarry S. Resource constrained innovation in a technology intensive sector: Frugal medical devices from manufacturing firms in South Africa. *Technovation*. 2022;112:102397. https://doi. org/10.1016/j.technovation.2021.102397.
- World Health Organization. Local production for access to medical products: developing a framework to improve public health.
  2011. [Cited:4 July 2023]. Available from: https://apps.who.int/iris/handle/10665/77934.
- Clark J. Mitigating Risk in the Biomaterial Cold Chain. 2009. Available from: https://www.contractpharma.com/issues/2009-05/view\_features/mitigating-risk-in-the-biomaterial-cold-chain/.
- London T, Hart SL. Reinventing strategies for emerging markets: beyond the transnational model. *J Int Bus Stud.* 2004;35(5):350-70. https://doi.org/10.1057/palgrave.jibs.8400099.
- Mahembe E, Odhiambo NM. Foreign direct investment and economic growth: A theoretical framework. J Gov Regul. 2014;3(2):63-70. https://doi.org/10.22495/jgr\_v3\_i2\_p6.
- Glew RH. Promoting collaborations between biomedical scholars in the U.S. and sub-Saharan Africa. Exp Biol Med (Maywood). 2008;233(3):277-85. [PubMed ID:18296733]. https://doi.org/10.3181/0707-MR-204.
- World Health Organization. Medical device regulations: global overview and guiding principles. 2003. Available from: https:// apps.who.int/iris/handle/10665/42744.
- Bai X, Hu X, Wang C, Lim MK, Vilela ALM, Ghadimi P, et al. Most influential countries in the international medical device trade: Network-based analysis. *Physica A*. 2022;**604**:127889. [PubMed ID:35813460]. [PubMed Central ID:9250171]. https://doi. org/10.1016/j.physa.2022.127889.
- Gopoza T. Deindustrialisation of Zimbabwe: Causes, Implications, and Remedies [master's thesis]. Johannesburg: University of Johannesburg; 2020.
- Mangla SK, Luthra S, Mishra N, Singh A, Rana NP, Dora M, et al. Barriers to effective circular supply chain management in a developing country context. *Prod Plan Control*. 2018;29(6):551-69. https://doi.org/10.1080/09537287.2018.1449265.
- Daniels R. Skills Shortages in South Africa: A Literature Review.
  2007. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=992111.
- Okafor EE. Development Crisis of Power Supply and Implications for Industrial Sector in Nigeria. Stud Tribes Tribals. 2008;6(2):83-92. https://doi.org/10.1080/0972639x.2008.11886580.
- Richardson CJ. How the Loss of Property Rights Caused Zimbabwe's Collapse. Econ Dev Bull. 2005(4):1-4.
- Barbu A, Militaru G. The Moderating Effect of Intellectual Property Rights on Relationship between Innovation and Company Performance in Manufacturing Sector. *Procedia Manuf.* 2019;32:1077-84. https://doi.org/10.1016/j.promfg.2019.02.324.
- Shahrubudin N, Koshy P, Alipal J, Kadir MHA, Lee TC. Challenges of 3D printing technology for manufacturing biomedical products: A case study of Malaysian manufacturing firms. Heliyon. 2020;6(4):e03734. [PubMed ID:32322726]. [PubMed Central ID:7160453]. https://doi.org/10.1016/j.heliyon.2020.

- e03734.
- Maphosa F. Remittances and development: the impact of migration to South Africa on rural livelihoods in southern Zimbabwe. *Dev South Afr.* 2007;24(1):123-36. https://doi. org/10.1080/03768350601165942.
- 60. Anadon LD, Chan G, Harley AG, Matus K, Moon S, Murthy SL, et al. Making technological innovation work for sustainable development. *Proc Natl Acad Sci U S A.* 2016;113(35):9682-90. [PubMed ID:27519800]. [PubMed Central ID:5024592]. https://doi.org/10.1073/pnas.1525004113.
- Pan American Health Organization. A Model Regulatory Program For Medical Devices: An International Guide. 2001. Available from: https://iris.paho.org/handle/10665.2/51975.
- 62. Lamph S. Regulation of medical devices outside the European Union. *J R Soc Med.* 2012;**105** Suppl 1(Suppl 1):S12-21. [PubMed ID:22508968]. [PubMed Central ID:3326589]. https://doi.org/10.1258/jrsm.2012.120037.
- 63. Hubner S, Maloney C, Phillips SD, Doshi P, Mugaga J, Ssekitoleko RT, et al. The Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa. *Glob Health Sci Pract.* 2021;9(1):136-48. [PubMed ID:33764886]. [PubMed Central ID:8087432]. https://doi.org/10.9745/GHSP-D-20-00578.
- 64. Gwaradzimba E, Shumba A. The nature, extent and impact of the brain drain in Zimbabwe and South Africa. *Acta Acad*. 2010;**42**(1):209-41. https://doi.org/doi:10.10520/EJC15473.
- United Nations Industrial Development Organization. Pharmaceutical Industry In Sub-Saharan Africa: A guide for promoting pharmaceutical production in Africa. 2019. Available from: https://www.unido.org/sites/default/files/files/2019-10/PHARMACEUTICAL\_INDUSTRY\_IN\_SUB-SAHARAN\_AFRICA\_Guide\_Book.pdf.
- 66. United Nations Conference on Trade and Development. Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies by the UNCTAD Secretariat. 2011. Available from: https://unctad.org/system/files/official-document/diaepcb2011d7\_en.pdf.
- Ncube BM, Dube A, Ward K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J Pharm Policy Pract. 2021;14(1):29. [PubMed ID:33685518]. [PubMed Central ID:7938385]. https://doi.org/10.1186/s40545-020-00281-9.
- World Health Organization. Towards improving access to medical devices through local production: Phase II: Report of a case study in four sub-Saharan countries. 2016. Available from: https://apps.who.int/iris/handle/10665/206545.
- 69. World Health Organization. The African Regional Health Report: The Health of the People. 2006. Available from: https://reliefweb.int/report/world/african-regional-health-report-health-people.
- Medicines Control Authority of Zimbabwe. Who We Are. 2023.
  [Cited:7 May 2023]. Available from: https://www.mcaz.co.zw/whowe-are/.
- Chimhundu C. Chapter 21: Healthcare Technology Management in Zimbabwe. In: Douglas TS, editor. Biomedical Engineering for Africa. Cape Town: University of Cape Town Libraries; 2019. p. 195-201.
- Chiku C, Maruta T, Mbiba F, Manasa J. Medical Devises Regulation in Zimbabwe: An Evaluation of operational readiness. Preprint. medRxiv. Posted online June 12, 2023. https://doi.org/10.1101/2023 .06.08.23291162.
- Sithole T, Mahlangu G, Salek S, Walker S. Evaluation of the Regulatory Review Process in Zimbabwe: Challenges and Opportunities. *Ther Innov Regul Sci.* 2021;55(3):474-89. [PubMed ID:33387356]. [PubMed Central ID:8021537]. https://doi.org/10.1007/s43441-020-020-021597
- 74. Regulations MD, Capabilities I, Africa S. Thesis. 2020.
- Wangwe S, Simonetti R, Tibandebage P, Mackintosh M, Israel C, Mujinja PGM. Upgrading under globalization in health-related industries in Tanzania: the case for dynamic industrial deepening. *Innovation and Development*. 2022;12(3):479-96. https://doi.or g/10.1080/2157930x.2021.1886415.
- Ncube BM, Dube A, Ward K. The domestication of the African Union model law on medical products regulation: Perceived benefits, enabling factors, and challenges. Front Med (Lausanne). 2023;10:1117439. [PubMed ID:36793874]. [PubMed Central ID:9922692]. https://doi.org/10.3389/fmed.2023.1117439.

- Rugera SP, McNerney R, Poon AK, Akimana G, Mariki RF, Kajumbula H, et al. Regulation of medical diagnostics and medical devices in the East African community partner states. *BMC Health Serv Res.* 2014;14:524. [PubMed ID:25366990]. [PubMed Central ID:4221680]. https://doi.org/10.1186/s12913-014-0524-2.
- 78. Russo G, Banda G. Re-Thinking Pharmaceutical Production in Africa; Insights from the Analysis of the Local Manufacturing Dynamics in Mozambique and Zimbabwe. *Stud Comp Int Dev.* 2015;**50**(2):258-81. https://doi.org/10.1007/s12116-015-9186-2.
- Wilson ML, Fleming KA, Kuti MA, Looi LM, Lago N, Ru K. Access to pathology and laboratory medicine services: a crucial gap. *Lancet*. 2018;391(10133):1927-38. [PubMed ID:29550029]. https://doi. org/10.1016/S0140-6736(18)30458-6.
- Tzenios N. The Determinants of Access to Healthcare: A Review of Individual, Structural, and Systemic Factors. J Humanit Appl Sci Res. 2019;2(1):1-14.
- Pecchia L, Pallikarakis N, Magjarevic R, Iadanza E. Health Technology Assessment and Biomedical Engineering: Global trends, gaps and opportunities. *Med Eng Phys.* 2019;72:19-26. [PubMed ID:31554572]. https://doi.org/10.1016/j.medengphy.2019.08.008.
- 82. Wamae W, Tibandebage P, Banda G, Mackintosh M. Making medicines in Africa: The political economy of industrializing for local health. London: Palgrave Macmillan; 2015.
- Yusuf S, Baden T, Prieto-Godino LL. Bridging the Gap: establishing the necessary infrastructure and knowledge for teaching and research in neuroscience in Africa. Metab Brain Dis. 2014;29(2):217-20. [PubMed ID:24166356]. https://doi.org/10.1007/s11011-013-9443-x.
- 84. World Bank Group. The manufacturing sector in Zimbabwe: dynamics and constraints (English) 2010. Available from: http://documents.worldbank.org/curated/en/278771468334842258/Themanufacturing-sector-in-Zimbabwe-dynamics-and-constraints.
- International Labour Organization. State of skills. 2022. Available from: https://www.ilo.org/wcmsp5/groups/public/--ed\_emp/-emp\_ent/documents/genericdocument/wcms\_736696.pdf.
- African Development Bank. African Development Bank. 2019.
  Available from: https://www.afdb.org/en.
- Xinhua. Zimbabwe faces critical skills gap which could hamper economic recovery: World Bank. 2021. Available from: http://www. xinhuanet.com/english/africa/2021-06/04/c\_139987730.htm.
- UNESCO. UNESCO Science Report: Towards 2030. 2015. Available from: https://unesdoc.unesco.org/ark:/48223/pf0000235406.
- Pan American Health Organization. Report on Strengthening Research Capacities for Health in the Caribbean, 2007-2017. 2017. Available from: https://iris.paho.org/handle/10665.2/34342.
- Magner LN. A History of the Life Sciences, Revised and Expanded. Boca Raton: CRC Press; 2002.
- 91. Atkins P, De Paula J. *Physical chemistry for the life sciences.* Oxford: Oxford University Press; 2011.
- Enderle JD, Bronzino JD. Introduction to Biomedical Engineering. Burlington, MA: Academic Press; 2012.
- 93. Houssein A, Lefor AK, Veloso A, Yang Z, Ye JC, Zeugolis DI, et al. BMC Biomedical Engineering: a home for all biomedical engineering research. *BMC Biomed Eng.* 2019;1:1. [PubMed ID:32903331]. [PubMed Central ID:7412665]. https://doi.org/10.1186/s42490-019-0004-1.
- 94. Hudak R, Penhaker M, Majernik J. Biomedical Engineering Technical Applications in Medicine. London: IntechOpen; 2012.
- Aronson JK, Heneghan C, Ferner RE. Medical Devices: Definition, Classification, and Regulatory Implications. *Drug Saf.* 2020;43(2):83-93. [PubMed ID:31845212]. https://doi.org/10.1007/s40264-019-00878-3.
- 96. Han X, Alu A, Liu H, Shi Y, Wei X, Cai L, et al. Biomaterial-assisted biotherapy: A brief review of biomaterials used in drug delivery, vaccine development, gene therapy, and stem cell therapy. *Bioact Mater.* 2022;17:29-48. [PubMed ID:35386442]. [PubMed Central ID:8958282]. https://doi.org/10.1016/j.bioactmat.2022.01.011.
- Expert Market Research. Global Medical Devices Market Share.
  2022. Available from: https://www.expertmarketresearch.com/reports/medical-devices-market.
- Pheage T. Dying from lack of medicines. Africa Renewal. 2017;30(3):24-5. https://doi.org/10.18356/01fc1a55-en.
- 99. World Bank. Poverty and Inequality Platform (version

- 20230328\_2017\_01\_02\_PROD). 2023. [Cited:30 April 2023]. Available from: https://pip.worldbank.org/country-profiles/ZWE.
- 100. Palombi L, Moramarco S. Health in Sub-Saharan Africa: HIV, TB and Malaria Epidemiology. In: Bartolo M, Ferrari F, editors. *Multidisciplinary Teleconsultation in Developing Countries. TELe-Health.* Cham: Springer; 2018. p. 3-16.
- 101. Oni T. Patterns of HIV, TB, and non-communicable disease multimorbidity in an informal peri-urban setting in Cape Town, South Africa [master's thesis]. Cape Town: University of Cape Town; 2015.
- 102. World Health Organization. Trends in local production of medicines and related technology transfer. 2011. [Cited:23 July 2023]. Available from: https://apps.who.int/iris/handle/10665/44712.
- 103. WHO Regional Office for Europe. Environmentally sustainable health systems: a strategic document. 2017. Available from: https://apps.who.int/iris/handle/10665/340375.
- 104. Aguado BA, Grim JC, Rosales AM, Watson-Capps JJ, Anseth KS. Engineering precision biomaterials for personalized medicine. Sci Transl Med. 2018;10(424):eaam8645. [PubMed ID:29343626]. [PubMed Central ID:6079507]. https://doi.org/10.1126/scitrans-lmed.aam8645.
- 105. Dzobo K, Senthebane DA, Pillay M, Ssemakalu C, Mkhumbeni N, Motaung K. The Future of Tissue Engineering and Regenerative Medicine in Africa. *Tissue Eng Part A*. 2017;23(19-20):1023-5. [PubMed ID:28847204]. https://doi.org/10.1089/ten.TEA.2017.0375.
- 106. The Ministry of Health and Child Welfare. The National Health Strategy for Zimbabwe (2009 - 2013): Equity and quality in health: A people's right. 2009. Available from: https://extranet. who.int/mindbank/item/2108.
- 107. Ministry of Health & Child Care Republic of Zimbabwe. 7th Essential Medicines List and Standard Treatment Guidelines for Zimbabwe. 2015. Available from: http://www.mdpcz.co.zw/wpcontent/uploads/2018/10/EDLIZ.pdf.
- Shonhe J, Bayat MS. Challenges in Public Procurement: An Analysis of Public Health Facilities in Zimbabwe. Administratio Publica. 2017;25(3):157-76.
- 109. Magidi M, Mahiya IT. Rethinking training: the role of the informal sector in skills acquisition and development in Zimbabwe. *Dev South Afr.* 2021;**38**(4):509-23. https://doi.org/10.1080/0376835x.2020.1799759.
- Zinyama T, Nhema AG. Public-private partnerships: critical review and lessons for Zimbabwe. Public Policy Adm Res. 2015;5(6):39-44.
- 111. Bhat N, Kilmarx PH, Dube F, Manenji A, Dube M, Magure T. Zimbabwe's national AIDS levy: A case study. SAHARA J. 2016;13(1):1-7. [PubMed ID:26781215]. [PubMed Central ID:4762022]. https://doi.org/10.1080/17290376.2015.1123646.
- 112. Zindiye S, Chiliya N, Masocha R. The impact of Government and other Institutions' support on the Performance of Small and Medium Enterprises in the Manufacturing Sector in Harare, Zimbabwe. Int J Bus Manag Econ Res. 2012;3(6):655-67.
- Magaisa G, Matipira L. Small and medium enterprises development in Zimbabwe. Int J Econ Manag Soc Sci. 2017;6(2):11-20.
- 114. Bvirindi J, Chikwawawa C. Exploring the Feasibility of Public Private Partnerships in the Healthcare Sector in Zimbabwe. Int J Sci Res Publ. 2019;9(11):p9503. https://doi.org/10.29322/IJSRP.9.11.2019.p9503.
- 115. Roth L, Nalim A, Turesson B, Krech L. Global landscape assessment of screening technologies for medicine quality assurance: stakeholder perceptions and practices from ten countries. *Global Health*. 2018;14(1):43. [PubMed ID:29695278]. [PubMed Central ID:5922304]. https://doi.org/10.1186/s12992-018-0360-y.
- 116. Mzumara M. Developing an export promotion strategy for the post-conflict reconstruction of Zimbabwe [dissertation]. Potchefstroom: North-West University; 2012.
- 117. Manyati T. Innovation through knowledge sharing: Evidence from the informal sector in Harare, Zimbabwe. Afr J Sci Technol Innov Dev. 2014;6(4):281-8. https://doi.org/10.1080/20421338.2014.947196.
- 118. Dube E. The build-back-better concept as a disaster risk reduction strategy for positive reconstruction and sustainable development in Zimbabwe: A literature study. Int J Disaster Risk Reduct. 2020;43:101401. https://doi.org/10.1016/j.ijdrr.2019.101401.