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Opinion Article

Pharmaceutical Supply Chain Design in Africa Leading to Diffusion of Responsibility for Quality Issues?

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Abstract: Medicines are important ingredient of healthcare, and their availability and affordability are of paramount importance for any health system. Africa is a land of opportunity but faces many systemic limitations in healthcare delivery at present. The pharmaceutical supply chain of the country has many inefficiencies. Most of the medicines used in Africa are imported from Europe and Asia. There have been serious quality concerns in the pharmaceutical supply chain in the recent past and this article attempts to explore the probable reasons and future directions for the same. This article is useful for supply chain professionals, public health professionals, and health policymakers.
Keywords: Sub-Saharan Africa, Pharmaceuticals Supply Chain, Quality Issues, Stakeholders.

Introduction

Pharmaceuticals, also known as drugs or medications, are substances used to diagnose, treat, prevent, or cure diseases or medical conditions. They can be produced from various sources, including chemical synthesis, biotechnology, and natural sources such as plants and animals [1].

The supply chain of these pharmaceuticals is truly global and crosses many geographies. The global value chain of pharmaceuticals is complex and highly regulated, with a focus on risk management and innovation [2, 3]. Some of the characteristics of the pharmaceutical value chain are the following:

1) Globalization: Pharmaceutical supply chains are highly globalized, with products and components sourced from multiple countries, and manufacturing and distribution taking place across different regions of the world [4, 5].

2) Complexity: Pharmaceutical supply chains are complex, with multiple stakeholders involved, including drug manufacturers, suppliers, distributors, retailers, and regulators [2, 6].

3) Regulatory compliance: The pharmaceutical industry is heavily regulated, and companies must comply with a wide range of regulations related to safety, efficacy, quality, and labeling [7, 8].

4) Risk management: Pharmaceutical supply chains are also characterized by a high degree of risk, including supply chain disruptions, counterfeiting, and product recalls [9, 10].

5) Innovation: The pharmaceutical industry is highly innovative, with new drugs and therapies being developed and brought to market regularly [11, 12].

A typical supply chain of drugs reaching an African country involves many countries such as molecule is developed in the USA, active pharma ingredient (API) is developed in China, manufactured in India, and traveling through the UAE to reach a destination in Africa.

A typical flow of innovation to the consumer is depicted in Figure 1.

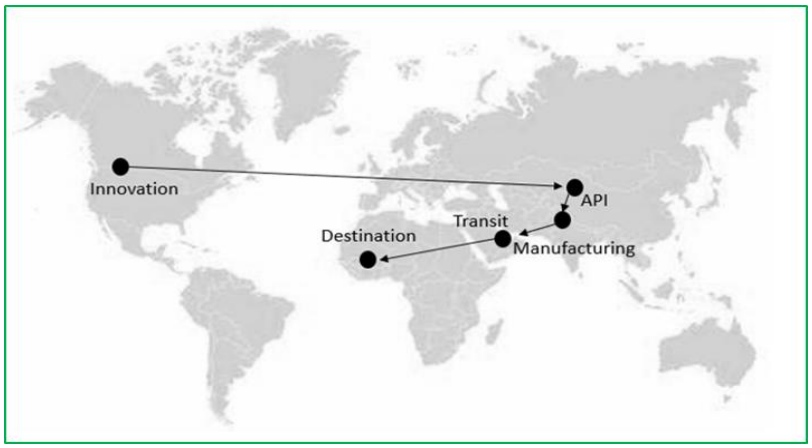

Figure-1: Global Value Chain for Pharmaceutical in Africa (Source: Author)

Pharmaceutical Industry in Africa

Sub-Saharan African countries import more than 70 percent of the drugs consumed and the majority of these medicines are imported from India. India's response to the needs of African countries has become even more collaborative and generous in recent times. Through its humanitarian aid by sending healthcare equipment, vaccines, and medicines, India has played a significant role in assisting African nations [13]. Considering the over-dependence on imports and the possible risk of supply chain disruption many African countries are considering whether it's time to promote more local production. A report by Mckinsey & Company opines that the success of an effort to develop local drug manufacturing will depend on impact and feasibility [14]. The success matrix for the development of the drug is depicted in Figure 2. But it is easily said than done to develop an industry in a continent that is low in financial resources and business ecosystem. Moreover, the pharmaceutical industry involves many stakeholders with various interests and makes it too complex to handle. We can draw a parallel between this situation and semiconductor manufacturing attempts in India [15]. Although India is one of the largest markets of semiconductors it has very few fabrications (Fab) units. Currently, the central government in India is offering a 50 percent subsidy on fab units and state governments offer a 10-25 percent subsidy over and above the central grant. A similar effort is required if African countries want to see if they want to reduce their overdependence on imports from India [16].

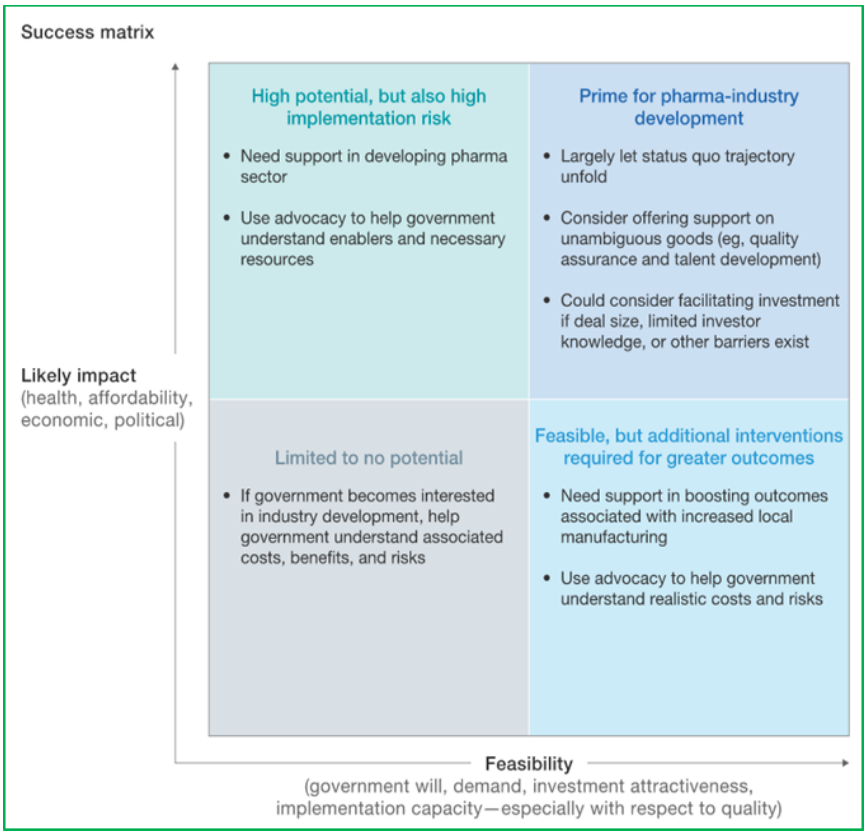

Figure-2: Success Matric for the Development of the Pharma Industry in Africa
Source: Mckinsey & Company

There have been many reported cases of a quality issues with drugs supplied to Africa. Klantschnig & Huang [17] highlight the issue of counterfeit drugs in Nigeria. A study published as a working paper by the US National Bureau of Economic Research claims that generic drugs exported from India to Africa are of lower quality than those exported to middle-income countries [18]. Some Experts claim that some Indian drug manufacturers cut corners and make substandard drugs for markets with nonexistent, underdeveloped, or emerging regulatory oversight, notably Africa [19]. These are serious allegations and the recent incident in Gambia further support this hypothesis.

Maiden Pharma Kills Innocents in Gambia

World Health Organization issued an alert over four cough and cold syrups–manufactured by an Indian pharmaceutical company–after their alleged linkage with the death of 66 children from diethylene glycol (DEG) poisoning in the Gambia. Later a Lab analysis confirmed "unacceptable" amounts of diethylene glycol and ethylene glycol in syrups. Which was the probable reason behind the acute kidney injury and deaths. The four medicines were manufactured by the Haryana-based company only for export to the Gambia. Maiden Pharma declined to comment, while the Drugs Controller General of India (DCGI) kept tightlipped on the episode. WHO later clarified that four syrups were procured by the Gambian agencies directly and the WHO was not involved in the procurement. It was not aware if any pre-qualification test was conducted before the drugs were shipped to the Gambia.

Recommendations

The evidence presented in this paper makes me conclude the following points:

1) African countries are not going to be self-reliant on medicine in recent future.
2) The pharmaceutical supply chain for Africa is inherently complex and needs to manage skillfully.
3) There is a diffusion of responsibility in case of an untoward quality issue in the value chain.

I have four recommendations to address the Gambia-like situation in the future. Firstly, African countries should start developing their pharmaceutical industry. It will increase their bargaining power and exporters will not consider them as dumping yards for their substandard drugs. Secondly, the WHO cannot jettison its responsibility because it was formed with a mandate to protect the health of people worldwide. Lack of finances put African countries at risk of exploitation and their people's life at risk and WHO can not be a spectator. Thirdly, an exporting country such as India should act more responsibly. How come a drug banned in India was available to be exported to an African country? Last but not the least, approval agencies should not only approve the API but also the substrates used in the formulation.

Information technologies if used in the right manner have the potential to address the inherent complexity in the pharmaceutical supply chain. The use of digital technologies can further improve the visibility in the value chain and all stakeholders can work collectively to ensure the quality of drugs in the supply chain. Blockchain technologies can help in the management of approvals and safeguards them against any manipulation. But above all, there is an urgent need to realize that the lives of Africans matter. We collectively failed in the case of the Gambia, and it should not be repeated in the future.

Declarations

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