An Evaluation of Local Pharmaceutical Manufacturing in Zimbabwe: How Prepared is Zimbabwe to Produce COVID-19 Vaccines?

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Abstract
Globally, the COVID-19 pandemic has had a significant impact, given the rise in the demand for novel therapeutics such as vaccines that can be used in the treatment of COVID-19 patients. Compared to other regions of the world, gross vaccine inequity exists in Africa due to several factors tied to the acute lack of vaccines in the region. As a result, efforts are currently being made to ramp up the production of COVID-19 vaccines in the region. However, there are concerns that most countries in Africa lack the adequate pharmaceutical manufacturing capacity required to produce COVID-19 vaccines, and Zimbabwe is not an exception. This article, therefore, aims to evaluate the preparedness and readiness efforts of the Zimbabwean pharmaceutical industry in the production of COVID-19 vaccines.

Keywords: Zimbabwe, Pharmaceutical Manufacturing, COVID-19, Vaccines, Africa

Introduction

Africa accounts for 17% of the global population but can presently provide just 1% of its vaccination needs due to a lack of adequate pharmaceutical manufacturing capacity [1]. Just eight countries in the region -Algeria, Egypt, Ethiopia, Morocco, Nigeria, Senegal, South Africa and Tunisia- have industries operating across the vaccine-manufacturing landscape. Of these countries, only Senegal exports vaccines with pre-qualification from the World Health Organization (WHO); the majority of these countries cannot even export [2]. Globally, differences in funding and manufacturing capacities exist across countries and this has resulted in uneven access to COVID-19 vaccines, especially for African countries that depend heavily on foreign sources. This dependence, particularly for Zimbabwe, is invariably causing uncertainties, affecting the ability of the Zimbabwean government to implement mass COVID-19 vaccinations, safeguard the lives and health of the populace, and subsequently rejoin the global economy.

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Country Background

Zimbabwe, a landlocked nation with a population of about 13 million, is located in the South-eastern region of Africa surrounded by Mozambique to the east, Zambia to the north, Malawi to the north-east, Namibia to the west, Botswana to the south-west and South Africa to the south [3]. Zimbabweans witnessed a political and institutional reform beyond the majority rule after gaining independence in 1980 as there was a significant improvement on multiple fronts in access to healthcare services and facilities which was largely attributed to the provision of social security by the government to the previously marginalized and disenfranchised black populations [3].

Zimbabwe witnessed some of the most significant breakthroughs in health, nutrition, and population metrics in Sub-Saharan Africa within the decade after independence. Before independence, the health system of Zimbabwe was in jeopardy and disarray [4]. Hospitals were operated without essential necessities, and health workers went on incessant strikes on multiple occasions due to non-payment of wages and harsh working environments [4]. Some of the reasons for this include neglect by the government and an overall economic meltdown which resulted in insufficient healthcare funding, as well as regulations that thwarted the efforts of donors and relief organizations [4]. Zimbabwe used to have a vibrant training hospital system, a robust primary healthcare system established by the Mugabe dictatorship in the 1980s, and a dedicated, competent health workforce [5]. The economic infrastructure of the country was crumbling in the 2000s due to excessive debts and corruption, resulting in the deterioration of national infrastructure and a shortage of essential health necessities. For context, healthcare expenditure by the government fell from 7% to 4% between 2000 and 2007 [4].

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Severe financial constraints were making it increasingly difficult to cater for the wages of health workers. Government physicians received just under $1 monthly in 2008 [6]. Throughout the subsequent years, 20% of health workers migrated due to deplorable working circumstances [6]. Due to the abundance of global health threats, particularly HIV/AIDS, which had the greatest health effect in Zimbabwe throughout the world, the healthcare system was rendered defenseless. However, as it is today, the progress of Zimbabwe in combating the HIV/AIDS epidemic remains remarkable. Notwithstanding a difficult economic and political situation, Zimbabwe lowered HIV incidence from 29% to 16% between 1997 and 2007, owing primarily to community engagement, and behavioral changes [5]. Even amid the present COVID-19 pandemic, this community resilience demonstrated by Zimbabwe allows us to reconstruct and build the health system rather than restarting totally. Political transitions may be times of major institutional transformation as democratic norms are evolving. Thus, there are emerging political alliances and renewed confidence that covers all aspects of the health sector, including local pharmaceutical manufacturing. To overcome this COVID-19 pandemic effectively, Zimbabwe must begin to consider the local manufacturing of COVID-19 vaccines and other novel therapeutics, given that there are tendencies and the possibility of future disease outbreaks. Thus, it is time to build resilience and strengthen the capacity of the country's pharmaceutical industry, particularly in terms of local pharmaceutical manufacturing. However, these are not without challenges.

The Zimbabwean Pharmaceutical Industry: Challenges and Insights on Local Pharmaceutical Manufacturing

According to recent data by the United Nations Industrial Development Organization (UNIDO), just eight pharmaceutical companies exist in Zimbabwe that manufacture finished pharmaceutical products [7]. These products are manufactured with imported Active Pharmaceutical Ingredients (APIs) and other pharmaceutical raw materials. Generics are manufactured by all of the pharmaceutical manufacturing companies. The majority of locally manufactured pharmaceuticals are oral solid and liquid pharmaceutical dosage forms. Companies that manufacture parenteral preparations such as large volume parenterals and injectable penicillins have all ceased operations [7]. Currently, there is an underutilized capacity to manufacture parenterals at two manufacturing plants. The primary components of the Zimbabwean pharmaceutical market are imported pharmaceuticals, donated pharmaceuticals (also imported), and locally manufactured pharmaceuticals. Notably, in previous years, the National Pharmaceutical Company of Zimbabwe (NatPharm), a government-owned body used to fund the local procurement of medicines but this progress was short-lived as the body no longer received funding from the National Treasury, which resulted in the gross reliance of the Zimbabwean pharmaceutical industry on the importation of pharmaceuticals. This, however, brought along significant costs and impact to the economy and the local pharmaceutical industry. For instance, in 2014, $124 million worth of pharmaceuticals were imported commercially, donated pharmaceuticals accounted for $97 million, while only $24 million worth of pharmaceuticals were produced locally [7], implying that the local pharmaceutical industry has a market share of below 10%. On the other hand, some possibilities exist that imported pharmaceuticals can provide the opportunity for substandard and counterfeit medicines to enter into the legitimate drug supply chain, as previously witnessed in Nigeria [8]. In 2014, the local pharmaceutical industry manufactured fewer than one-third of the medications listed in Zimbabwe's 7th Essential Medicines List [7]. Local pharmaceutical manufacturers place more focus on older-generation pharmaceuticals that are not substantially linked with present and key market demands. This is a possible explanation as to why locally manufactured pharmaceuticals have a low proportion of the pharmaceutical market share. The capacity of pharmaceutical manufacturing companies in Zimbabwe to manufacture new products is also hampered by financial constraints and technical incapacities. In a study carried out to evaluate the capacities of the pharmaceutical manufacturing companies in Zimbabwe, it was revealed that all the companies could not partake in Research and Development, which is essential for the discovery of novel therapeutics such as vaccines [7]. Also, it was revealed that pharmaceutical manufacturing companies in Zimbabwe could not produce pharmaceutical starting materials such as APIs. In Africa, very few countries such as South Africa [9], Ghana [9], and Nigeria [10] have witnessed relative success in plans to start the local manufacture of APIs. All the pharmaceutical companies in Zimbabwe are solely limited to the manufacture of pharmaceutical products from already-imported APIs, and the repackaging of already finished pharmaceutical dosage forms into capsules, tablets, or other packaging materials. However, as it is, the pharmaceutical industry of Zimbabwe is not competent enough to manufacture medicines that can sustain the Zimbabwean population, which raises concerns and uncertainties if the country can produce COVID-19 vaccines for its populations [2]. This is particularly worrisome given the unprecedented effect of the present COVID-19 pandemic and spread of novel variants throughout African countries [11] including Zimbabwe.

Can Zimbabwe Produce COVID-19 Vaccines?

With 134,625 recorded COVID-19 cases in Zimbabwe as of December 1st, 2021, just about 4 million people have been administered the first dose of the COVID-19 vaccine, while about 3 million people are completely vaccinated [12]. This current scenario in addition to the underdeveloped health system and disproportionate burden of disease of the country [5] implies that vaccines are likely to constitute an important component of adequate health security, even beyond COVID-19. Notably, donor initiatives such as the COVID-19 Vaccine Global Access (COVAX) are solely responsible for the availability of vaccines in the country. If this demand and supply imbalance between available COVID-19 vaccines and Zimbabwe's entire

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population is not addressed immediately, it is likely to worsen in time to come. Efforts are now being intensified in Africa to accelerate the manufacture of COVID-19 vaccines. For context, about twelve COVID-19 manufacturing facilities have been established or are in the planning stages in six African countries, including Algeria, Egypt, Morocco, Nigeria, Senegal, and South Africa [13] as of September 2021.

The disparity in access to COVID-19 vaccines between high- and low- and middle-income countries (LMICs) is still widening as LMICs such as Zimbabwe are struggling with a severe lack of COVID-19 vaccines [14]. Given that LMICs lack the capacity to produce COVID-19 vaccines [10,11,15], a call for big pharmaceutical companies to temporarily abolish the intellectual property (IP) rights on their COVID-19 vaccines was proposed by India and South Africa in October 2020 but this was met with significant opposition and resistance [16,17,18]. This waiver was intended to allow LMICs to manufacture COVID-19 vaccines -via technical and technology transfer- without compensating the big pharmaceutical companies. This is because IP rights such as patents, industrial designs, trademarks, etc. obstruct timely availability and access to vaccines in LMICs [16]. Indeed, more difficulties are encountered when manufacturing vaccines compared to oral medications, but UNICEF as well as other international bodies have previously depended on LMICs, notably India to manufacture their vaccines under strict quality control [17]. In the past, most LMICs developed and manufactured their own vaccines, like the hepatitis B vaccine manufactured by Shanta Biotechnics in India [17]. The temporary abolishment of IP rights will therefore be a remarkable step if Zimbabwe -like other LMICs- is to achieve considerable success in the local manufacturing of COVID-19 vaccines. However, the focus ought to be to steer the country away from dependence and more towards competency and self-sufficiency. Therefore, relying or hoping on big pharmaceutical companies to waive IP rights remains a setback and limitation on the path to self-sufficiency. Since the waiver was requested in October 2020, it has not been approved over one year later. Further delays like this can potentially exacerbate the already-felt unprecedented impact and disease burden of the COVID-19 pandemic in Zimbabwe. Strengthening local pharmaceutical manufacturing must be prioritized rapidly in order to avoid a recurrence given the possibility of future pandemics -as these are unavoidable.

Strengthening Local Pharmaceutical Manufacturing in Zimbabwe: The Way Out

To develop sufficient pharmaceutical manufacturing capacity in the country, we propose these country-specific recommendations:

1. **Provision of Adequate Funding for Establishing Vaccine Manufacturing Facilities**

According to a 2015 study co-funded by the WHO and UNIDO, the financial cost required to build a manufacturing plant was estimated to be between $60 million and $130 million [2]. According to the United Nations, Zimbabwe recorded a loss in revenue of about $400 million in 2020 due to the COVID-19 pandemic [19]. This implies that if Zimbabwe had an already established vaccine manufacturing facility before the COVID-19 pandemic, the economic impact and loss in revenue would not have been as severe as imposed by the COVID-19 pandemic as there would have been vaccines readily available to curb the pandemic. Pharmaceutical manufacturers in Zimbabwe are likely to encounter unfair disadvantages and greater operational costs in the local production of COVID-19 vaccines compared to pharmaceutical manufacturers in richer countries unless similar funding as evident in these rich countries are provided.

2. **National public-private sector partnerships and commitment**

Political leaders have consistently emphasized the need for strengthened pharmaceutical manufacturing capacity in not only Zimbabwe, but Africa as a whole. The COVID-19 pandemic has united leaders and relevant stakeholders around the manufacturing issue, but this enthusiasm must be maintained and sustained in the long run. Political commitment, intersectoral partnership, strong regulatory frameworks, transfer of technology, pooled procurement, and infrastructural development are some of the enabling factors that public and private sector stakeholders can explore in order to improve the state of pharmaceutical manufacturing in Zimbabwe.

3. **Formulation of National Frameworks and Pharmaceutical Manufacturing Roadmaps**

On a number of fronts, country-specific advancements in the formulation of national frameworks and pharmaceutical manufacturing roadmaps can already be seen. Ethiopia and South Africa, for example, have developed extensive strategies to solve common challenges such as procuring APIs, overcoming financial constraints, and improving quality in line with global standards, and these initiatives are beginning to deliver significant results [13]. Egypt, Nigeria, and South Africa are beginning to manufacture APIs on their own [13], which is the fundamental path to overcoming a major obstacle that African pharmaceutical manufacturers face, making it extremely difficult to compete with foreign manufacturers. In addition, Ethiopia is constructing a pharmaceutical manufacturing industrial park in order to scale up pharmaceutical production in the country and throughout the continent [10]. As a result, Zimbabwe should learn from the performance of these countries and leverage them as growth indicators to expand its local pharmaceutical manufacturing capacity.

4. **Deepening Collaboration with Local Schools of Pharmacy**

In terms of undergraduate pharmaceutical training, Zimbabwe currently has two schools of pharmacy. Although this appears to be a setback in the provision of an adequate pharmaceutical workforce particularly as regards pharmacy students who will

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eventually practice in the pharmaceutical industry, significant progress can still be achieved, notwithstanding. To strengthen local pharmaceutical manufacturing in Zimbabwe, industry-academia collaboration must be implemented because significant local pharmaceutical manufacturing cannot occur without an adequate and competent pharmaceutical workforce. New models of interaction with these pharmacy schools must be developed to help fill in the gap in pharma pipelines and complement other activities which will address major new areas of research with the potential for new product formulation -such as vaccines.

Conclusion

Local production of COVID-19 vaccines in Zimbabwe requires the collaboration of the government, regulatory agencies, pharmacy schools and the private sector. If vaccines are to be rolled out early, it means countries that will be able to provide for themselves will experience fewer financial constraints as there would be no costs of procurement or supply. Furthermore, overall orientation of the local manufacturing industry is also a necessity, as to ensure that there is focus on not just profit-making but also on sustaining industry development irrespective of the accompanying challenges. Hence, it is ideal for Zimbabwe to rethink producing vaccines for its population using the available resources by strengthening its local pharmaceutical manufacturing capacity. This will significantly solve the issue of vaccine scarcity and inequity in Zimbabwe, and also shift the balance towards total pandemic containment and control.

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